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DRUG INDUSTRY ACT OF 1962

HEARINGS

BEFORE THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE HOUSE OF REPRESENTATIVES

EIGHTY-SEVENTH CONGRESS

SECOND SESSION

ON

H.R. 11581

A BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO ASSURE THE SAFETY, EFFICACY, AND RELIABILITY OF DRUGS, AUTHORIZE STANDARDIZATION OF DRUG NAMES, ESTABLISH SPECIAL CONTROLS FOR BARBITURATE AND STIMULANT DRUGS, AND CLARIFY AND STRENGTHEN EXISTING INSPECTION AUTHORITY WITH RESPECT TO ANY ARTICLES SUBJECT TO THE ACT; AND TO AMEND RELATED LAWS

H.R. 11582

A BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO REQUIRE A PREMARKETING SHOWING OF THE SAFETY OF COSMETICS; ASSURE THE SAFETY, EFFICACY, AND RELIABILITY OF THERAPEUTIC, DIAGNOSTIC, AND PROSTHETIC DEVICES; AND AMEND THE ACT WITH RESPECT TO CAUTIONARY LABELING; AND FOR OTHER PURPOSES

JUNE 19, 20, 21, 22; AUGUST 20, 21, 22, 23, 1962

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Committee on Interstate and Foreign Commerce

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DRUG INDUSTRY ACT OF 1962

TUESDAY, JUNE 19, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to notice, at 10:20 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

This morning the committee is meeting for hearings on two very important bills, and, two bills of wide interest, judging by the mail and telephone calls I received.

H.R. 11581 and H.R. 11582 were introduced by me on May 3, to give effect to a part of the President's message on consumer protection; that is, that portion of the message dealing with strengthening the regulatory authority with respect to food, drugs, cosmetics, and devices.

H.R. 11581, referred to as "Drug and Factory Inspection Amendments of 1962," proposes to authorize the Department of Health, Education, and Welfare, first, to issue regulations requiring drug manufacturers to maintain facilities and controls that will assure the reliability of their products; second, to require a showing that new drugs and biologicals are effective for their intended use—as well as safe—before they may be marketed; third, to withdraw clearances granted on new drugs when there is substantial doubt as to the drug's safety or efficacy; fourth, to require manufacturers to advise the Food and Drug Administration of clinical experience and reports of any adverse reactions to new drugs and antibiotics; fifth, to require the same safety testing and certification procedures for all antibiotics as are now applicable to only a few antibiotics; sixth, to assign generic names to drugs; seventh, to establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines; and, eighth, to institute more effective factory inspection for all products subject to the act.

It would also authorize the Federal Trade Commission to require the disclosure of ingredients of prescription drugs, their efficacy and their adverse effects in advertisements directed to physicians.

H.R. 11582, cited as the "Cosmetics and Therapeutic Devices Amendments of 1962," would authorize the Department of Health, Education, and Welfare, first, to require a manufacturer of cosmetics to show that the products are safe before they may be marketed; second, to issue regulations requiring manufacturers of devices subject to the act to maintain facilities and controls that will assure the reliability of their products; third, to require the manufacturer of

devices to show that products are safe and efficacious before they may be marketed; and, fourth, to require appropriate cautionary labeling of hazardous substances or pressurized containers of articles subject to the act.

This bill also provides that the anticancer clause in the food and color additive amendments to the act would not apply to additives used in feed for animals raised for food production where the chemical does not harm the animal and its use does not leave a residue in the edible products from the treated animal.

Copies of the bills along with agency reports may appear at this point in the record.

(H.R. 11581, H.R. 11582 and various agency reports are as follows:)

[H.R. 11581, 87th Cong., 2d sess.]

A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the Act; and to amend related laws

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug and Factory Inspection Amendments of 1962".

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TITLE I—DRUGS

PART A—AMENDMENTS TO ASSURE SAFETY, EFFICIENCY, AND RELIABILITY

REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

SEC. 101. (a) Clause (2) of paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows: "(2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) (i) to insure that its identity and strength do not differ from, and that its purity, quality, and

efficacy do not fall below, those which it purports or is represented to possess, or (ii) to insure that it will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with its labeling), or (iii) to insure that its labeling is not such as to cause it to be adulterated or misbranded;".

(b) Section 701(e) of such Act is amended by striking out, in the first sentence, "501(b)" and inserting in lieu thereof "501 (a) or (b)".

PREMARKETING SHOWING OF NEW-DRUG EFFICACY

SEC. 102. (a) Paragraph (p) of section 201 of the Federal Food, Drug, and Cosmetic Act is amended by—

(1) inserting in subparagraphs (1) and (2) thereof the words "and efficacy" after the word "safety" each time such word occurs therein; and

(2) inserting in subparagraph (1) "and efficacious" after "safe".

(b) Section 505 of such Act is amended by—

(1) inserting "and efficacious" after the word "safe" each time such word occurs in subsections (b) and (d) thereof;

(2) inserting "or inefficacious" after the word "unsafe" in subsection (d) thereof;

(3) inserting "or inefficacious" after the word "unsafe" in subsection (e) thereof;

(4) striking out "quality, and purity" in clause (3) of subsection (d) and inserting in lieu thereof "quality, purity, safety, and efficacy"; and

(5) inserting in subsection (i) "and efficacy" after the word "safety".

RECORDS AND REPORTS AS TO EXPERIENCE ON NEW DRUGS

SEC. 103. (a) Section 505 of such Act is amended by adding at the end thereof the following new subsction:

"(j)(1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(b) Subsection (i) of section 505 of such Act, as amended by section 102(b)(5) of this Act, is further amended (1) by inserting "the foregoing subsections of" after "operation of", and (2) by adding at the end thereof the following new sentence: "Such regulations may provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such drugs, as the Secretary finds will enable him to evaluate the safety and efficacy of such drugs in the event of the filing of an application pursuant to subsection (b)."

(c) The first sentence of subsection (e) of section 505 of such Act, as amended by section 102(b)(3) of this Act, is further amended by inserting immediately before the period at the end of such sentence a comma and the following: "or (3) that the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection".

(d) Paragraph (e) of section 301 of such Act is amended to read as follows:

"(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or the refusal to permit access to or verification or copying of any such required record."

(e) Subsection (a) of section 302 of such Act is amended by striking out "(e),".

PROCEDURAL CHANGES AS TO NEW DRUGS, AND ADDITIONAL GROUNDS FOR WITHDRAWAL OR SUSPENSION OF APPROVAL OF NEW-DRUG APPLICATIONS

SEC. 104. (a)(1) Subsection (a) of section 505 of such Act is amended by striking out the phrase "unles an application filed pursuant to subsection (b) is effective", and inserting in lieu thereof "unless an application has been filed pursuant to subsection (b), and there is in effect an approval of such application by the Secretary under this section,".

(2) The first sentence of subsection (b) of section 505 of such Act is amended to read as follows: "Any person may file with the Secretary an application for determination by the Secretary of the safety and efficacy of any drug subject to the provisions of subsection (a)."

(3) Subsection (c) of section 505 of such Act is amended to read as follows:

"(c) Within ninety days after the filing of an application under this subsection or within such additional period (not exceeding one hundred and eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable."

(4) Subsection (d) of section 505 of such Act, as amended by section 102(b) of this Act, is further amended by striking out the phrase ", prior to the effective date of the application, issue an order refusing to permit the application to become effective." and inserting in lieu thereof the following: "issue an order denying approval of the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (4) do not apply, he shall issue an order approving the application."

(b) Subsection (e) of section 505 of such Act, as amended by sections 102(b)(3) and 103(c) of this Act, is further amended to read as follows:

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe or inefficacious, or show that there is substantial doubt as to the safety or efficacy of such drug, for use under the conditions of use upon the basis of which the application was approved, or (2) that the application contains any untrue statement of a material fact, or (3) that the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are then inadequate to assure and preserve its identity, strength, quality, purity, safety, and efficacy, or (5) that any condition attached to approval of the application has been violated: *Provided*, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection. The order shall state the findings upon which it is based."

(c) Subsection (f) of such section 505 is amended to read as follows:

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate."

(d) (1) The first four sentences of subsection (h) of such section 505 are amended to read as follows:

"(h) An appeal may be taken by the applicant from an order of the Secretary denying or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated

by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order."

(2) The ninth sentence of such subsection (h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

(e) (1) Subsection (l) of section 301 of such Act is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

(2) Clause (C) of section 503(b)(1) of such Act is amended by striking out "effective" and inserting in lieu thereof "approved".

CERTIFICATION OF ALL ANTIBIOTICS

SEC. 105. (a) The heading of section 507, as amended, of such Act is further amended to read "CERTIFICATION OF DRUGS CONTAINING ANTIBIOTICS", and the first sentence of subsection (a) of such section 507 is amended to read as follows: "The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin or any derivative thereof, or composed wholly or partly of any other kind of antibiotic substance (including the chemically synthesized equivalent of any such substance)."

(b) Paragraph (1) of section 502 of such Act is amended to read as follows:

"(1) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any deriviative thereof, or a drug composed wholly or partly of any other kind of substance within the purview of section 507, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d)."

RECORDS AND REPORTS AS TO EXPERIENCE ON ANTIBIOTICS

SEC. 106. (a) Section 507 of such Act, as amended by section 105(a), is further amended by adding at the end thereof the following new subsection:

"(g)(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed.

"(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

(b) Subsection (d) of section 507 is amended by adding at the end thereof the following new sentence: "Such regulations may provide for conditioning the exemption under clause (3) upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such drugs, as the Secretary finds will enable him to evaluate the safety and efficacy for use of such drugs in the event of an application for certification or release pursuant to subsection (a)."

(c) Paragraph (e) of section 301 of such Act, as amended by section 103(d) of this Act, is further amended by striking out "505 (i) or (j)" and inserting in lieu thereof "505 (i) or (j), or 507 (d) or (g)".

BIOLOGICAL DRUGS

SEC. 107. (a) The first sentence of subsection (d) of section 351 of the Public Health Service Act is amended to read as follows:

"(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing (1) that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and (2) that such products are efficacious under the conditions prescribed, recommended, or suggested by the manufacturer, and licenses for new products may be issued only upon a showing that they meet the foregoing requirements."

(b) (1) Section 501 of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, is further amended by adding at the end thereof the following new paragraph:

"(e) If it is a drug that is a product within the purview of section 351 of the Public Health Service Act and (1) it has not been propagated or manufactured and prepared, in conformity with such section and regulations and standards prescribed thereunder, by a manufacturer holding a license therefor issued by the Secretary, and in accordance with the terms of such license, or (2) at any time (A) it is not in conformity with such section or regulations or standards, or (B) the expiration date on its labeling has passed, or (C) such license has been suspended or revoked."

(2) Section 502 of such Act, as amended by this Act, is further amended by adding at the end thereof the following new paragraph:

"(n) If it is a drug that is a product within the purview of section 351 of the Public Health Service Act and its packaging or labeling is not in conformity with such section or with regulations or standards prescribed thereunder."

(c) Subsection (c) of section 902 of such Act is amended by striking out "the Virus, Serum, and Toxin Act of July 1, 1902", and inserting in lieu thereof the following: "section 351 of the Public Health Service Act (U.S.C., 1958 ed., title 42, ch. 6A, sec. 262, relating to viruses, serums, toxins, and analogous products for humans); the Animal-Virus-Serum-Toxin Act of March 4, 1913 (U.S.C., 1958 ed., title 21, ch. 5, secs. 151–158)".

EFFECTIVE DATES AND APPLICATION OF PART A

SEC. 108. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A shall take effect on the date of enactment.

(b) The amendments made by sections 101, 103, 105, and 106 of this part A shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

(c) The amendments made by section 102 of this Act, except subsection (b) (3) of such section, shall not apply to any drug with respect to which an application under section 505 of the Federal Food, Drug, and Cosmetic Act was effective on the day immediately preceding the date of enactment of this Act, so long as amendment of such application is not proposed and approval of such application has not been suspended or withdrawn under section 505 of such Act, as amended by this Act. An application filed pursuant to section 505(b) of such Act which was effective on the day immediately preceding the date of enactment of this Act shall, upon the date of enactment of this Act, be deemed to be an application approved by the Secretary. If an application filed with respect to a new drug, pursuant to such section 505(b) prior to the date of enactment of this Act, is still pending before the Secretary on such date, the running of the period within which the Secretary must act on such application pursuant to section 505(c) of such Act, as amended by this Act, shall be deemed to have commenced on the day immediately following the date on which such application was in fact filed, and any time extension notified by the Secretary pursuant to such section 505(c) as in force prior to the date of enactment of this Act shall (to the extent the period of extension so notified exceeds ninety days from the date of such filing) be deemed to be an extension of time notified pursuant to such section 505(c) as amended by this Act.

(d) The amendment made by section 107(a) shall not apply to any biological product with respect to which a license issued under section 351(d) of the Public Health Service Act was effective on the day immediately preceding the

date of enactment of this Act, so long as the license has not been suspended or revoked and there is no application for amendment of the license, unless the Secretary finds that there is substantial doubt as to whether such product is efficacious under the conditions prescribed, recommended, or suggested by the manufacturer.

PART B—STANDARDIZATION OF DRUG NAMES

AUTHORITY TO STANDARDIZE NAMES

SEC. 111. (a) The Federal Food, Drug, and Cosmetic Act, as amended by this Act, is further amended by adding at the end of chapter V the following new section:

"SEC. 508. Whenever in the judgment of the Secretary such action is necessary or desirable in the interest of achieving usefulness or simplicity of drug nomenclature, or because of the existence of two or more nonproprietary names (other than the systematic chemical name) for the same drug (or for two or more drugs which are identical in their active ingredients and substantially identical in their pharmacological action, strength, quality, and purity), or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name for a drug, he may promulgate regulations establishing a single standard name for such drug (or for such identical drugs), together with any related or additional information which in the judgment of the Secretary is desirable to facilitate the correct and effective use of such standard name."

(b) This section shall take effect on the date of its enactment.

NAME TO BE USED ON DRUG LABEL

SEC. 112. (a) Paragraph (e) of section 502 of such Act is amended by—

(1) inserting the subparagraph designation "(1)" after "(e)";

(2) striking out the words "If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient", and inserting in lieu thereof "If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient";

(3) striking out the words "the name" and inserting in lieu thereof the words "the established name";

(4) inserting before the colon preceding the proviso the following: "; and (B) the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is given precedence in position over any proprietary name or designation for such drug or ingredient and is in type at least as large and prominent as that used for such proprietary name or designation";

(5) striking out the words "clause (2) of this paragraph" in the proviso to such paragraph and inserting in lieu thereof "clause (A)(ii) or clause (B) of this subparagraph"; and

(6) adding at the end of such paragraph the following new subparagraph:

"(2) As used in this paragraph (e), the term 'established name', with respect to a drug or ingredient thereof, means (A) the applicable standard name established pursuant to section 508, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compenduim, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply."

(b) Section 502(g) of such Act is amended by inserting immediately before the period at the end thereof a colon and the following proviso: "*Provided fur-*

ther, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail".

(c) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

PART C—SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

FINDINGS AND DECLARATION

SEC. 121. The Congress hereby finds and declares that there is a widespread illicit traffic in barbiturates and in amphetamines and other habit-forming central nervous system stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highway and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that the regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act, would discriminate against and depress interstate commerce in such drugs.

CONTROL OF BARBITURATE AND STIMULANT DRUGS

SEC. 122. Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by this Act, is further amended by adding at the end thereof a new section as follows:

"BARBITURATES AND HABIT-FORMING STIMULANT DRUGS

"SEC. 509. (a) As used in this section—

"(1) the term 'barbiturate' means any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid, which derivative has been designated by the Secretary under section 502(d) as habit forming; and

"(2) the term 'habit-forming stimulant drug' means a drug which contains any quantity of (A) amphetamine or any of its optical isomers; or (B) any salt of amphetamine, or any salt of an optical isomer of amphetamine; or (C) any substance which the Secretary, after investigation, has found to be, and by regulation, designated as, habit forming because of its stimulant effect on the central nervous system.

"(b) No person shall manufacture, compound, or process any barbiturate or any habit-forming stimulant drug, except the following persons:

"(1) Manufacturers, compounders, and processors who have listed their names and places of business with the Secretary and who are regularly engaged or seek to be engaged, and are otherwise qualified, in preparing pharmaceutical chemicals or prescription drugs for distribution through branch outlets, through wholesale druggists, or by direct shipment, (A) to pharmacies or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for any use described in paragraph (5).

"(2) Wholesale druggists who maintain establishments in conformance with local laws and are regularly engaged in supplying prescription drugs (A) to pharmacies, or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for any use described in paragraph (5).

"(3) Pharmacies, hospitals, clinics, and public health agencies, which maintain establishments, in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, for patients under the care of such practitioners in the course of their professional practice.

"(4) Practitioners licensed by law to prescribe or administer barbiturates or habit-forming stimulant drugs, who have such drugs in their possession for use in the course of their professional practice.

"(5) Persons who possess barbiturates or habit-forming stimulant drugs for use in research, teaching, or chemical anlysis and not for sale.

"(6) Officers and employees of Federal, State, Territorial, or local governments, whose possession of such drugs is in the course of their official duties.

"(7) An employee of any person described in paragraph (1) through paragraph (6), and a nurse or other medical technician under the supervision of a practitioner licensed by law to administer such drugs, having possession of such drugs by reason of his employment or occupation and not on his own account.

"(c) No person, other than—

"(1) a person described in subsection (b), or

"(2) an individual to whom such drug in his possession has been dispensed, or for whom it has been prescribed in conformance with section 503(b), by a practitioner licensed by law to prescribe and administer such drugs in the course of such practitioner's professional practice, or

"(3) a carrier or warehouseman whose possession of such drug is in the usual course of his business as such,

shall possess any barbiturate or any habit-forming stimulant drug.

"(d) No person shall sell, deliver, or otherwise dispose of any barbiturate or any habit-forming stimulant drug to a person not authorized by subsection (c) to possess such drugs.

"(e) (1) Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any barbiturate or any habit-forming stimulant drug shall, upon the effective date of this section, prepare a complete and accurate record of all stocks of each such drug on hand and shall keep such record for three years. On and after the effective date of this section, every such person manufacturing, compounding, or processing any barbiturate or any habit-forming stimulant drug shall prepare and keep, for not less than three years, a complete and accurate record of the kind and quantity of each such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and every such person selling, delivering, or otherwise disposing of any barbiturate or any habit-forming stimulant drug shall prepare or obtain, and keep for not less than three years, a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person from whom it was received and to whom it was sold, delivered, or otherwise disposed of, and the date of such transaction.

"(2) Every person required by paragraph (1) of this subsection to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing barbiturates or habit-forming stimulant drugs, and every person in charge or custody of such records, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at reasonable times to have access to and copy such records. For the purposes of verification of such records and of enforcement of this section, officers or employees designated by the Secretary are authorized, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to enter, at reasonable times, any factory, warehouse, establishment, or vehicle in which barbiturates or habit-forming stimulant drugs are held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of, and to inspect, within reasonable limits and in a reasonable manner such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers, and labeling therein, and to inventory any stock of such drugs therein, and obtain samples of such drugs. If a sample is thus obtained, the officer or employee making the inspection shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample obtained.

"(3) The provisions of paragraphs (1) and (2) of this subsection shall not

apply to a licensed practitioner described in subsection (b)(4) with respect to drugs received, prepared, possessed, administered, or dispensed by him in the course of his professional practice.

"(f) The Secretary may by regulation exempt any barbiturate or any habit-forming stimulant drug from the application of all or part of this section when he finds that regulation of its manufacture, compounding, processing, possession, and disposition, as provided in this section or in such part thereof, is not necessary for the protection of the public health."

PROHIBITED ACTS

SEC. 123. Section 301 of such Act is amended by adding at the end thereof the following new paragraph:

"(o) (1) The manufacture, compounding, or processing of a drug in violation of section 509(b); (2) the possession of a drug in violation of section 509(c); (3) the sale, delivery, or other disposition of a drug in violation of section 509(d); (4)(A) the failure to prepare or obtain, or the failure to keep, a complete and accurate record with respect to any drug as required by section 509(e), or (B) the refusal to permit access to or copying of any record as required by section 509(e); or (5) the refusal to permit entry or inspection as authorized by section 509(e)."

GROUNDS AND JURISDICTION FOR JUDICIAL SEIZURE AND CONDEMNATION

SEC. 124. The first sentence of section 304(a) of such Act is amended by inserting before ": *Provided, however*" the following: "; and any drug which is a barbiturate or a habit-forming stimulant drug within the meaning of section 509 and which has been manufactured, compounded, processed, possessed, sold, delivered, or disposed of in violation of section 509 shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found".

APPLICATION OF STATE LAW

SEC. 125. Nothing in this part shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State or territory in contravention of the laws of such State or territory.

EFFECTIVE DATE

SEC. 126. The foregoing provisions of this part C shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted; except that the Secretary shall permit manufacturers, compounders, and processors referred to in section 509(b)(1) of the Federal Food, Drug, and Cosmetic Act, as enacted by this part, to list their names and places of business with the Secretary prior to such effective date, and except that the definitions of terms and the provisions of section 125 shall take effect upon the date of enactment of this Act.

PART D—AMENDMENTS AS TO ADVERTISING

REQUIREMENT OF INFORMATIVE PRESCRIPTION DRUG ADVERTISEMENTS

SEC. 131. Subsection (a) of section 15 of the Federal Trade Commission Act is amended (1) by striking out the last sentence of paragraph (1); (2) by redesignating paragraph (2) as paragraph (3); and (3) by inserting immediately after paragraph (1) the following new paragraph:

"(2) An advertisement of a prescription drug shall be deemed to be misleading in a material respect if such advertisement fails to contain (A) a conspicuous, full, and accurate statement of the efficacy of the drug, and (B) a conspicuous and truthful disclosure of (i) the quantitative formula of the drug with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contraindications of the drug. For the purposes of this paragraph a prescription drug is one intended for use of man that Federal law requires to be dispensed only upon the prescription of a practitioner licensed by law to administer such drug. The Commission is authorized and directed to prescribe such rules and regulations as may be necessary for purposes of administration and enforcement of this paragraph."

TITLE II—CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

FACTORY INSPECTION

SEC. 201. (a) The first sentence of subsection (a) of section 704 of the Federal Food, Drug, and Cosmetic Act is amended to read as follows: "For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any consulting laboratory, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, consulting laboratory, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, and all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this Act."

(b) The first sentence of subsection (b) of section 704 of such Act is amended to read as follows:

"(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, or (3), in the case of a drug, has been or is being manufactured, processed, packed, or held under conditions which may cause it to be adulterated within the meaning of section 501(a)(2)(B) of this Act."

(c) Section 704 of such Act is further amended by adding at the end thereof the following new subsection:

"(e) As used in this section, the term 'consulting laboratory' means a laboratory or other establishment which, for a fee or other remuneration, performs or agrees to perform assays or other laboratory services for a manufacturer, processor, compounder, packer, or distributor of food, drugs, devices, or cosmetics, if such manufacturer, processor, compounder, packer, or distributor owns or has under his control an establishment which (other than as a consulting laboratory) is subject to inspection under this section."

(d) Subsection (a) of section 302 of such Act, as amended by section 103(e) of this Act, is further amended by striking out "(f),".

CONFIDENTIALITY OF INFORMATION OBTAINED BY INSPECTION, AND SO FORTH

SEC. 202. Paragraph (j) of section 301 of such Act is amended by—

(1) inserting "or as authorized by law," after "Act."; and

(2) striking out the following: "concerning any method or process which as a trade secret is entitled to protection".

EFFECTIVE DATE

SEC. 203. The amendments made by this title shall take effect on the date of enactment of this Act.

[H.R. 11582, 87th Cong., 2d sess.]

A BILL To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the Act with respect to cautionary labeling; and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Cosmetics and Therapeutic Devices Amendments of 1962".

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TITLE I—PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

NEW COSMETICS

SEC. 101. (a) Section 601, as amended, of the Federal Food, Drug, and Cosmetic Act (relating to cosmetics deemed adulterated) is further amended by adding at the end thereof the following new paragraph:

"(f) If it is unsafe within the meaning of section 605(a)."

(b) Chapter VI of such Act is amended by adding at the end thereof a new section as follows:

"NEW COSMETICS

"SEC. 605. (a) A cosmetic shall be deemed unsafe for the purposes of section 601(f) if—

"(1) its composition is such that such cosmetic is not generally recognized, among experts qualified by scientific training and expeirence to evaluate the safety of cosmetics, as having been adequately shown to be safe for its intended use and other reasonably foreseeable uses, or

"(2) its composition is such that such cosmetic, as a result of investigations to determine its safety for such a use, has become so recognized, but such cosmetic has not, otherwise than in such investigations, been so used to a material extent or for a material time,

unless an application with respect to such cosmetic has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or unless such cosmetic is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i).

"(b) Any person may file with the Secretary an application for determination by the Secretary of the safety of any cosmetic described in clause (1) or (2) of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such cosmetic is safe for use; (2) a full list of the articles used as components of such cosmetic; (3) a full statement of the composition of such cosmetic; (4) a full description of the methods used in, and the facilities and control used for, the manufacture, processing, and packing of such cosmetic; (5) such samples of such cosmetic and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such cosmetic.

"(c) Within ninety days after the filing of an application under this subsection or within such additional period (not exceeding one hundred and eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—

"(1) approve the application if he then finds that none of tne grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary to be held under subsection (d) on the question whether such application is approvable.

"(d)(1) If the Secretary finds, after due notice and opportunity for a hearing to the applicant, that (A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such cosmetic is safe for its intended use and other reasonably foreseeable uses; (B) the results of such tests show that such cosmetic is unsafe for any such use or do not show that such cosmetic is safe for such uses; (C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic are inadequate to preserve its identity, strength, quality, purity, and safety; (D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such cosmetic, he has insufficient information to determine whether such cosmetic is safe for its intended use and other reasonably foreseeable uses; or (E) approval is precluded by paragraph (2) or (3) of this subsection, he shall issue an order denying approval of the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (A) through (E) do not apply, he shall issue an order approving the application.

"(2) A cosmetic shall be deemed unsafe for purposes of section 601(f) and an application with respect to such cosmetic pursuant to this section 605 may not be approved—

"(A) if its intended use or any reasonably foreseeable use will or may result in ingestion of all or part of such cosmetic and (i) the cosmetic is found by the Secretary to induce cancer when ingested by man or animal or (ii) it is found by the Secretary, after tests or other experience appropriate for the evaluation of the safety of cosmetics for any such use, to induce cancer in man or animal, or

"(B) if its intended use or any reasonably foreseeable use wil lnot result in ingestion of any part of such cosmetic and, after tests which are appropriate for the evaluation of the safety of cosmetics for any such use, or after other relevant exposure of man or animal to such cosmetic, it is found by the Secretary to induce cancer in man or animal.

"(3) An application with respect to a cosmetic may not be approved under this section if the data before the Secretary show that its intended use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application under this section if the Secretary finds that (1) for reasons set forth by him, there is substantial doubt as to the safety of the cosmetic for its intended use or any other reasonably foreseeable use, or (2) the application filed pursuant to subsection (b) contains any untrue statement of a material fact, or (3) the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic are then inadequate to assure and preserve its identity, strength, quality, purity, and safety, or (5) any condition attached to approval of the application has been violated: *Provided*, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection.

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

"(g) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last-known address in the records of the Secretary.

"(h) The applicant may obtain judicial review of a final order of the Secretary denying or withdrawing approval of an application under this section in accordance with the provisions of subsection (f) (1)–(5) of section 701.

"(i) The Secretary shall promulgate regulations for exempting from the operation of this section cosmetics intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of cosmetics. Such regulations may provide for conditioning such exemptions upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such cosmetics as the Secretary finds will enable him to evaluate the safety of such cosmetics in the event of the filing of an application pursuant to subsection (b).

"(j) (1) Every person engaged in manufacturing, compounding, or processing any cosmetic with respect to which approval of an application, filed pursuant to this section, is in effect shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such person with respect to such cosmetic, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or to facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."

PROHIBITED ACTS, AND SO FORTH

SEC. 102. (a) Paragraph (e) of section 301 of such Act is amended by inserting before the period at the end thereof a semicolon and the following: "or the failure to establish or maintain any record, or make any report, required under section 605 (i) or (j), or the refusal to permit access to or verification or copying of any such required record."

(b) Paragraph (j) of section 301 of such Act is amended by inserting "605," after "507,".

(c) Paragraph (1) of such section 301 is amended (1) by inserting "or cosmetic" after the word "drug" each time it appears therein; (2) by inserting "or approval thereof" after "application"; and (3) by striking out "505," and inserting in lieu thereof "505 or 605, as the case may be,".

(d) Subsection (a) of section 302 of such Act is amended by striking out "(e),".

REPEAL OF SPECIAL EXEMPTIONS FOR HAIR DYES

SEC. 103. (a) Paragraph (a) of section 601 of such Act is amended by striking out the colon which precedes "*Provided*" and all that follows down to but not including the period at the end of such subsection.

(b) Paragraph (e) of such section 601 is amended by striking out "it is not a hair dye and".

(c) Paragraph (e) of section 602 of such Act is amended by striking out the second sentence of such paragraph.

(d) Subsection (a) of section 706 of such Act is amended by striking out "other than a hair dye (as defined in the last sentence of section 601(a))".

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 104. (a) Except as provided in subsections (b) and (c) of this section, the foregoing provisions of this title shall take effect on the date of enactment of this Act.

(b) Except as provided in subsection (c) of this section, section 601(f) of the Federal Food, Drug, and Cosmetic Act, as added to such Act by section 101(a) of this Act, shall, with respect to any particular use or uses of a cosmetic, take effect (1) on the first day of the seventh calendar month following

the month in which this Act is enacted, or (2) if sooner, on the effective date of an order of the Secretary approving or denying approval of an application with respect to such use or uses of such cosmetic under section 605 of the Federal Food, Drug, and Cosmetic Act, as added by section 101 of this Act.

(c)(1) In the case of any cosmetic which was commercially used or sold for any particular use or uses on the day immediately prior to the date of the enactment of this Act, such section 601(f) of the Federal Food, Drug, and Cosmetic Act shall, with respect to such use or uses of such cosmetic, become effective on the closing date (as defined in this subsection) or, if sooner, on the effective date of an order of the Secretary approving or denying approval of an application with respect to such use or uses of such cosmetic under section 605 of such Act as added by section 101 of this Act.

(2) For the purposes of this subsection, the term "closing date" means the first day of the thirteenth calendar month which begins after such date of enactment, except that, if in the opinion of the Secretary it would not involve any undue risk to the public health, he may on application postpone such closing date with respect to any such use or uses of such cosmetic until such later date (but in no event subsequent to the first day of the thirty-first calendar month following such month) as he determines is necessary to permit completion, in good faith and as soon as reasonably practicable, of the scientific investigations necessary to establish the safety thereof. The Secretary may terminate any such postponement at any time if he finds that such postponement should not have been granted or that, by reason of a change in circumstances, the basis for such postponement no longer exists or that there has been a failure to comply with a requirement of the Secretary for submission of progress reports or with other conditions attached by him to such postponement.

TITLE II—SAFETY, EFFICACY, AND RELIABILITY OF DEVICES

REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

SEC. 201. (a) Section 501(a) of the Federal Food, Drug, and Cosmetic Act is amended by inserting before the period at the end thereof a semicolon and the following: "or (5) if it is a device and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) (i) to insure that its identity does not differ from, and that its efficacy and quality do not fall below, those which it purports or is represented to possess, or (ii) to insure that it will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with its labeling), or (iii) to insure that its labeling is not such as to cause it to be adulterated or misbranded".

(b) Section 701(e) of such Act is amended by striking out, in the first sentence, "501(b)" and inserting in lieu thereof "501 (a) or (b)".

PREMARKETING CLEARANCE OF NEW DEVICES

SEC. 202. (a) Section 501(a) of such Act, as amended by section 201 of this Act, is further amended by inserting before the period at the end thereof a semicolon and the following: "or (6) if it is a device which is unsafe within the meaning of section 508".

(b) Chapter V of such Act is amended by adding at the end thereof a new section as follows:

"SEC. 508. (a) A device shall be deemed unsafe for the purposes of section 501(a)(6) if—

"(1) its composition, construction, or properties are such that such device is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and efficacy of devices, as safe and efficacious for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or

"(2) its composition, construction, or properties are such that such device, as a result of investigations to determine its safety and efficacy for use under such conditions, has become so recognized, but such device has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions,

unless (A) an application with respect to such device has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or (B) such device is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i), or (C) such device confroms to the terms of an exemption which is in effect with respect theereto under subsection (k).

"(b) Any person may file with the Secretary an application for determination by the Secretary of the safety and efficacy of any device described in clause (1) or (2) of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such device is safe and efficacious for use; (2) a full list of the articles used as components of such device; (3) a full statement of the composition, properties, and construction, and of the principle or principles of operation, of such device; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device; (5) such samples of such device and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such device.

"(c) Within ninety days after the filing of an application under this subsection or within such additional period (not exceeding one hundred and eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary to be held under subsection (d) on the question whether such application is approvable.

"(d) If the Secretary finds, after due notice to the applicant and opportunity for a hearing to the applicant, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such device is safe and efficacious for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such device is unsafe or inefficacious for such use under such conditions or do not show that such device is safe and efficacious for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device are inadequate to preserve its identity, quality, safety, and efficacy; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such device, he has insufficient information to determine whether such device is safe and efficacious for use under such conditions, he shall issue an order denying approval of the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (4) of this subsection do not apply, he shall issue an order approving the application.

"(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application under this section if the Secretary finds that (1) for reasons set forth by him, there is substantial doubt as to the safety or efficacy of the device for its intended use or any other reasonably foreseeable use, or (2) the application filed pursuant to subsection (b) contains any untrue statement of a material fact, or (3) the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device are then inadequate to assure and preserve its identity, quality, safety, and efficacy, or (5) any condition attached to approval of the application has been violated: *Provided*, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection.

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

"(g) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last-known address in the records of the Secretary.

"(h) The applicant may obtain judicial review of a final order of the Secretary denying or withdrawing approval of an application under this section in accordance with the provisions of subsection (f)(1)–(5) of section 701.

"(i) The Secretary shall promulgate regulations for exempting from the operation of this section devices intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of devices. Such regulations may provide for conditioning such exemptions upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such devices as the Secretary finds will enable him to evaluate the safety and efficacy of such devices in the event of the filing of an application pursuant to subsection (b).

"(j)(1) Every person engaged in manufacturing or processing any device with respect to which approval of an application, filed pursuant to this section, is in effect shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such person with respect to such device, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or to facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

"(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

"(k) The Secretary shall by regulation exempt from this section, or from one or more of the requirements imposed by or pursuant to this section, devices licensed by the Atomic Energy Commission under the Atomic Energy Act of 1954 to the extent he finds it to be appropriate to avoid duplication of regulatory controls or procedures and to be consistent with the purposes of this Act."

PROHIBITED ACTS, AND SO FORTH

SEC. 203. (a) Paragraph (u) of section 201 of such Act is amended to read as follows:

"(u) The term 'safe', except when used with respect to cosmetics, refers to the health of man or animal."

(b) Paragraph (e) of section 301 of such Act, as amended by section 102 of this Act, is further amended by striking out "605 (i) or (j)" and inserting in lieu thereof "508 (i) or (j) or 605 (i) or (j)".

(c) Paragraph (j) of section 301 of such Act, as amended by section 102 of this Act, is further amended by inserting "508," immediately after "507,".

(d) Paragraph (1) of such section, as amended by section 102 of this Act, is further amended (1) by striking out "or cosmetic" each time it appears therein, and inserting in lieu thereof ", device, or cosmetic"; and by striking out "505 or 605" and inserting in lieu thereof "505, 508, or 605".

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 204. (a) Except as provided in subsections (b) and (c) of this section, the foregoing provisions of this title shall take effect on the date of the enactment of this Act.

(b) Except as provided in subsection (c) of this section, clause (6) of paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act, as added to such paragraph by section 202(a) of this Act, shall, with respect to any particular use of a device, take effect (1) on the first day of the seventh calendar month following the month in which this Act is enacted, or (2) if sooner, on the effective date of an order of the Secretary approving or denying approval of such use of the device under section 508 of such Act as added by section 202(b) of this Act.

(c)(1) Where, on the day immediately prior to the date of enactment of this Act, a device was in use in the diagnosis, cure, mitigation, treatment, or preven-

tion of disease in man or animal, or for the purpose of affecting the structure of any function of the body of man or animal, such clause (6) of paragraph (a) of section 501 of the Federal Food, Drug, and Cosmetic Act shall become effective with respect to such preexisting use or uses of such device on the closing date (as defined in this subsection) or, if sooner, on the effective date of an order of the Secretary approving or denying approval of such use of the device under such section 508 of such Act.

(2) For the purposes of this subsection, the term "closing date" means the first day of the nineteenth calendar month which begins after the month in which this Act is enacted, except that, if in the opinion of the Secretary it would not involve any undue risk to the public health, he may on application postpone such closing date with respect to any particular use or uses of a device until such later date (but in no event later than the first day of the thirty-first calendar month following such month of enactment) as he determines is necessary to permit completion, in good faith and as soon as reasonably practicable, of the scientific investigations necessary to establish the safety and efficacy of such use or uses. The Secretary may terminate any such postponement at any time if he finds that such postponement should not have been granted or that, by reason of a change in circumstances, the basis for such postponement no longer exists or that there has been a failure to comply with a requirement of the Secretary for submission of progress reports or with other conditions attached by him to such postponement.

TITLE III—MISCELLANEOUS

CAUTIONARY LABELING OF HAZARDOUS SUBSTANCES OR CONTAINERS UNDER FOOD, DRUG, AND COSMETIC ACT

SEC. 301. (a) Section 403 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end thereof a new paragraph as follows:

"(n) If it is contained in a dispenser pressurized by a gaseous propellant unless it bears such cautionary labeling with respect to handling, storage, and use of such container as is necessary to prevent the causing of injury to the health of any user or other individual during, or as the result of, reasonably foreseeable handling, storage, or use thereof, intentional or otherwise."

(b) Section 502(f) of such Act is amended to read as follows:

"(f) Unless its labeling bears (1) adequate directions for use; and (2) such adquate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, or against a substantial and reasonably foreseeable risk of causing accidental injury, in such manner and form, as are necessary for the protection of users, including instructions for first-aid treatment when necessary or appropriate: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirements."

(c) Section 602 of such Act is amended by adding at the end thereof the following new paragraph:

"(f) If because of its nature, composition, or packaging it involves a substantial risk of causing injury to health during or as the result of any reasonably foreseeable handling, storage, or use by any individuals, whether intentional or otherwise, unless in either case it bears (in addition to any other prescribed labeling) (1) such cautionary labeling as is necessary for the protection of such individuals and (2), where necessary or appropriate, instructions for first-aid treatment. Whenever the Secretary finds that any cosmetic or class of cosmetics is subject to the provisions of this paragraph and in his judgment a declaration to that effect will promote the objectives of this paragraph by avoiding or resolving uncertainty as to its application, he may by regulation declare any such cosmetic or class of cosmetics to be, and it shall during the effectiveness of such regulation be deemed to be, subject to such provisions. Nothing in this paragraph shall be construed to exempt any article otherwise subject to the requirements of this paragraph from such requirements by reason of the absence of such a regulation."

(d) The first sentence of section 701(e) of such Act, as amended by section 201(b) of this Act, is further amended by striking out "or 502 (d) or (h)" and inserting in lieu thereof the following: ", 502 (d) or (h), or 602(f)".

(e) Section 18 of the Federal Hazardous Substances Labeling Act is amended by striking out the following: ", except that the Federal Caustic Poison Act shall remain in full force and effect with respect to any 'dangerous caustic or corrosive substance' (as defined by that Act) which is an article subject to the Federal Food, Drug, and Cosmetic Act and which is, by virtue of paragraph 2 of section 2(f) of this Act, excluded from the term 'hazardous substance' as defined in this Act".

(f) This section shall take effect on the first day of the seventh calendar month which begins after the month in which this Act is enacted, or, with respect to any particular class of article or container to which this section applies, on such subsequent date (not later than the first day of the nineteenth month following the month of enactment of this Act), as the Secretary may, by order specifying such class of article or container, prescribe on the basis of a finding that conditions exist which necessitate such postponement of the effective date.

FEED ADDITIVES LEAVING NO RESIDUE IN FOOD FOR HUMANS

SEC. 302. (a) The proviso to clause (A) of paragraph (3) of section 409(c) of the Federal Food, Drug, and Cosmetic Act, relating to food additives found to induce cancer, is amended by inserting before the semicolon at the end of such proviso the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

(b) Such Act is further amended by inserting before the period at the end of subparagraph (B) of paragraph (5) of section 706(b), relating to color additives found to induce cancer, a colon and the following proviso: "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

(c) The amendments made by this section shall take effect on the date of enactment of this Act.

MODIFICATION OF PRIOR-SANCTION CLAUSE OF FOOD ADDITIVES AMENDMENT

SEC. 303. Clause (4) of section 201(s) of the Federal Food, Drug, and Cosmetic Act is amended by inserting in such clause, before the period, a colon and the following: "*Provided*, That, with respect to any sanction or approval granted pursuant to this Act, this clause shall be inapplicable, and the provisions of this Act (other than this clause) relating to food additives shall apply, to any such previously sanctioned or approved use of a substance if, on the basis of the information then available, the Secretary finds that, for the reasons set forth by him, there is substantial doubt as to its safety. Except when the Secretary finds that there is an imminent hazard to public health, he shall take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public, and only after sending reasonable notice of his proposed action and the reasons therefor to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised thereof unless such personal notice is impracticable."

DEPARTMENT OF AGRICULTURE,
Washington, D.C., June 21, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We wish to thank you for your letter of May 11, 1962, giving us the opportunity to make a report on House bill 11581. The bill is entitled to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws.

We favor the enactment of H.R. 11581.

Enactment of the proposed legislation would not affect the jurisdiction of this Department over products coming within the purview of the Virus-Serum-Toxin Act (21 U.S.C. 151–158) which is administered by this Department. This act prohibits the preparation, sale, or shipment in commerce of any virus, serum, toxin, or analogous product manufactured in the United States and intended for use in the treatment of domestic animals, unless such products have been prepared under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding a license issued by the Secretary. It authorizes the said Secretary to inspect such establishments and such products and their preparation; inspect viruses, serums, toxins, and analogous products for use in the treatment of domestic animals which are being imported or offered for importation into the United States; issue permits for the importation of such products or deny their entry; and issue rules and regulations to carry out the provisions of the act. Criminal penalty is provided for violation of any provision of the act. Pursuant to the authority contained in the act, the Secretary has issued rules and regulations thereunder (9 CFR, ch. 1, subch. E, pts. 101–123).

H.R. 11581 would impose additional requirements with respect to drugs under the Federal Food, Drug, and Cosmetic Act. Some products that are drugs under that act with respect to their drug uses are also economic poisons, with respect to their pest control uses, under the Federal Insecticide, Fungicide, and Rodenticide Act, administered by this Department. There are some products which are now subject to both acts and liaison has been established between this Department and the Food and Drug Administration to avoid conflicts in the application of the two acts. We are, therefore, assuming that the proposed bill would not adversely affect this Department's jurisdiction over such products under the Federal Insecticide, Fungicide, and Rodenticide Act.

This proposed legislation is in accord with the President's message (H. Doc. 364, 87th Cong., 2d sess.) relative to consumers' protection and interest program. In this message he recommended legislation to strengthen and broaden existing laws in the food and drug field to provide consumers with better, safer, and less expensive drugs.

The Bureau of the Budget advises that the enactment of H.R. 11581 would be in accord with the President's program.

Sincerely yours,

ORVILLE L. FREEMAN, *Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., June 25, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Bureau of the Budget on H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability or drugs, authorize standardization of drug names, establish special controls for barbiturate and stimul and drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, and H.R. 11582, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and

reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling; and for other purposes.

H.R. 11581 and H.R. 11582 would strengthen and broaden the existing statutory authority of the Food and Drug Administration so that agency could more adequately safeguard the consumers of foods, drugs, and cosmetics. In addition, H.R. 11581 would amend the Federal Trade Commission Act to give that agency additional authority to monitor prescription drug advertisements.

In his special message to the Congress of May 15, 1962, on consumer protection, the President stated that legislation was needed "* * * to assure the necessary protection the American consumer deserves." Specifically, the President recommended "* * * legislation to strengthen and broaden existing laws in the food and drug field to provide consumers with better, safer, and less expensive drugs, by authorizing the Department of Health, Education, and Welfare to—

"(a) Require a showing that new drugs and therapeutic devices are effective for their intended use—as well as safe—before they are placed on the market;

"(b) Withdraw approval of any such drug or device when there is substantial doubt as to its safety or efficacy, and require manufacturers to report any information bearing on its safety or efficacy;

"(c) Require drug and therapeutic device manufacturers to maintain facilities and controls that will assure the reliability of their product;

"(d) Require batch-by-batch testing and certification of all antibiotics;

"(e) Assign simple common names to drugs;

"(f) Establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines;

"(g) Require cosmetics to be tested and proved safe before they are marketed; and

"(h) Institute more effective inspection to determine whether food, drug, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law."

In addition, the President recommended legislation "* * * to authorize the Federal Trade Commission to require that advertising of prescription drugs directed to physicians disclose the ingredients, the efficacy, and the adverse effects of such drugs * * *."

The two instant bills contain the specifics of new legislation which is required to meet the needs in this area as set forth by the President in the foregoing statement. Accordingly, I am authorized to advise you that enactment of H.R. 11581 and H.R. 11582 would be in accord with the program of the President.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

THE SECRETARY OF COMMERCE,
Washington, D.C., July 26, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in further reply to your request for the views of this Department with respect to H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, and H.R. 11582, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling; and for other purposes.

The Department of Commerce recommends enactment of H.R. 11581 and H.R. 11582.

The Bureau of the Budget advised there would be no objection to the submission of this report from the standpoint of the administration's program.

Sincerely yours,

(For Edward Gudeman, Secretary of Commerce).

FEDERAL TRADE COMMISSION,
Washington, D.C., June 13, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your letter of May 11, 1962, requesting the Commission's comments on H.R. 11581, 87th Congress, 2d session, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws.

The only section of this bill which pertains to the activities of the Commission is "Part D. Amendments as to Advertising." It would amend section 15 of the Federal Trade Commission Act so as to require certain specified disclosures in the advertisements of prescription drugs. The provisions of this part, although not worded precisely in the same manner, are for all practical purposes identical to those in H.R. 6471, 87th Congress, 1st session.

The President, in his message to the Congress on March 15 on "Protecting the Consumer Interest," recommended "* * * legislation to authorize the Federal Trade Commission to require that advertising of prescription drugs directed to physicians disclose the ingredients, the efficacy, and the adverse effects of such drugs." These objectives, which part D of the subject bill seeks to attain, are highly laudable and have the wholehearted endorsement of the Commission.

By direction of the Commission:

PAUL RAND DIXON, *Chairman.*

N.B.—Pursuant to regulations, this report was submitted to the Bureau of the Budget on May 31, 1962, and on June 12, 1962, the Bureau of the Budget advised that there is no objection to the submission of this report from the standpoint of the administration's program.

JOSEPH W. SHEA, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
June 21, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in reply to your request of May 11, 1962, for a report on H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws.

This bill, to be known as the Drug and Factory Inspection Amendments of 1962, would carry forward a number of the measures recommended by President Kennedy in his message to the Congress on March 15, 1962, relative to consumers' protection and interest program.

The bill would amend the Food, Drug, and Cosmetic Act to—

(1) Require adequate controls in the manufacture of drugs.

(2) Require new drugs to be proved effective as well as safe before they are marketed.

(3) Require manufacturers of new drugs and antibiotics to report information to this Department bearing on the safety or efficacy of their products.

(4) Permit approval of a new drug application to be withdrawn when substantial doubt arises as to the safety or efficacy of the drug, and make certain desirable changes in the procedure for handling new drug applications.

(5) Require all antibiotics to be certified.

(6) Give this Department authority to assign simple common names to drugs, and require these names to be used prominently on drug labels.

(7) Provide for more effective inspection to determine whether food, drugs, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law.

The bill would amend the Public Health Act to require biological drugs for humans to be effective as well as safe, and round out the enforcement protection now accorded with respect to such drugs under the Food and Drug Act.

Finally, it would amend the Federal Trade Commission Act to require advertisements for prescription drugs to be truthful and to supply certain information needed by physicians, as recommended by the President.

Enclosed are a detailed section-by-section analysis of the bill, and a comparative print showing graphically the effect of the amendments on existing law.

For the reasons stated in the President's message, and as has been brought out in more detail in our testimony on the bill, this legislation is needed to enhance consumer protection. We urge its enactment at this session.

The Bureau of the Budget advises that enactment of this bill would be in accord with the program of the President.

Sincerely,

ABE RIBICOFF, *Secretary.*

SECTION-BY-SECTION ANALYSIS OF DRUG AND FACTORY INSPECTION AMENDMENTS OF 1962

SHORT TITLE

The first section of the bill would provide that the act may be cited as the "Drug and Factory Inspection Amendments of 1962."

TITLE I—DRUGS

PART A—AMENDMENTS TO ASSURE SAFETY, EFFICACY, AND RELIABILITY

Section 101(a) of the bill would amend section 501(a)(2) of the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as the "basic act") to deem any drug to be adulterated if the methods, controls, facilities, or personnel used in its manufacture were inadequate, as determined in accordance with regulations promulgated by the Secretary based on good manufacturing practice, to insure that its identity, strength, purity, quality, and efficacy are as represented, that the drug will not be injurious to health when used as directed or prescribed, and that its labeling is not violative of the act.

Section 101(b) of the bill would make the formal rulemaking procedures of section 701(e) of the basic act applicable to regulations referred to in section 101(a) of the bill.

Section 102 of the bill would amend subsections (b), (d), (e), and (i) of section 505 (the new-drug section) of the basic act so as to require that any new drug be cleared for efficacy (in addition to safety, as at present) before being introduced or delivered for introduction in interstate commerce. Any clearance of a new drug would have to be withdrawn if it is inefficacious. This section of the bill would correspondingly amend section 201(p) of the basic act—which now defines a drug as a "new drug"—so as to introduce the factor of efficacy as an element of the definition coordinate with the factor of safety.

It should be noted that in certain types of cases the question of the efficacy of a new drug is already considered under existing law in determining whether the drug is "safe." For example, for obvious reasons a "harmless" but inefficacious new drug offered for the treatment of a life-threatening disease, such as cancer, is not considered "safe." Again, a drug the use of which involves the risk of toxic side reactions is considered "safe" only if the drug is so valuable from the point of its efficacy as to overbalance this risk and if these side reactions are warned against in the proposed labeling of the drug.

The bill would require a showing of efficacy not only in the above-mentioned types of cases, but with respect to any new drug. Under present law, except where the question of efficacy enters into a determination of safety, an innocuous new drug has to be cleared for the market by the Department unless the application itself contains a demonstrably untrue statement of a material fact, even though the drug may be worthless for the purpose for which it is to be sold. In some of these cases the Department may be able, after extensive investigation, to gather the necessary proof to have the drug removed from the market by judicial action under the misbranding provisions of the act, but in the meantime the product may have been on the market for years.

The "efficacy" to which the bill refers is not efficacy in the abstract, but efficacy of the drug for use under the conditions prescribed, recommended, or suggested in its proposed labeling. Moreover, except as the relative efficacy of a drug (as compared with other drugs) may be a relevant factor under existing law in the determination of its safety, a drug which meets the test of efficacy when considered by itself could not be barred merely because the evidence does not show that the drug's efficacy is superior to that of other known drugs.

Section 103(a) of the bill would amend section 505 of the basic act by adding a new subsection (j) at the end thereof, which would authorize the Secretary to require "new-drug" applicants to keep such records, and to make such reports, of clinical and other data obtained by them, as the Secretary may (by general regulation or by specific order) prescribe in order to enable or help the Department to determine whether approval of a new-drug application should be withdrawn or suspended. Also, officers or employees designated by the Secretary would have the right to have access to and copy such records.

Section 103(b) of the bill would amend section 505(i) of the basic act to authorize the Secretary to condition investigational-use exemptions of new drugs upon the establishment and maintenance of such records, and the making of such reports, as the Secretary finds will enable him to evaluate the safety and efficacy of such drugs in the event of the filing of a new-drug application.

Section 103(c) of the bill would amend section 505(e) of the basic act to make the failure of an applicant to establish or maintain any required records, or to make any required report, or to refuse to permit access to or copying of any such record, a ground for withdrawal of approval of a new-drug application.

Section 103(d) of the bill would amend section 301(e) of the basic act so as to make the failure to establish or maintain a record, or make a report, required under section 505 (i) or (j) of the basic act (as amended by the bill), or the refusal to permit access to or verification or copying of such a record, a prohibited act.

Section 103(e) of the bill would amend subsection (a) of section 302 of the basic act to authorize injunctions to restrain prohibited acts referred to in section 301(e) of the basic act as amended by the bill.

Section 104(a) of the bill would amend section 505 of the basic act so that new-drug applications would no longer become effective by the mere failure of the Secretary to act timely. (Under existing law, unless the Secretary, after opportunity for hearing, issues an order within 60 days (or an extended period specified by the Secretary, up to 180 days) refusing to permit the application to become effective, the application becomes effective automatically.) Specifically, the bill would amend section 505(c) of the basic act to provide that the Secretary shall, within 90 days after the filing of a new-drug application or within such additional period (not to exceed 180 days after filing) as he deems necessary, either (1) approve the application if he then finds that none of the statutory grounds for denial applies, or (2) give the applicant notice of an opportunity for hearing on the question whether such application is approvable. The hearing itself, and action thereon, would not be subject to specific time limits. Also, conforming amendments would be made in section 505 (a), (b), and (d) of the basic act. Section 505 of the basic act, as so amended, would require the Secretary to deny approval of the new-drug application if he finds that there is ground for such denial on one of four statutory grounds, and to approve the application if none of these grounds applies.

Section 104(b) of the bill would make certain procedural and substantive changes, set forth below, in section 505(e) of the basic act (which now provides for suspension of the effectiveness of a new-drug application because the drug is unsafe or the new-drug application contained an untrue statement). (These changes would be in addition to those made by earlier parts of the bill, i.e., section 102(b) of the bill which would add inefficacy, and section 103(c) which would add failure to establish or maintain certain records or make certain reports, to the grounds for suspension of a new-drug application.)

In the first place, section 104(b) of the bill would, in conformity with the procedural changes made by section 104(a) of the bill, amend section 505(e) of the basic act so as to require withdrawal of approval, rather than suspension of the effectiveness, of a new-drug application (after opportunity for hearing) upon the basis of the requisite findings. Secondly, if the Secretary finds that there is an imminent hazard to the public health, immediate suspension of approval of a new-drug application would be permitted pending opportunity for hearing.

Thirdly, a finding of substantial doubt as to the safety or efficacy of a new drug would suffice as ground for withdrawal of approval; and the evidentiary basis for a finding of lack, or substantial doubt, of safety or efficacy of the drug could be based on clinical or other experience, tests, or other scientific data, whereas existing law requires the drug to be found unsafe on the basis of clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective. Finally, approval of a new-drug application could be withdrawn also because the facilities and controls used for the manufacture, processing, and packing of a new drug are then inadequate to assure and preserve its identity, strength, quality, purity, safety, and efficacy, or because any conditions upon which the application was approved have been violated.

Section 104(c) of the bill would make certain conforming amendments in section 505(f) of the basic act which are required by the procedural amendments made by section 104 (a) and (b) of the bill.

Section 104(d) of the bill would amend section 505(h) (the judicial-review provisions) of the basic act to (1) provide for judicial review of adverse orders on new-drug applications initially in the Federal courts of appeals rather than the district courts, (2) conform these provisions to procedural amendments of other judicial-review provisions of the basic act effected by Public Law 86–545 and Public Law 85–791 on recommendation of the Judicial Conference of the United States, and (3) conform section 505(h) of the basic act to changes made by section 104 (a) and (b) of the bill, so that the judicially reviewable order would be one denying or withdrawing approval of a new-drug application (rather than an order refusing to permit such an application to become effective or one suspending the effectiveness of such an application). Under other provisions of the basic act, judicial review of the Department's orders on the basis of an administrative hearing record is directly in the U.S. courts of appeals, in conformity with prevailing practice, and the departure from this pattern seems to have been overlooked when, during congressional consideration of what is now the Food, Drug, and Cosmetic Act, a special bill to safeguard the public health against inadequately tested new drugs was introduced and, in revised form, incorporated in the then pending food, drug, and cosmetic bill as section 505.

Section 104(e) of the bill would amend section 301(l) and section 503(b)(1)(C) of the basic act to conform the language of these sections to the procedural amendments made by section 104 (a) and (b) of the bill.

Section 105 (a) and (b) would amend sections 507 and 502(l) of the basic act to extend to all antibiotics the requirement of batch-by-batch certification which now applies only to drugs composed wholly or partly of one of five specified antibiotics (i.e., penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin) or their derivatives. The present power of the Secretary to exempt from the certification requirement any drug or class of drugs with respect to which he does not consider the requirement necessary in order to insure safety and efficacy of use of the drug, would also apply to the antibiotics brought within the scope of section 507 by the bill.

Section 106(a) of the bill would add a new subsection (g) to section 507 of the basic act to authorize the Secretary to require manufacturers and others who make, compound, or process antibiotics to keep such records, and to make such reports, of clinical and other data obtained by them, as will enable the Secretary to determine whether a batch certification or release should be rescinded or whether any regulation issued under section 507 should be amended or repealed. Similarly, section 106(b) of the bill would amend section 507(d) of the basic act to authorize the Secretary to issue regulations conditioning an investigational-use exemption of any drug within the purview of this section from the requirements of section 507 upon the establishment and maintenance of such records, and the making of such reports, of data obtained as the result of such investigational use of such drugs, as the Secretary finds will enable him to evaluate the safety and efficacy for use of such drug. An additional provision in section 106(a) of the bill would also, by a provision in the new section 507(g), direct persons who maintain the above-mentioned records, and persons in charge of such records, to let officers or employees designated by the Secretary have access to and copy or verify such records. All of these provisions parallel requirements added to the new-drug section of the basic act by section 103 of the bill.

Section 106(c) of the bill would further amend section 301(e) of the basic act, as amended by section 103(d) of the bill, to make the failure to establish or maintain any record, or make any report, required under the new section 507(g)

of the basic act, or the failure to permit access to or verification or copying of such a record, a prohibited act.

Section 107(a) of the bill would amend section 351(d) of the Public Health Service Act, providing for licensing of biological products, so as to require a showing that the drug is efficacious under the conditions prescribed, recommended, or suggested by the manufacturer. This amendment would, of course, necessarily authorize the Department to require full reports of investigations as to efficacy, not merely a selective presentation of those data which are favorable to the applicant.

Section 107(b) would add a new paragraph (e) to section 501 and a new paragraph (n) to section 502 of the Federal Food, Drug, and Cosmetic Act to round out the protection afforded by that act with respect to drugs subject to licensing under section 351 of the Public Health Service Act (relating to viruses, serums, toxins, and analogous products for humans). The new paragraph (e) of section 501 would deem such a drug to be adulterated within the meaning of the Food and Drug Act if it is a product within the purview of section 351 of the Public Health Service Act and (1) it has not been manufactured in conformity with such section and regulations and standards thereunder, by a licensed manufacturer, and in accordance with the terms of such license, or (2) at any time (A) it is not in conformity with such section and regulations and standards thereunder, or (B) the expiration date on its labeling has passed, or (C) such license has been suspended or revoked. The new paragraph (n) of section 502 would deem such a drug to be misbranded under the Food and Drug Act if it is a drug that is a product within the purview of section 351 of the Public Health Service Act and its packaging or labeling is not in conformity with such section or with regulations thereunder. For instance, under these amendments the seizure and condemnation provisions and other sanctions of the Food and Drug Act could be invoked with respect to a drug that is a product within the purview of section 351 of the Public Health Service Act if it is discovered after shipment in interstate commerce that the drug was not manufactured under requisite license (i.e., both an establishment license and an applicable product license) or was not made, packaged, or labeled in full conformity with the requirements established under section 351 of the Public Health Service Act, or if the drug or its packaging or labeling ceases to meet such requirements, or if the expiration date on the label expires or the license (i.e., either the establishment or applicable product license) is suspended or revoked. (It should be noted that existing provisions of the Food and Drug Act afford protection where the expiration date on the label is falsified.)

Section 107(c) would amend section 902(c) of the Food, Drug, and Cosmetic Act—which provides that nothing in the act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of certain enumerated laws—to include in the enumeration the Animal-Virus-Serum-Toxin Act of March 4, 1913 (21 U.S.C. 151–158), an act relating to viruses, serums, toxins, and analogous products intended for use in treating domestic animals. At the same time, it would substitute a reference to section 351 of the Public Health Service Act for the reference to the Virus, Serum, and Toxin Act of July 1, 1902, which was repealed and replaced by the Public Health Service Act.

Section 108 of the bill provides for the effective dates of the various sections of part A of title I, and contains transitional provisions.

Section 102 of the bill (amending section 505 of the Food, Drug, and Cosmetic Act with respect to new-drug efficacy) and section 104 of the bill (amending section 505 of the Food, Drug, and Cosmetic Act in procedural respects and by adding additional grounds for withdrawal or suspension of approval of a new-drug application) would take effect on the date of enactment, except that, in the case of new drugs cleared for the market under section 505 of the act prior to enactment of the bill, the amendments (section 102(a); section 102(b)(2), (4), and (5)) requiring a showing of efficacy of a new drug before the new-drug application is approved would apply only if an amendment to the new-drug application is submitted or if (under section 505(e) of the Food, Drug, and Cosmetic Act as amended by other provisions of the bill) approval of the new-drug application is suspended or withdrawn. (It will be noted that this exception does not apply to the authority to withdraw or suspend approval (because of substantial doubt of safety or efficacy, under the amendments made by section 102(b)(3) and section 104(b) of the bill) of a new-drug application covering a new drug cleared for the market before enactment, but prior to institution of a formal proceeding to withdraw approval of such a new-drug application on the ground of lack of efficacy or substantial doubt as to efficacy

the Department intends to afford the applicant an opportunity to furnish any data as to efficacy available to the applicant which might obviate the need for such a proceeding.) An application effective on the day immediately preceding the date of enactment of the act would, on the date of enactment, be deemed to be an approved application. If an application filed prior to the date of enactment of the act is still pending on the date of enactment, the running of the period within which the Secretary must act on such application would be deemed to have commenced on the day immediately following the date on which the application was, in fact, filed, and any time extension in force (pursuant to section 505(c)) prior to the date of enactment would (to the extent it exceeds 90 days from the date of filing) be deemed to be an extension of time notified pursuant to section 505(c), as amended by the bill.

Sections 101, 103, 105, and 106 of the bill (respectively relating to records and reports as to experience on new drugs, deeming a drug or device to be adulterated if not manufactured under adequate controls, providing for certification of all antibiotics, and relating to records and reports as to experience on antibiotics) would be effective on the first day of the seventh calendar month following the month in which the bill is enacted.

Section 107(a) of the bill (amending sec. 351 of the Public Health Service Act so as to require a showing of efficacy for biological drugs) would be effective on the date of enactment; except that it would not apply with respect to any biological products with respect to which a license issued under section 351(d) of the Public Health Service Act was effective on the date immediately preceding the date of enactment of this act, so long as the license has not been suspended or revoked and there is no application for amendment of the license, unless the Secretary finds that there is a substantial doubt as to whether such product is efficacious under the conditions prescribed, recommended, or suggested by the manufacturer.

Section 107(b) of the bill (amending secs. 501 and 502 of the Food and Drug Act with respect to biological drugs within the purview of sec. 351 of the Public Health Service Act), and section 107(c) of the bill (amending sec. 902(c) of the Food and Drug Act by inserting a reference to the Animal-Virus-Serum-Toxin Act and bringing up to date the reference to the law requiring licenses for biological drugs (for humans) now covered by sec. 351 of the Public Health Service Act) would take effect on the date of enactment of the bill.

PART B—STANDARDIZATION OF DRUG NAMES

Section 111(a) of the bill would add a new section 508 to chapter V of the Federal Food, Drug, and Cosmetic Act.

New section 508 of the basic act would authorize the Secretary to promulgate regulations establishing a single standard name for a drug whenever in his judgment such action is necessary or desirable in order to achieve usefulness and simplicity of drug nomenclature, or because two or more names (in addition to the systematic chemical name) exist for the same drug (or for two or more drugs which are identical in their active ingredients and substantially identical in their pharmacological action, strength, quality, and purity) or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name (other than the systematic chemical name) for a drug. Such regulations could include any related or additional information—e.g., information as to the drug's systematic chemical name, or formula, or composition, or as to other names under which the drug is or has been known—which in the Secretary's judgment is desirable to facilitate the correct and effective use of such standard name.

The Secretary, in establishing a standard name for a drug, could either coin a new name or could choose one of the nonproprietary names already in use, including the systematic chemical name or the official title or a synonym for the drug in an official compendium. The word "name" is intended to include any type of designation, such as code letters or symbols. It is intended that in defining a drug to which a particular standard name shall apply, the regulation establishing such name may allow for optional inactive ingredients, in which event the inclusion of such ingredients in a preparation would not affect the applicability of the standard name to the preparation. On the other hand, where differences in the inactive ingredients significantly affect the action of a drug, these differences could be reflected by him in establishing a basic standard name with appropriate modifiers of the name for different actions.

Section 111(b) of the bill would provide that section 111 would take effect on the date of enactment.

Section 112(a) of the bill would amend section 502(e) of the basic act. Under existing law, paragraph (e) of section 502 requires that the label of a drug that is not designated solely by a name recognized in an official compendium bear (i) the common or usual name (if any) of the drug, and (ii) if fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of certain specified ingredients (or derivatives or preparations thereof) contained therein. A proviso in paragraph (e) directs the Secretary to establish exemptions from the requirements as to ingredients to the extent that compliance is impracticable.

The bill would amend paragraph (e) in the following respects: (1) It would make paragraph (e) apply whether or not the drug is designated solely by a name recognized in an official compendium. (2) Wherever paragraph (e) now requires the "common or usual name" (or simply "the name") of a drug or of an ingredient to be stated, the bill would require statement of the "established name," which is defined as the applicable standard name established under the new section 509 or, in the absence of such a standard name, the official title (if any) of the drug in the United States Pharmacopoeia (or Homoeopathic Pharmacopoeia in the case of a homoeopathic drug) or other official compendium or, in the absence of both a standard name and official title, the common or usual name of the drug. (3) Except for the systematic chemical name or formula, the established name (if any) of a drug or ingredient required to appear on the label would be the only nonproprietary (so-called generic) name permitted on the label to identify such drug or ingredient. (4) The established name for a drug on the label (and on any labeling where a name for the drug or ingredient is used) would have to be given precedence in position over any proprietary name or designation for such drug, and would have to be in type at least as large and prominent as such proprietary name or designation; and the relationship between the established name of any of the drug's ingredients and a proprietary name or designation for such ingredient (on the drug's label or labeling) would be subject to the same requirement. The Secretary would be required to establish exemptions from this requirement to the extent (if any) to which compliance is impracticable. (The Secretary's present authority to issue regulations as to location and prominence of required information on drug labeling—see sections 502(c), 701(a) of the basic act—will, of course, have to be exercised consistently with this provision of the bill.) (5) The label would have to state the quantity of each active ingredient.

Section 112(b) of the bill would amend section 502(g) of the basic act to provide that in case of any inconsistency between the requirements of paragraph (g) and paragraph (e) of section 502 of the basic act, paragraph (e) shall prevail. Paragraph (g) requires that a drug the name of which is recognized in an official compendium must be packaged and labeled as prescribed therein (though the method of packing may be modified with the consent of the Secretary).

Section 112(c) of the bill would provide that section 112 of the bill shall take effect on the first day of the seventh calendar month following the month in which the bill is enacted.

PART C—SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

Section 121 of the bill would contain congressional findings as to the need for additional regulation of barbiturates and of amphetamines and other habit-forming central-nervous-system stimulant drugs, whether in interstate or intrastate commerce.

Section 122 of the bill would add a new section 509 to chapter V of the Federal Food, Drug, and Cosmetic Act.

New section 509(a) of the basic act would define the term "barbiturate" as any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any barbituric-acid derivative designated by the Secretary under section 502(d) of the basic act as habit forming. The term "habit-forming stimulant drug" would be defined as meaning a drug which contains any quantity of (A) amphetamine or any of its optical isomers; or of (B) any salt of amphetamine, or any salt of an optical isomer of amphetamine; or of (C) any substance which the Secretary, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system. (For authority to establish exemptions from all or part of section 509, see subsection (f)).

Subsection (b) of section 509 of the basic act would prohibit the manufacturing, compounding, or processing of any barbiturate and any habit-forming stimulant drug, except by the following concerns and other persons:

(1) Manufacturers, compounders, and processors who have listed their names and places of business with the Secretary and who are regularly engaged in preparing pharmaceutical chemicals or prescription drugs for distribution through branch outlets, through wholesale druggists, or by direct shipment to pharmacies, hospitals, clinics, public health agencies, physicians, laboratories, or research or educational institutions;

(2) Prescription-drug wholesalers;

(3) Pharmacies, hospitals, clinics, and public health agencies;

(4) Licensed practitioners;

(5) Persons who possess such drugs for use in research, teaching, or chemical analysis and not for sale;

(6) Officers and employees of Federal, State, territorial or local governments, whose possession is in the course of their official duties; and

(7) An employee of any person described in paragraphs (1) through (6), and a nurse or other medical technician under the supervision of a licensed practioner, having possession of such drugs by reason of his employment or occupation.

Subsection (c) of section 509 of the basic act would prohibit possession except by (1) a person described in section 509(b), (2) an individual to whom a drug in his possession has been dispensed or prescribed, in conformance with section 503(b) of the act, by a licensed practitioner in the course of such practitioner's professional practice, or (3) a carrier or warehouseman whose possession of such drug is in the usual course of his business as such.

Subsection (d) of section 509 of the basic act would prohibit the sale, delivery, or other disposition of such drugs to a person not authorized to possess such drugs under subsection (c) of section 509.

Subsection (e) of section 509 of the basic act would require persons engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any such drugs to prepare, and to keep for 3 years, a complete and accurate record of all stocks of each such drug on hand on the effective date of this part of the bill, and prepare a record of the kind and quantity, and relevant dates, concerning such drugs thereafter received, manufactured, compounded, processed, or sold or otherwise disposed of and the persons from whom they were received or to whom they were disposed of. It is intended that invoices of drugs received, containing the required information, would be sufficient records of drugs received.

Records required to be kept under this section, and records of carriers who with respect to shipments of barbiturates or habit-forming stumulant drugs would be subject to inspection and copying of such records, and premises or vehicles where such drugs are kept, held, etc., would likewise be subject to inspection. These provisions are considered necessary in addition to the bill's amendments to section 704 of the basic act (see title II of the bill) because the special provisions relating to barbiturates and habit-forming stimulant drugs are applicable regardless of whether such drugs have been or are intended to be introduced in interstate commerce.

The provisions of this subsection would not apply to a licensed practitioner with respect to drugs received, prepared, possessed, administered, or dispensed by him in the course of his professional practice.

Subsection (f) of section 509 of the basic act would authorize the Secretary to issue regulations exempting any barbiturate or habit-forming stimulant drug from the application of all or part of this section to the extent that he finds regulation is not necessary to protect the public health.

Section 123 of the bill would add to section 301 of the basic act a new subsection (o) which would add to the list of prohibited acts set forth in section 301 the various possible violations of the new section 509.

Section 124 of the bill would amend section 304(a) of the basic act to authorize judicial seizure and condemnation of drugs in cases involving violation of the new section 509.

Section 125 of the bill would provide that nothing in part C of title I of the bill shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State or territory in contravention of the laws of such State or territory.

Section 126 of the bill would make the provisions of part C of title I of the bill effective the first day of the seventh calendar month following the month in which the bill is enacted; except that the Secretary would be required to permit manufacturers, compounders, and processors referred to in the new section 509(b)(1) of the basic act to list their names and places of business with the Secretary prior to such effective date, and the definitions of terms under the new section 509(a) of the basic act and the provisions of section 125 of the bill would take effect on the date of enactment.

PART D—AMENDMENTS AS TO ADVERTISING

Section 131 of the bill would amend section 15 of the Federal Trade Commission Act, defining "false advertisement," in two substantive respects. The last sentence of paragraph (1) of the present section 15—which provides that no advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied by truthful disclosure of, the formula showing quantitatively each ingredient of such drug—would be deleted. Further, present paragraph (2) would be redesignated as paragraph (3), and a new paragraph (2) would provide that an advertisement of a prescription drug shall be deemed to be misleading in a material respect if such advertisement fails to contain (A) a conspicuous, full, and accurate statement of the efficacy of the drug, and (B) a conspicuous and truthful disclosure of (i) the quantitative formula of the drug, with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contra-indications of the drug. Also, new paragraph (2) would define "prescription drug" in terms of drugs intended for use by man and required to be dispensed by prescription under Federal law, and would authorize the Commission to prescribe such rules and regulations as may be necessary in order to administer and enforce the paragraph.

TITLE II—STRENGTHENING OF FACTORY INSPECTION AUTHORITY

Section 201 of the bill would amend section 704 of the basic act to clarify and strengthen existing inspection authority by specifically requiring the owner or person in charge of an establishment (which is subject to inspection) to permit inspection "all things" in the establishment (or vehicle) bearing on whether there is a violation or potential violation of the act, "including records, files, papers, processes, controls, and facilities" having such a bearing. This amendment is needed in order to overcome doubt as to the present scope of the inspector's authority, engendered by the legislative history of the reenactment of section 704 of the act in the 83d Congress. Further, the bill would amend section 704 of the act to make clear that factories, warehouses, or establishments in which food, drugs, devices, or cosmetics are processed or packed (as well as establishments in which they are merely held) after introduction into interstate commerce are subject to the inspection authority.

Section 201 of the bill would further clarify section 704 of the basic act by expressly authorizing like inspection of independent commercial consulting laboratories performing (or undertaking to perform) assay or other laboratory services for manufacturers, packers, or distributors of food, drugs, devices, or cosmetics. While the Department now interprets section 704 to include authority for the inspection of such laboratories, it is felt that this matter should be put beyond cavil at the same time that section 704 is otherwise strengthened.

Section 201(d) would amend section 302(a) of the basic act to authorize the district courts of the United States to restrain violations of section 301(f) of the act, relating to the refusal to permit an inspection under section 704 of the act.

Section 202 of the bill would amend section 301(j) of the basic act so as to prohibit unauthorized disclosure of any information obtained by inspection or in certain other proceedings under the act. Under section 301(j) as now in force, only methods or processess which are trade secrets are so protected from disclosure. (See, however, 18 U.S.C. 1905.)

Section 203 of the bill would make title II effective on the date of enactment of the bill.

RAMSEYER PRINT OF THE DRUG AND FACTORY INSPECTION AMENDMENTS OF 1962

FEDERAL FOOD, DRUG, AND COSMETIC ACT

(New matter in italics; deleted matter in black brackets)
(Most of the section headings are not part of the act and have been inserted for convenience)

* * * * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * * * *

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety *and efficacy* of drugs, as safe *and efficacious* for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety *and efficacy* for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

Prohibited Acts

SEC. 301. The following acts and the causing thereof are prohibited:

* * * * * * *

(e) The refusal to permit access to or copying of any record as required by section 703; *or the failure to establish or maintain any record, or make any report, required under section 505(i) or (j), or 507(d) or (g), or the refusal to permit access to or verification or copying of any such required record.*

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceedings under this Act, *or as authorized by law*, any information acquired under authority of section 404, 409, 505, 506, 507, 704, or 706 [concerning any method or process which as a trade secret is entitled to protection].

* * * * * * *

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that *approval of* an application with respect to such drug, is [effective] *in effect* under section 505, or that such drug complies with the provisions of such section.

* * * * * * *

(o)(1) The manufacture, compounding, or processing of a drug in violation of section 509(b); (2) the possession of a drug in violation of section 509(c); (3) the sale, delivery, or other disposition of a drug in violation of section 509(d); (4)(A) the failure to prepare or obtain, or the failure to keep, a complete and accurate record with respect to any drug as required by section 509(e), or (B) the refusal to permit access to or copying of any record as required by section 509(e); or (5) the refusal to permit entry or inspection as authorized by section 509(e).

Injunction Proceedings

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended,[1] to restrain violations of section 301, except paragraphs [(e), (f),] (h), (i), and (j).

* * * * * * *

Seizure

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found; *and any drug which is a barbiturate or a habit-forming stimulant drug within the meaning of section 509 and which has been manufactured, compounded, processed, possessed, sold, delivered, or disposed of in violation of section 509 shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found* * * *.

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

Adulterated Drugs and Devices

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) * * * (2)(*A*) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (*B*) *if it is a drug and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) (i) to insure that its identity and strength do not differ from, and that its purity, quality, and efficacy do not fall below, those which it purports or is represented to possess, or (ii) to insure that it will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with its labeling), or (iii) to insure that its labeling is not such as to cause it to be adulterated or misbranded*; (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).

* * * * * * *

(e) *If it is a drug that is a product within the purview of section 351 of the Public Health Service Act and (1) it has not been propagated or manufactured and prepared, in conformity with such section and regulations and standards prescribed thereunder, by a manufacturer holding a license therefor issued by the Secretary, and in accordance with the terms of such license, or (2) at any time (A) it is not in conformity with such section or regulations or standards, or (B) the expiration date on its labeling has passed, or (C) such license has been suspended or revoked.*

[1] Sec. 17 of the act of Oct. 15, 1914, which appeared as United States Code title 28, sec. 381, has been repealed. It is now covered by Rule 65, Federal Rules of Civil Procedure.

Misbranded Drugs and Devices

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * * * *

(e)(*1*) If it is a drug [and is not designated solely by a name recognized in an official compendium], unless (*A*) its label bears, *to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)*, [(1)] (*i*) the [common or usual] *established* name (*as defined in subparagraph* (*2*)) of the drug, if such there be [;], and [(2)] (ii), in case it is fabricated from two or more ingredients, the [common or usual] *established* name *and quantity* of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the *established* name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein *; and* (*B*) *the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is given precedence in position over any proprietary name or designation for such drug or ingredient and is in type at least as large and prominent as that used for such proprietary name or designation*: *Provided*, That to the extent that compliance with the reuqirements of clause [(2)] (*A*)(*ii*) *or clause* (*B*) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(*2*) *As used in this paragraph* (*e*), *the term "established name," with respect to a drug or ingredient thereof, means* (*A*) *the applicable standard name established pursuant to section 508, or* (*B*), *if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or* (*C*) *if neither clause* (*A*) *nor clause* (*B*) *of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: Provided further, That where clause* (*B*) *of this subparagraph applies to an article recognized in the United States Pharmacopoeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply.*

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, *or against a substantial and reasonably foreseeable risk of causing accidental injury*, in such manner and form, as are necessary for the protection of users, *including instructions for first aid treatment when necessary or appropriate: Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia: *Provided further, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph* (*e*) *as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph* (*e*) *shall prevail.*

* * * * * * *

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, of bacitracin, or any derivative thereof, *or a drug composed wholly or partly of any other kind of substance within the purview of section 507*, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect

to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).

* * * * * * *

(n) If it is a drug that is a product within the purview of section 351 of the Public Health Service Act and its packaging or labeling is not in conformity with such section or with regulations or standards prescribed thereunder.

* * * * * * *

Exemptions in Case of Drugs and Devices

SEC. 503. * * *

(b) (1) A drug intended for use by man which—

* * * * * * *

(C) is limited by an [effective] *approved* application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only * * * upon * * * prescription * * *.

* * * * * * *

New Drugs

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug unless an application *has been* filed pursuant to subsection (b) [is effective], *and there is in effect an approval of such application by the Secretary under this section*, with respect to such drug.

(b) Any person may file with the Secretary an application *for determination by the Secretary of the safety and efficacy of* [with respect to] any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe *and efficacious* for use; (2) a full list of the articles used as components of such drug; (3) in the case of a drug, a full statement of the composition of such drug, (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) [An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one-hundred-and-eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application]. *Within ninety days after the filing of an application under this subsection or within such additional period (not exceeding one-hundred-and-eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—*

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe *and efficacious* for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe *or inefficacious* for use under such conditions or do not show that such drug is safe *and efficacious* for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, [and] purity, *safety, and efficacy;* or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe

and efficacious for use under such conditions, he shall [, prior to the effective date of the application,] issue an order [refusing to permit] *denying approval of* the application [to become effective]. *If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (4) do not apply, he shall issue an order approving the application.*

(e) The *Secretary* [effectiveness of an application with respect to any drug] shall, after due notice and opportunity for hearing to the applicant, [by] *issue an* order *withdrawing approval of an application with respect to any drug under this section* [of the Secretary be suspended] if the Secretary finds (1) that clinical *or other* experience, tests [by new methods, or tests by methods not deemed reasonably applicable when such application became effective], *or other scientific data* show that such drug is unsafe *or inefficacious, or show that there is substantial doubt as to the safety or efficacy of such drug*, for use under the conditions of use upon the basis of which the application [became effective] *was approved*, or (2) that the application contains any untrue statement of a material fact, *or (3) that the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are then inadequate to assure and preserve its identity, strength, quality, purity, safety, and efficacy, or (5) that any condition attached to approval of the application has been violated: Provided, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection.* The order shall state the findings upon which it is based.

(f) [An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever] *Whenever* the Secretary finds that the facts so require, *he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.*

* * * * * * *

(h) An appeal may be taken by the applicant from an order of the Secretary [refusing to permit the] *denying or withdrawing approval of an* application [to become effective, or suspending the effectiveness of the application] *under this section.* Such appeal shall be taken by filing in the [district court of the] United States *court of appeals for the circuit* [within any district] wherein such applicant resides or has his principal place of business, or in the [district court of the] United States *Court of Appeals* for the District of Columbia *Circuit*, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith [served upon] *transmitted by the clerk of the court to* the Secretary, or [upon] any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court [a transcript of] the record upon which the order complained of was entered, *as provided in section 2112 of title 28, United States Code.* Upon the filing of such [transcript] *petition* such court shall have exclusive jurisdiction to affirm or set aside such order, *except that until the filing of the record the Secretary may modify or set aside his order.* No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceedings before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment [and decree] of the court affirming or setting aside any such order of the Secretary shall

be final, subject to review [as provided in sections 128, 239, and 240 of the Judicial Code, as amended, and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia," approved February 9, 1893.] *by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code.* The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations for exempting from the operation of *the foregoing subsections of* this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety *and efficacy* of drugs. *Such regulations may provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such drugs, as the Secretary finds will enable him to evaluate the safety and efficacy of such drugs in the event of the filing of an application pursuant to subsection (b).*

(j)(1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

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Certification of Drugs Containing [Penicillin, Streptomycin, Chlortetracycline, Chloramphenicol, or Bacitracin] *Antibiotics*

SEC. 507. (a) The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin or any derivative thereof, *or composed wholly or partly of any other kind of antibiotic substance (including the chemically synthesized equivalent of any such substance).*

* * * * * * *

(d) The Secretary shall promulgate regulations exempting from any requirement of this section and of section 502(e), (1) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs. *Such regulations may provide for conditioning the exemption under clause (3) upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such drugs, as the Secretary finds will enable him to evaluate the safety and efficacy for use of such drugs in the event of an application for certification or release pursuant to subsection (a).*

* * * * * * *

(g)(1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Sec-

retary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed.

(2) Every person required under this section to maintain records, and every person having charge or custody thereof, shall upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

Sec. 508. Whenever in the judgment of the Secretary such action is necessary or desirable in the interest of achieving usefulness or simplicity of drug nomenclature, or because of the existence of two or more nonproprietary names (other than the systematic chemical name) for the same drug (or for two or more drugs which are identical in their active ingredients and substantially identical in their pharmacological action, strength, quality, and purity), or because the common or usual name of a drug is misleading, confusing, or not sufficiently informative, or because there exists no common or usual name for a drug, he may promulgate regulations establishing a single standard name for such drug (or for such identical drugs), together with any related or additional information which in the judgment of the Secretary is desirable to facilitate the correct and effective use of such standard name.

Barbiturates and Habit-Forming Stimulant Drugs[2]

Sec. 509. (a) As used in this section—

(1) the term "barbiturate" means any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid, which derivative has been designated by the Secretary under section 502(d) as habit forming; and

(2) the term "habit-forming stimulant drug" means a drug which contains any quantity of (A) amphetamine or any of its optical isomers; or (B) any salt of amphetamine, or any salt of an optical isomer of amphetamine; or (C) any substance which the Secretary, after investigation, has found to be, and by regulation designated as, habit forming because of its stimulant effect on the central nervous system.

(b) No person shall manufacture, compound, or process any barbiturate or any habit-forming stimulant drug, except the following persons:

(1) Manufacturers, compounders, and processors who have listed their names and places of business with the Secretary and who are regularly engaged or seek to be engaged, and are otherwise qualified, in preparing pharmaceutical chemicals or prescription drugs for distribution through branch outlets, through wholesale druggists, or by direct shipment, (A) to pharmacies or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for any use described in paragraph (5).

(2) Wholesale druggists who maintain establishments in conformance with local laws and are regularly engaged in supplying prescription drugs (A) to pharmacies, or to hospitals, clinics, public health agencies, or physicians, for dispensing by registered pharmacists upon prescriptions, or for use by or under the supervision of practitioners licensed by law to administer such drugs in the course of their professional practice, or (B) to laboratories or research or educational institutions for any use described in paragraph (5).

(3) Pharmacies, hospitals, clinics, and public health agencies, which maintain establishments, in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, for patients under the care of such practitioners in the course of their professional practice.

(4) Practitioners licensed by law to prescribe or administer barbiturates or habit-forming stimulant drugs, who have such drugs in their possession for use in the course of their professional practice.

(5) Persons who possess barbiturates or habit-forming stimulant drugs for use in research, teaching, or chemical analysis and not for sale.

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[2] Sec. 125 of the bill provides that nothing in the part of the bill relating to barbiturates and habit-forming stimulant drugs "shall be construed as authorizing the manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State or Territory in contravention of the laws of such State or Territory."

(6) Officers and employees of Federal, State, Territorial, or local governments, whose possession of such drugs is in the course of their official duties.

(7) An employee of any person described in paragraph (1) through paragraph (6), and a nurse or other medical technician under the supervision of a practitioner licensed by law to administer such drugs, having possession of such drugs by reason of his employment or occupation and not on his own account.

(c) No person, other than—

(1) a person described in subsection (b), or

(2) an individual to whom such drug in his possession has been dispensed, or for whom it has been prescribed in conformance with section 503(b), by a practitioner licensed by law to prescribe and administer such drugs in the course of such practitioner's professional practice, or

(3) a carrier or warehouseman whose possession of such drug is in the usual course of his business as such,

shall possess any barbiturate or any habit-forming stimulant drug.

(d) No person shall sell, deliver, or otherwise dispose of any barbiturate or any habit-forming stimulant drug to a person not authorized by subsection (c) to possess such drugs.

(e)(1) Every person engaged in manufacturing, compounding, processing, selling, delivering, or otherwise disposing of any barbiturate or any habit-forming stimulant drug shall, upon the effective date of this section, prepare a complete and accurate record of all stocks of each such drug on hand and shall keep such record for three years. On and after the effective date of this section, every such person manufacturing, compounding, or processing any barbiturate or any habit-forming stimulant drug shall prepare and keep, for not less than three years, a complete and accurate record of the kind and quantity of each such drug manufactured, compounded, or processed and the date of such manufacture, compounding, or processing; and every such person selling, delivering, or otherwise disposing of any barbiturate or any habit-forming stimulant drug shall prepare or obtain, and keep for not less than three years, a complete and accurate record of the kind and quantity of each such drug received, sold, delivered, or otherwise disposed of, the name and address of the person from whom it was received and to whom it was sold, delivered, or otherwise disposed of, and the date of such transaction.

(2) Every person required by paragraph (1) of this subsection to prepare or obtain, and keep, records, and any carrier maintaining records with respect to any shipment containing barbiturates or habit-forming stimulant drugs, and every person in charge or custody of such records, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at reasonable times to have access to and copy such records. For the purposes of verification of such records and of enforcement of this section, officers or employees designated by the Secretary are authorized, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, to enter, at reasonable times, any factory, warehouse, establishment, or vehicle in which barbiturates or habit-forming stimulant drugs are held, manufactured, compounded, processed, sold, delivered, or otherwise disposed of, and to inspect, within reasonable limits and in a reasonable manner such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished material, containers, and labeling therein, and to inventory any stock of such drugs therein, and obtain samples of such drugs. If a sample is thus obtained, the officer or employee making the inspection shall, upon completion of the inspection and before leaving the premises, give to the owner, operator, or agent in charge a receipt describing the sample obtained.

(3) The provisions of paragraphs (1) and (2) of this subsection shall not apply to a licensed practitioner described in subsection (b)(4) with respect to drugs received, prepared, possessed, administered, or dispensed by him in the course of his professional practice.

(f) The Secretary may by regulation exempt any barbiturate or any habit-forming stimulant drug from the application of all or part of this section when he finds that regulation of its manufacture, compounding, processing, possession, and disposition, as provided in this section or in such part thereof, is not necessary for the protection of the public health.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

Regulations and Hearings

SEC. 701. * * *

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(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406 (a) or (b), 501 (*a*) *or* (b), 502 (d) or (h), *or 602(f)* of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary.

* * * * * * *

Factory Inspection

SEC. 704. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or [are held] after such introduction, *or to enter any consulting laboratory*, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, *consulting laboratory*, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, *and all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this Act.* A separate notice shall be given for each inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(b) Upon completion of any such inspection of a factory, warehouse, *consulting laboratory*, or other establishment and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, *or (3), in the case of a drug, has been or is being manufactured, processed, packed, or held under conditions which may cause it to be adulterated within the meaning of section 501(a)(2)(B) of this Act.* A copy of such report shall be sent promptly to the Secretary.

* * * * * * *

(e) As used in this section, the term "consulting laboratory" means a laboratory or other establishment which, for a fee or other remuneration, performs or agrees to perform assays or other laboratory services for a manufacturer, processor, compounder, packer, or distributor of food, drugs, devices, or cosmetics, if such manufacturer, processor, compounder, packer, or distributor owns or has under his control an establishment which (other than as a consulting laboratory) is subject to inspection under this section.

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CHAPTER IX—MISCELLANEOUS

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SEC. 902. * * *

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(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of [the virus, serum, and toxin Act of July 1, 1902] *section 351 of the Public Health Service Act (U.S.C., 1958 ed., title 42, ch. 6A, sec. 262, relating to viruses, serums, toxins, and anal-*

ogous products for humans); *the Animal-Virus-Serum-Toxin Act of March 4, 1913 (U.S.C., 1958 ed., title 21, ch. 5, secs. 151–158)*; the Filled Cheese Act of June 6, 1896 (U.S.C., 1946 ed., title 26, ch. 17, secs. 2350–2362); the Filled Milk Act of March 4, 1923 (U.S.C., 1946 ed., title 21, ch. 3, secs. 61–64); or the Import Milk Act of February 15, 1927 (U.S.C., 1946 ed., title 21, ch. 4, secs. 141–149).

PUBLIC HEALTH SERVICE ACT

(New matter in italic; deleted matter in black brackets)

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SEC. 351.

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(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing (1) that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, *and (2) that such products are efficacious under the conditions prescribed, recommended, or suggested by the manufacturer*, and licenses for new products may be issued only upon a showing that they meet [such standards] *the foregoing requirements.*

* * * * * * *

FEDERAL TRADE COMMISSION ACT

(New matter in italic; deleted matter in black brackets)

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SEC. 15. For the purposes of sections 12, 13, and 14—

(a)(1) The term "false advertisement" means an advertisement, other than labeling, which is misleading in a material respect; and in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual. [No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of such drug.]

(2) An advertisement of a prescription drug shall be deemed to be misleading in a material respect if such advertisement fails to contain (A) a conspicuous, full, and accurate statement of the efficacy of the drug, and (B) a conspicuous and truthful disclosure of (i) the quantitative formula of the drug with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contraindications of the drug. For the purposes of this paragraph a prescription drug is one intended for use of man that Federal law requires to be dispensed only upon the prescription of a practitioner licensed by law to administer such drug. The Commission is authorized and directed to prescribe such rules and regulations as may be necessary for purposes of administration and enforcement of this paragraph.

[(2)] *(3)* In the case of oleomargarine or margarine an advertisement shall bedeemed misleading in material respect if in such advertisement representations are made or suggested by statement, word, grade designation, design, device, symbol, sound, or any combination thereof, that such oleomargarine or margarine is a dairy product, except that nothing contained herein shall prevent a truthful, accurate, and full statement in any such advertisement of all the ingredients contained in such oleomargarine or margarine.

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., August 24, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department on H.R. 11581, the Drug and Factory Inspection Amendments of 1962.

The bill would make a number of amendments to the Federal Food, Drug, and Cosmetic Act. Distribution of drugs manufactured without adequate measures (as determined by the Secretary of Health, Education, and Welfare) taken to insure that they are of the correct identity and strength, safe, and properly labeled, would be prohibited. The marketing of new drugs would be prohibited unless found by the Secretary to be efficacious as well as safe, and the Secretary would be authorized to require reports and the keeping of records by producers of new drugs. All antibiotic drugs would have to be certified by the Secretary, who also would be authorized to require recordkeeping and reporting by producers and processors of such drugs. Biological drugs subject to provisions of the Public Health Service Act would be subjected to the enforcement procedures of the Food, Drug, and Cosmetic Act if the requirements of the former act are not met. The Public Health Service Act would be amended by adding an efficacy requirement to the conditions for licensing biological drug producers.

The Secretary would be authorized to designate standard names for drugs when, in his judgment, such action would result in simplicity of drug nomenclature. The designated standard name (or, in the event the Secretary does not find it necessary to designate a name, either the name used in an official compendium or, if the drug is not listed in a compendium, the common or usual name) of a drug would have to be included, in a dominant position, on the labeling.

Traffic in barbiturates (sleeping pills) and amphetamines and similar habit-forming stimulant drugs would be more stringently and effectively regulated. This would be accomplished by subjecting dealings in such drugs in intrastate as well as interstate commerce to Federal regulation and by requiring close accounting of the handling of such drugs by manufacturers, dealers, et cetera.

The authority of the Food and Drug Administration to inspect factories and other food, drug, and cosmetic facilities would be clarified and expanded. It would be made clear that all things (including records) in such establishments bearing on compliance with the adulteration and misbranding provisions of the act are within the Secretary's inspection authority.

The Federal Trade Commission Act would also be amended so as to require advertisements of prescription drugs to include (in a conspicuous manner) full information as to efficacy, ingredients, side effects, and contraindications.

It is the view of this Department that the foregoing provisions would afford a large measure of aid in providing better protection to the consumers of foods and drugs. Enforcement will be facilitated by the additional inspection and recordkeeping provisions, and violations in many instances will be forestalled or will be detected at their sources.

The President, in his message to Congress of March 15, 1962, concerning consumer protections, recommended legislation in the areas covered by this bill. The measure would provide means of effectively accomplishing the additional consumer protection which the President indicated was needed in the covered areas.

The Bureau of the Budget has advised that the enactment of this legislation would be in accord with the program of the President.

Sincerely yours,

NICHOLAS DEB. KATZENBACH,
Deputy Attorney General.

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DEPARTMENT OF AGRICULTURE,
Washington, D.C., June 21, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in reply to your request of May 11, 1962, for a report on House bill 11582. The bill is entitled "To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the Act with respect to cautionary labeling; and for other purposes."

We favor the enactment of H.R. 11582.

Title I relates to premarketing clearance of cosmetics for safety. This is a matter outside of the jurisdiction of this Department.

Title II relates to the safety, efficacy, and reliability of devices under the Federal Food, Drug, and Cosmetic Act, that is, those intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or intended to affect the structure of any function of the body of man or other animals. It appears to us that the provisions of that act relating to devices are not intended to apply to devices for trapping, destroying, repelling, or mitigating rodents and other pests designated by the Secretary of Agriculture, which are regulated by this Department under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135 et seq.).

Title III of the bill relates to miscellaneous matters. Section 301 would provide additional conditions under which food, drugs, devices, and cosmetics would be deemed to be misbranded under the Federal Food, Drug, and Cosmetic Act. Section 301 also would amend the Federal Hazardous Substances Labeling Act (15 U.S.C. 1261 et seq.) to make the Federal Caustic Poisons Act (15 U.S.C. 401 et seq) ineffective with respect to dangerous caustic or corrosive substances which are subject to the Federal Food, Drug, and Cosmetic Act and as such are excluded from the definition of "hazardous substance" in the Federal Hazardous Substances Labeling Act. It appears that application of the Federal Caustic Poisons Act to any articles under the Federal Food, Drug, and Cosmetic Act would not be necessary for public protection in view of the provisions in the bill adding conditions under which such articles would be deemed misbranded under the Federal Food, Drug, and Cosmetic Act.

Section 302 of the bill would amend the provisions of the Federal Food, Drug, and Cosmetic Act prohibiting the issuance of a regulation permitting the use of any food additive or color additive if the additive is found to induce cancer. The amendment would make the prohibition inapplicable to ingredients of food for animals raised for food production, when the Secretary of Health, Education, and Welfare makes specified findings to protect the public and agricultural interests.

Section 303 of the bill would amend the definition of "food additive" in the Federal Food, Drug, and Cosmetic Act so as to include within the definition any substance used in accordance with a sanction or approval granted prior to September 6, 1958 under said act, when the Secretary of Health, Education, and Welfare finds that there is substantial doubt as to its safety. This amendment would not affect the status of substances approved under the Poultry Products Inspection Act or the Meat Inspection Act administered by this Department.

This proposed legislation is in accord with the President's message (H. Doc. 364, 87th Cong., 2d sess.) relative to consumers' protection and interest program. In this message he recommended legislation to strengthen and broaden existing laws in the food-and-drug field to provide consumers with better, safer, and less expensive drugs.

Thank you for giving us the opportunity to report on H.R. 11582.

The Bureau of the Budget advises that the enactment of H.R. 11582 would be in accord with the President's program.

Sincerely yours,

ORVILLE L. FREEMAN, *Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., June 25, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Bureau of the Budget on H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws, and H.R. 11582, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling; and for other purposes.

H.R. 11581 and H.R. 11582 would strengthen and broaden the existing statutory authority of the Food and Drug Administration so that Agency could more adequately safeguard the consumers of foods, drugs, and cosmetics. In addition, H.R. 11581 would amend the Federal Trade Commission Act to give that agency additional authority to monitor prescription drug advertisements.

In his special message to the Congress of May 15, 1962, on consumer protection, the President stated that legislation was needed "* * * to assure the necessary protection the American consumer deserves." Specifically, the President recommended "* * * legislation to strengthen and broaden existing laws in the food and drug field to provide consumers with better, safer, and less expensive drugs, by authorizing the Department of Health, Education, and Welfare to:

"(a) Require a showing that new drugs and therapeutic devices are effective for their intended use—as well as safe—before they are placed on the market;

"(b) Withdraw approval of any such drug or device when there is substantial doubt as to its safety or efficacy, and require manufacturers to report any information bearing on its safety or efficacy;

"(c) Require drugs and therapeutic device manufactures to maintain facilities and controls that will assure the reliability of their product;

"(d) Require batch-by-batch testing and certification of all antibiotics;

"(e) Assign simple common names to drugs;

"(f) Establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines;

"(g) Require cosmetics to be tested and proved safe before they are marketed; and

"(h) Institute more effective inspection to determine whether food, drug, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law."

In addition, the President recommended legislation "* * * to authorize the Federal Trade Commission to require that advertising of prescription drugs directed to physicians disclose the ingredients, the efficacy, and the adverse effects of such drugs * * *."

The two instant bills contain the specifics of new legislation which is required to meet the needs in this area as set forth by the President in the foregoing statement. Accordingly, I am authorized to advise you that enactment of H.R. 11581 and H.R. 11582 would be in accord with the program of the President.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

THE SECRETARY OF COMMERCE,
Washington, D.C., July 26, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in further reply to your request for the views of this Department with respect to H.R. 11581, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, efficacy, and reliability of drugs, authorize standardization of drug

names, establish special controls for barbiturate and stimulant drugs, and clarify and strengthen existing inspection authority with respect to any articles subject to the act; and to amend related laws; and H.R. 11582, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling; and for other purposes.

The Department of Commerce recommends enactment of H.R. 11581 and H.R. 11582.

The Bureau of the Budget advised there would be no objection to the submission of this report from the standpoint of the administration's program.

Sincerely yours,

(For Edward Gudeman, Secretary of Commerce).

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 21, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representative, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in reply to your request of May 11, 1962, for a report on H.R. 11582, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to require a premarketing showing of the safety of cosmetics; assure the safety, efficacy, and reliability of therapeutic, diagnostic, and prosthetic devices; and amend the act with respect to cautionary labeling; and for other purposes.

This bill, to be known as the Cosmetics and Therapeutic Devices Amendments of 1962, would carry forward certain measures recommended by President Kennedy in his message to the Congress on March 15, 1962, relative to consumers' protection and interest program, and would otherwise improve the law in the food, drug, and cosmetic field.

The bill would amend the Food, Drug, and Cosmetic Act to—

(1) Require proof of safety of cosmetics before they can be marketed. This change in the law was recommended in the report of the Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics (H.R. No. 2182, 82d Cong.) chaired by Congressman Delaney.

(2) Require new devices to be proved safe and effective before they are marketed.

(3) Require precautionary labeling of potentially hazardous drugs, devices, and cosmetics, and of pressurized food dispensers.

(4) Make the anticancer clause of the Food Additives Amendment of 1958 inapplicable to animal feed additives if they leave no residue in food for humans, and modify the so-called grandfather clause of the food additives amendment so that a prior sanction for a food additive would be inapplicable, and the requirements of the food additives amendment would apply if substantial doubt as to the safety of the additive arises.

The first three provisions are needed to enhance consumer protection.

The two provisions referred to under point 4 would correct a needless and unintentional inequity in the application of the food additive anticancer proviso to additives for animal feed, while fully preserving the consumer protection now afforded by that provision. Additionally the last-mentioned proposal would strengthen consumer protection in that it would permit action to be taken with respect to an additive which has a prior sanction under the new-drug provisions if substantial doubt as to the additive's safety arises.

Enclosed herewith is a section-by-section analysis of the bill, together with a comparative print showing graphically the effect of the amendments on existing law.

As explained in the President's message with respect to the first two items above mentioned, and as has been brought out in more detail in our testimony on the bill, there is a pressing need for these amendments, and we recommend enactment of this bill. (Such enactment should, we think, include a special transitional provision with respect to section 103 of the bill, relating to hair dyes, so as to allow such dyes which are already on the market, and which appear to be safe, to continue to be marketed after enactment of the bill pending

completion of tests to confirm their safety. We are preparing, and expect to submit shortly, such an amendment.)

The Bureau of the Budget advises that enactment of this bill would be in accord with the program of the President.

Sincerely,

ABE RIBICOFF, *Secretary.*

SECTION-BY-SECTION ANALYSIS OF COSMETICS AND THERAPEUTIC DEVICES AMENDMENTS OF 1962

SHORT TITLE

The first section of the bill would provide that the act may be cited as the "Cosmetics and Therapeutic Devices Amendments of 1962."

TITLE I—PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

Section 101(a) of the bill would add to section 601 (relating to cosmetics deemed adulterated) of the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as the basic act) a new paragraph (f), providing that a cosmetic shall be deemed adulterated if it is unsafe within the meaning of section 605(a) of the basic act (see below).

Section 101(b) of the bill would amend chapter VI of the basic act by adding a new section 605 to provide for the premarketing clearance of cosmetics with respect to safety.

Subsection (a) of the new section 605 of the basic act would deem a cosmetic unsafe for the purposes of section 601(f) (see above) in the absence of an approval, by the Secretary, of an application filed with respect to the cosmetic under this section, or an exemption of such cosmetic for investigational use pursuant to subsection (i), if (1) the composition of the cosmetic is such that it is not generally recognized, among qualified experts, as having been adequately shown to be safe of its intended use and other reasonably foreseeable uses, or (2) the cosmetic has not been so used to a material extent or for a material time except in investigations to determine its safety.

Subsection (b) of the new section 605 provides for the filing of an application (containing specified information similar to that required by the present new-drug section of the act) for determination by the Secretary of the safety of any cosmetic described in subsection (a).

Subsection (c) of the new section 605 would require the Secretary, within 90 days after the filing of the application or within such additional period (not to exceed 180 days after filing) as the Secretary deems necessary, either (1) to approve the application if he then finds that none of the grounds for denial specified in subsection (d) applies, or (2) to give the applicant notice of an opportunity for hearing before the Secretary to be held under subsection (d) on the question whether such application is approvable.

Subsection (d)(1) of the new section 605 would require the Secretary to deny approval of the application if he finds, after due notice and opportunity for hearing, that the investigations reported as part of the application do not include adequate tests by all reasonably applicable methods to show whether the cosmetic is safe for its intended use and other reasonably foreseeable uses; or that the results of such tests show that such cosmetic is unsafe for any such use or do not show that it is safe for such uses; or that the methods, facilities, and controls used in the manufacture, processing, and packing of the cosmetic are inadequate to preserve the identity, strength, quality, purity, and safety of the cosmetic; or that he has insufficient information to determine whether the cosmetic is safe for such uses; or that approval is precluded by paragraph (2) or (3) of this subsection (described below). If, after such notice and opportunity for hearing, the Secretary finds that these grounds are not applicable, he would be required to approve the application.

Paragraph (2) of subsection (d) of the new section 605 would deem unsafe, and require denial of approval of an application with respect to, a cosmetic, (A) if any part of it will or may be ingested and the substance is found by the Secretary to induce cancer in man or animal either when ingested or by other appropriate tests or experience, or (B) if no part of it will be ingested and the substance is found, after appropriate tests or other relevant exposure of man or animal, to induce cancer in man or animal. This clause is patterned after the anticancer clause governing color additives for food, drugs, and cos-

metics, adopted as part of the Color Additive Amendments of 1960 (Public Law 86-618).

Paragraph (3) of subsection (d) of the new section 605 would require denial of approval of an application if the data before the Secretary show that the intended use of the cosmetic would promote deception of the consumer in violation of the basic act or would otherwise result in misbranding or adulteration within the meaning of the act. This provision is patterned after similar provisions in the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960.

Subsection (e) of the new section 605 would require the Secretary, after due notice and opportunity for hearing to the applicant, to withdraw approval of an application if he found that there is substantial doubt as to the safety of the cosmetic, that the application contained an untrue statement of a material fact, that the applicant has failed to establish or maintain any required records or to make any required report, or has refused to permit access to or copying or verification of any such record, or that the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug are then inadequate to assure and preserve its identity, strength, quality, purity, and safety, or that any condition attached to approval of the application has been violated. If the Secretary finds that there is an imminent hazard to the public health, he may upon notice suspend the approval of such application immediately, pending the opportunity for hearing.

Subsection (f) of the new section 605 would direct the Secretary to revoke any previous order denying, withdrawing, or suspending approval of an application when the facts so require.

Subsection (g) of the new section 605 would provide for the service of orders of the Secretary under this section.

Subsection (h) of the new section 605 would provide for judicial review, on the record, of final orders denying or withdrawing approval of an application. Such review would be in accordance with section 701(f)(1)-(3) of the basic act.

Subsection (i) of the new section 605 would require the Secretary to provide by regulation for exempting from the foregoing requirements cosmetics which are intended solely for investigational use by qualified experts. Such regulations could include provisions for conditioning such exemptions on the maintenance of records, and making of reports, of results of such investigational use bearing on the safety of the cosmetic.

Subsection (j) of the new section 605 would require manufacturers, compounders, and processors of a cosmetic act with respect to which an approved application is in effect to establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information as the Secretary may deem necessary to enable him to determine whether there is or may be ground for invoking subsection (e) of section 605. Also, such persons would be required to permit access to and copying of such records by officers or employees designated by the Secretary.

Section 102 of the bill would amend (1) section 301(e) of the basic act to prohibit a failure to keep any record or make any report, or a refusal to permit access to or copying of any records, required under section 605, (2) section 301 (j) of the basic act to prohibit the unauthorized use or disclosure of information acquired under the new section 605, (3) section 301(l) to prohibit use on the label or in advertising of any representation or suggestion that an approved application is in effect, and (4) section 302(a) to authorize injunctions to restrain prohibited acts referred to in section 301(e) of the basic act as amended by this bill.

Section 103 would repeal various exemptions in the Food, Drug, and Cosmetic Act as to hair dyes. This is in consonance with the new section 605 of the act, added by section 101 of the bill, which does not exempt coal-tar or other hair dyes. The specific provisions of section 103 of the bill are described below.

Section 103(a) of the bill would repeal the proviso in section 601(a) of the basic act that now exempts a coal-tar hair dye, if it bears certain cautionary labeling, from the provision which deems adulterated a cosmetic that bears or contains a poisonous or deleterious susbtance which may render it injurious to users. Section 103(a) would also repeal (as no longer necessary in view of the other changes made by this section) the special definition of hair dye in section 601(a) of the basic act.

Section 103(b) of the bill would repeal the exception as to hair dyes contained in section 601(e) of the basic act which deems a cosmetic to be adulterated

if it is, bears, or contains a color additive that is unsafe within the meaning of section 706(a) of the basic act relating to listing and certification of color additives.

Section 103(c) of the bill would repeal the exception as to hair dyes in section 602(e) of the basic act which deems a color additive to be misbranded unless its packaging and labeling are in conformity with any applicable regulations issued under section 706 of the basic act.

Section 103(d) of the bill would delete from the last sentence of section 706(a) of the basic act (relating to listing and certification of color additives) a special exception as to hair dyes because no longer necessary in view of the changes made by other provisions of section 103 of the bill.

Section 104 of the bill would make the proposed section 601(f) of the basic act, as added by section 101(a) of the bill, effective on the first day of the seventh calendar month following the month of enactment, except that, as to cosmetics commercially used or sold before enactment, section 601(f) would become effective on the first day of the 13th month after the month of enactment, with authority to postpone such date until the 31st calendar month following the month of enactment. All these deferred dates would be accelerated if the Secretary sooner approves or denies approval of a cosmetic clearance application under the new section 605 of the basic act (as added by section 101(b) of the bill). The other parts of title I would take effect upon enactment.

TITLE II—SAFETY, EFFICACY, AND RELIABILITY OF DEVICES

Section 201(a) of the bill would amend section 501(a) of the basic act to deem any device to be adulterated if the methods, controls, facilities, or personnel used in its manufacture were inadequate, as determined in accordance with regulations promulgated by the Secretary based on good manufacturing practice, to insure that its identity, efficacy, and quality are as represented, that the device will not be injurious to health when used as directed or prescribed, and that its labeling is not violative of the act.

Section 201(b) of the bill would make the formal rulemaking procedures of section 701(e) of the basic act applicable to regulations referred to in section 201(a) of the bill.

Section 202(a) of the bill would add to section 501(a) of the basic act (relating to drugs or devices deemed to be adulterated) a new paragraph (6), providing that a device shall be deemed adulterated if it is unsafe within the meaning of section 508 (see below).

Section 202(b) of the bill would add a new section 508 to chapter V of the basic act.

New section 508(a) of the basic act would deem a device unsafe for the purposes of section 501(a)(6) (see above) in the absence of an approval, by the Secretary, of an application filed with respect to the device under this section, or an exemption of such device pursuant to subsection (i) for investigational use, or an exemption of such device pursuant to subsection (k) (relating to devices licensed by the Atomic Energy Commission), if (1) the composition of the device is such that it is not generally recognized, among qualified experts, as having been adequately shown to be safe and efficacious for use under the conditions prescribed in the labeling, or (2) the device has not been so used to a material extent or for a material time except in investigations to determine its safety and efficacy.

Subsection (b) of the new section 508 provides for the filing of an application (containing specified information similar to that required by the present new-drug section of the act) for determination by the Secretary of the safety and efficacy of any device described in subsection (a).

Subsection (c) of the new section 508 would require the Secretary, within 90 days after the filing of an application or within such additional period (not to exceed 180 days after filing) as the Secretary deems necessary, either (1) to approve the application if he then finds that none of the grounds for denial specified in subsection (d) applies, or (2) to give the applicant notice of an opportunity for hearing before the Secretary under subsection (d) on the question whether such application is approvable.

Subsection (d) of the new section 508 would require the Secretary to deny approval of the application if he finds, after due notice and opportunity for hearing, that investigations reported as part of the application do not include adequate tests by all reasonably applicable methods to show whether the device will be safe and efficacious for use under the conditions prescribed in the proposed

labeling, or that the results of such tests show that such device will be unsafe or inefficacious for such use or do not show that it is safe for such use, or that the methods, facilities, and controls used in the manufacture, processing, and packing of the device are inadequate to preserve the identity, quality, safety, and efficacy of the device or that he has insufficient information to determine whether the device is safe for such use. If, after such notice and opportunity for hearing, the Secretary finds that these grounds are not applicable, he would be required to approve the application.

Subsection (e) of the new section 508 would require the Secretary, after due notice and opportunity for hearing to the applicant, to withdraw approval of an application if he found that there is substantial doubt as to the safety or efficacy of the device for its intended or any other reasonably foreseeable use, that the application contained an untrue statement of a material fact, that the applicant has failed to establish or maintain any required records or to make any required report, or has refused to permit access to or copying or verification of any such record, or that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device are then inadequate to assure and preserve its identity, quality, safety, and efficacy, or that any condition attached to approval of the application has been violated. If the Secretary finds that there is an imminent hazard to the public health, he may, upon notice, suspend the approval of such application immediately pending the opportunity for hearing.

Subsection (f) of the new section 508 would direct the Secretary to revoke any previous order denying, withdrawing, or suspending approval of an application when the facts so require.

Subsection (g) of the new section 508 would provide for the service of orders of the Secretary under this section.

Subsection (h) of the new section 508 would provide for judicial review, on the record, of final orders denying or withdrawing approval of an application. Such review would be in acordance with section 701(f)(1)-(5) of the basic act.

Subsection (i) of the new section 508 would require the Secretary to provide by regulation for exempting from the foregoing requirements devices which are intended solely for investigational use by qualified experts. Such regulations could include provisions for conditioning such exemptions on the maintenance of records, and making of reports, of results of such investigational use bearing on the safety and efficacy of the device.

Subsection (j) of the new section 508 would require mnaufacturers and processors of a device with respect to which an approved application is in effect to establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information as the Secretary may deem necessary to enable him to determine whether there is or may be ground for invoking subsection (e) of section 508. Also, such persons would be required to permit access to and copying of such records by officers or employees designated by the Secretary.

Subsection (k) would require the Secretary to exempt from one or more of the requirements of section 508 devices licensed by the Atomic Energy Commission to the extent he finds it appropriate to avoid duplication of regulatory controls or procedures and to be consistent with the purposes of the basic act.

Section 203(a) of the bill would make the definition of "safe", appearing in section 201(u) of the basic act, applicable wherever it appears in the act, except when used with respect to cosmetics.

Subsections (b), (c), and (d) of section 203 of the bill would amend (1) section 301(e) of the basic act to prohibit a failure to keep any record or make any report, or a refusal to permit access to or copying of any records, required under section 508, (2) section 301(j) of the basic act to prohibit the unauthorized use or disclosure of information acquired under the new section 508, and (3) section 301(2) to prohibit use on the label or in advertising of any representation or suggestion that an approved application is in effect.

Section 204 of the bill would make the proposed section 501(a)(6) of the basic act, as added by section 202(a) of the bill, effective on the first day of the 7th calendar month following the month of enactment, except that, as to devices in use before enactment, section 501(a)(6) would become effective on the first day of the 19th month after the month of enactment, with authority to postpone such date until the 31st calendar month following the month of en-

actment. All these deferred dates would be accelerated if the Secretary sooner approves or denies approval of a device clearance application under the new section 508 of the basic act (as added by section 202(b) of the bill). The other parts of title II would take effect upon enactment.

TITLE III—MISCELLANEOUS

CAUTIONARY LABELING

Section 301(a) of the bill would amend section 403 of the basic act by adding a new paragraph (n) at the end thereof to deem misbranded a food contained in a dispenser pressurized by a gaseous propellant (which would include a liquid propellant that becomes gaseous when the dispenser is operated) unless it bears such cautionary labeling with respect to handling, storage, and use as is necessary to prevent the causing of injury to the health of any user or other individual during, or as the result of, reasonably foreseeable handling, storage, or use thereof, whether or not intentional.

Section 301(b) of the bill would amend section 502(f) of the basic act, relating to cautionary labeling of drugs and devices, to make clear that such labeling is, among other things, required to warn against any substantial and reasonably foreseeable risk of accidental injury, and that cautionary labeling under section 502(f) must include instructions for first-aid treatment when necessary or appropriate.

Section 301(c) of the bill would amend section 602 of the basic act by adding a new paragraph (f) to deem misbranded any cosmetic if, because of its nature, composition, or packaging, it involves a substantial risk of causing injury to health during or as the result of any intentional or unintentional, reasonably foreseeable, handling, storage, or use by any individuals unless in either case it bears such cautionary labeling as is necessary for the protection of individuals, and instructions for first-aid treatment where appropriate. In order to avoid or resolve uncertainty, the Secretary would be authorized to declare by binding regulation a cosmetic or class of cosmetics to be subject to such provisions.

Section 301(d) of the bill would make such declaratory regulations under the new section 602(f) of the basic act subject to the formal rulemaking procedures of section 701(e) of the basic act.

Section 301(e) of the bill would amend section 18 of the Federal Hazardous Substances Labeling Act (Public Law 86-613; 74 Stat. 372, 381), which repealed the Federal Caustic Poison Act, by deleting from section 18 an exception that preserved the Federal Caustic Poison Act insofar as it applied to "dangerous caustic or corrosive substances" subject to the Federal Food, Drug, and Cosmetic Act. This exception from the repeal of the Federal Caustic Poison Act would no longer be necessary upon enactment of the more inclusive amendments to the Food, Drug, and Cosmetic Act proposed by the preceding subsections of section 301 of this bill.

Section 301(f) of the bill provides that section 301 shall take effect on the first day of the 7th calendar month after the month of enactment, or, with respect to any particular class of articles or containers to which section 301 applies, on such subsequent date (not later than the first day of the 19th month following the month of enactment) as the Secretary may prescribe.

FEED ADDITIVES LEAVING NO RESIDUE IN FOOD FOR HUMANS

Section 302(a) would correct a needless and unintentional inequity in the application of the food-additive anticancer proviso (sec. 409(c)(3) of the basic act) to additives for animal feed, while preserving in its full vigor the consumer protection now afforded by that provision. The basic principle of the anticancer provision, which would remain unimpaired, is that no tolerance for the addition of carcinogenic chemicals to food shall be granted in any amount, because in the present state of scientific knowledge no one can tell how much or little of a carcinogen would be required to produce cancer in any human being, or how long it would take such a cancer to develop. However, this principle is not, properly, fully applicable to feed for farm animals, since tests may demonstrate that a particular chemical, though cancer inciting (at particular feeding levels) in laboratory animals such as rats, will not induce cancer in the farm animal during its expected or intended life cycle; yet the anticancer provision fails to allow for such cases, even where it conclusively appears that no residue of the feed additive will remain in any of the animal's food products.

Hence, section 302(a) of the bill would provide that the anticancer proviso shall not apply with respect to the use of a substance (e.g., a veterinary drug) as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found in any edible portion of such animals after slaughter or in any food product of the living animal (such as milk or eggs).

This change would not only correct an inequity directly inherent in the anticancer proviso, but would also avoid the discrimination (in this respect) in treatment under the act as between veterinary drugs mixed with animal feed, which are per se considered "food additives" subject to the proviso, and veterinary drugs directly administered (by implantation, injection, or otherwise), which are considered "food additives" only if the added drug leaves a residue in, or otherwise affects the characteristics of, either (1) food products (such as milk or eggs) of the living animal or (2) some edible portion or product of the animal after slaughter.

Section 302(b) of the bill would similarly amend section 706(b)(5)(B) of the basic act—which is the corresponding anticancer clause contained in the Color Additive Amendments of 1960 to the basic act.

For the purpose of determining, under the amendments made by section 302 (a) and (b) of the bill, whether an additive to animal feed will leave a residue in the edible portions or products of the animal, the Secretary would be authorized to prescribe or approve by regulation applicable methods of examination.

Section 302(c) of the bill would make the amendments made by section 302 effective on the date of enactment.

Section 303 of the bill would amend clause (4) of section 201(s) of the basic act (relating to substances used in accordance with a sanction or approval granted prior to enactment of provisions concerning food additives), in order to make the clause inapplicable to any previously sanctioned or approved use of a substance, if the Secretary finds that there is substantial doubt as to its safety. The Secretary's action would be required to conform with section 4 of the Administrative Procedure Act if such prior sanction or approval has been made public, and reasonable notice of his action would have to be given to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised unless such personal notice is impracticable; such requirements would not apply when the Secretary finds that there is an imminent hazard to public health.

RAMSEYER PRINT OF THE COSMETICS AND THERAPEUTIC DEVICES AMENDMENTS OF 1962

FEDERAL FOOD, DRUG, AND COSMETIC ACT

(New matter in italic; deleted matter in black brackets)

(Most of the section headings are not part of the act and have been inserted)

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * * * *

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on

common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following): *Provided, That, with respect to any sanction or approval granted pursuant to this Act, this clause shall be inapplicable, and the provisions of this Act (other than this clause) relating to food additives shall apply, to any such previously sanctioned or approved use of a substance if, on the basis of the information then available, the Secretary finds that, for the reasons set forth by him, there is substantial doubt as to its safety. Except when the Secretary finds that there is an imminent hazard to public health, he shall take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public, and only after sending reasonable notice of his proposed action and the reasons therefor to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised thereof unless such personal notice is impracticable.*

* * * * * * *

(u) The term "safe" [as used in paragraph (s) of this section and in sections 409 and 706 of this Act], *except when used with respect to cosmetics,* [has reference] *refers* to the health of man or animal.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

Prohibited Acts

SEC. 301. The following acts and the causing thereof are hereby prohibited:

* * * * * * *

(e) The refusal to permit access to or copying of any record as required by section 703; *or the failure to establish or maintain any record, or make any report, required under section 508 (i) or (j) or 605 (i) or (j), or the refusal to permit access to or verification or copying of any such required record.*

* * * * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 507, *508, 605,* 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

* * * * * * *

(l) The using, on the labeling of any drug, *device, or cosmetic* or in any advertising relating to such drug, *device, or cosmetic,* of any representation or suggestion that an application *or approval thereof* with respect to such, drug *device, or cosmetic is* [effective] *in effect* under section 505, *508, or 605, as the case may be,* or that such drug, *device, or cosmetic* complies with the provisions of such section.

* * * * * * *

Injunction Proceedings

SEC. 302. (a) the district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes," approved October 15, 1914, as amended [1] to restrain violations of section 301, except paragraphs [(e),] (f), (h), (i), and (j).

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[1] Sec. 17 of the act of Oct. 15, 1914, which appeared as United States Code title 28, sec. 381, has been repealed. It is now covered by Rule 65, Federal Rules of Criminal Procedure.

CHAPTER IV—FOOD

* * * * * * *

Misbranded Food

SEC. 403. A food shall be deemed to be misbranded—

* * * * * * *

(n) If it is contained in a dispenser pressurized by a gaseous propellant unless it bears such cautionary labeling with respect to handling, storage, and use of such container as is necessary to prevent the causing of injury to the health of any user or other individual during, or as the result of, reasonably foreseeable handling, storage, or use thereof, intentional or otherwise.

Food Additives

SEC. 409(a) * * *

(b) * * *

(c) (1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) * * *

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additives, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, *except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adveersely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animals after slaughter or in any food yieldeed by or derived from the living animal*; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

Adulterated Drugs and Devices

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packaged, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color

additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a); *or (5) if it is a device and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) (i) to insure that its identity does not differ from, and that its efficacy and quality do not fall below, those which it purports or is represented to possess, or (ii) to insure that it will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with its labeling), or (iii) to insure that its labeling is not such as to cause it to be adulterated or misbranded; or (6) if it is a device which is unsafe within the meaning of section 508.*

* * * * * * *

Misbranded Drugs and Devices

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, *or against a substantial and reasonably foreseeable risk of causing accidental injury,* in such manner and form, as are necessary for the protection of users, *including instructions for first aid treatment when necessary or appropriate: Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

* * * * * * *

SEC. 508. (a) A device shall be deemed unsafe for the purposes of section 501(a)(6) if—

(1) its composition, construction, or properties are such that such device is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and efficacy of devices, as safe and efficacious for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or

(2) its composition, construction, or properties are such that such device, as a result of investigations to determine its safety and efficacy for use under such conditions, has become so recognized, but such device has not, otherwise, than in such investigations, been used to a material extent or for a material time under such conditions,

unless (A) an application with respect to such device has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or (B) such device is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i), or (C) such device conforms to the terms of an exemption which is in effect with respect thereto under subsection (k).

(b) Any person may file with the Secretary an application for determination by the Secretary of the safety and efficacy of any device described in clause (1) or (2) of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such device is safe and efficacious for use; (2) a full list of the articles used as components of such device; (3) a full statement of the composition, properties, and construction, and of the principle or principles of operation, of such device; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device; (5) such samples of such device and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such device.

(c) Within ninety days after the filing of an application under this subsection or within such additional period (not exceeding one-hundred-and-eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary to be held under subsection (d) on the question whether such application is approvable.

(d) If the Secretary finds, after due notice to the applicant and opportunity for a hearing to the applicant, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such device is safe and efficacious for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such device is unsafe or inefficacious for such use under such conditions or do not show that such device is safe and efficacious for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device are inadequate to preserve its identity, quality, safety, and efficacy; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such device, he has insufficient information to determine whether such device is safe and efficacious for use under such conditions, he shall issue an order denying approval of the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (4) of this subsection do not apply, he shall issue an order approving the application.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application under this section if the Secretary finds that (1) for reasons set forth by him, there is substantial doubt as to the safety or efficacy of the device for its intended use or any other reasonably foreseeable use, or (2) the application filed pursuant to subsection (b) contains any untrue statement of a material fact, or (3) the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j) or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such device are then inadequate to assure and preserve its identity, quality, safety, and efficacy, or (5) any condition attached to approval of the application has been violated: Provided, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last-known address in the records of the Secretary.

(h) The applicant may obtain judicial review of a final order of the Secretary denying or withdrawing approval of an application under this section in accordance with the provisions of subsection (f)(1)—(5) of section 701.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section devices intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of devices. Such regulations may provide for conditioning such exemptions upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such devices as the Secretary finds will enable him to evaluate the safety and efficacy of such devices in the event of the filing of an application pursuant to subsection (b).

(j)(1) Every person engaged in manufacturing or processing any device with respect to which approval of an application, filed pursuant to this section, is in effect shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such person with respect to such device, as the Secretary may by general regulation, or by other with respect to such application, prescribe on the basis of a finding that such records and reports are necessary

in order to enable the Secretary to determine, or to facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(k) The Secretary shall by regulation exempt from this section, or from one or more of the requirements imposed by or pursuant to this section, devices licensed by the Atomic Energy Commission under the Atomic Energy Act of 1954 to the extent he finds it to be appropriate to avoid duplication of regulatory controls or procedures and to be consistent with the purposes of this Act.

CHAPTER VI—COSMETICS

Adulterated Cosmetics

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual [*Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend, conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dying the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bear adequate directions for such preliminary testing. For the purpose of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes].

* * * * * * *

(e) If [it is not a hair dye and] it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

(f) If it is unsafe within the meaning of section 605(a).

* * * * * * *

Misbranded Cosmetics

SEC. 602. A cosmetic shall be deemed to be misbranded—

* * * * * * *

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. [This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).]

* * * * * * *

(f) If because of its nature, composition, or packaging it involves a substantial risk of causing injury to health during or as the result of any reasonably foreseeable handling, storage, or use by any individuals, whether intentional or otherwise, unless in either case it bears (in addition to any other prescribed labeling) (1) such cautionary labeling as is necessary for the protection of such individuals and (2), where necessary or appropriate, instructions for first-aid treatment. Whenever the Secretary finds that any cosmetic or class of cosmetics is subject to the provisions of this paragraph and in his judgment a declaration to that effect will promote the objectives of this paragraph by avoiding or resolving uncertainty as to its application, he may by regulation declare any such cosmetic or class of cosmetics to be, and it shall during the effectiveness of such regulation be deemed to be, subject to such provisions. Nothing in this paragraph shall be construed to exempt any article otherwise subject to the requirements of this paragraph from such requirements by reason of the absence of such a regulation.

* * * * * * *

New Cosmetics

Sec. 605. (a) A cosmetic shall be deemed unsafe for the purposes of section 601(f) if—

(1) its composition is such that such cosmetic is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of cosmetics, as having been adequately shown to be safe for its intended use and other reasonably foreseeable uses, or

(2) its composition is such that such cosmetic, as a result of investigations to determine its safety for such a use, has become so recognized, but such cosmetic has not, otherwise than in such investigations, been so used to a material extent or for a material time,

unless an application with respect to such cosmetic has been filed pursuant to subsection (b) and there is in effect an approval of such application by the Secretary under this section, or unless such cosmetic is for investigational use and conforms to the terms of an exemption which is in effect pursuant to subsection (i).

(b) Any person may file with the Secretary an application for determination by the Secretary of the safety of any cosmetic described in clause (1) or (2) of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such cosmetic is safe for use; (2) a full list of the articles used as components of such cosmetic; (3) a full statement of the composition of such cosmetics; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic; (5) such samples of such cosmetic and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such cosmetic.

(c) Within ninety days after the filing of an appliaction under this subsection or within such additional period (not exceeding one-hundred-and eighty days after such filing) as the Secretary deems necessary to enable him to study and investigate the application and specifies in a written notice to the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary to be held under subsection (d) on the question whether such application is approvable.

(d)(1) If the Secretary finds, after due notice and opportunity for a hearing to the applicant, that (A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such cosmetic is safe for its intended use and other reasonably foreseeable uses; (B) the results of such tests show that such cosmetic is unsafe for any such use or do not show that such cosmetic is safe for such uses; (C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic are inadequate to preserve its identity, strength, quality, purity, and safety; (D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such cosmetic, he has insufficient information to determine whether such cosmetic is safe for its intended use and other reasonably foreseeable uses; or (E) approval is precluded by paragraph (2) or (3) of this subsection, he shall issue an order denying approval of the application. If, after such notice and opportunity for hearings the Secretary finds that clauses (A) through (E) do not apply, he shall issue an order approving the application.

(2) A cosmetic shall be deemed unsafe for purposes of section 601(f) and an application with respect to such cosmetic pursuant to this section 605 may not be approved—

(A) if its intended use or any reasonably forseeable use will or may result in ingestion of all or part of such cosmetic and (i) the cosmetic is found by the Secretary to induce cancer when ingested by man or animal or (ii) it is found by the Secretary, after tests or other experience appropriate for the evaluation of the safety of cosmetics for any such use, to induce cancer in man or animal, or

(B) if its intended use or any reasonably foreseeable use will not result in ingestion of any part of such cosmetic and, after tests which are appropriate for the evaluation of the safety of cosmetics for any such use, or

after other relevant exposure of man or animal to such cosmetic, it is found by the Secretary to induce cancer in man or animal.

(3) An application with respect to a cosmetic may not be approved under this section if the data before the Secretary show that its intended use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application under this section if the Secretary finds that (1) for reasons set forth by him, there is substantial doubt as to the safety of the cosmetic for its intended use or any other reasonably foreseeable use, or (2) the application filed pursuant to subsection (b) contains any untrue statement of a material fact, or (3) the applicant has failed to establish or maintain any required records, or to make any required report, in accordance with an applicable regulation or order under subsection (j), or that the applicant or any person under his control has refused to permit access to, or copying or verification of, any such record as required by paragraph (2) of such subsection, or (4) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such cosmetic are then inadequate to assure and preserve its identity, strength, quality, purity, and safety, or (5) any condition attached to approval of the application has been violated: Provided, That if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately upon notice, pending the opportunity for hearing required by this subsection.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) denying, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or certified mail addressed to the applicant at his last-known address in the records of the Secretary.

(h) The applicant may obtain judicial review of a final order of the Secretary denying or withdrawing approval of an application under this section in accordance with the provisions of subsection (f) (1)–(5) of section 701.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section cosmetics intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of cosmetics. Such regulations may provide for conditioning such exemptions upon the establishment and maintenance of such records, and the making of such reports to the Secretary, of data obtained as the result of such investigational use of such cosmetics as the Secretary finds will enable him to evaluate the safety of such cosmetics in the event of the filing of an application pursuant to subsection (b).

(j) (1) Every person engaged in manufacturing, compounding, or processing any cosmetic with respect to which approval of an application, filed pursuant to this section, is in effect shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such person with respect to such cosmetic, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or to facilitate a determination, whether there is or may be ground for invoking subsection (e) of this section.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

Regulations and Hearings

SEC. 701. * * *

* * * * * * *

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406(a) or (b) , 501 (*a*) or (b), 502 (d) or (h), *or 602(f)* of this Act shall be begun by a proposal made (A) by the

Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary.

* * * * * * *

Listing and Certification of Color Additives for Foods, Drugs, and Cosmetics

SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic [other than hair dye (as defined in the last sentence of section 601(a))].

Listing of Colors

(b)(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

* * * * * * *

(5)(A) * * *

* * * * * * *

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal: *Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.*

FEDERAL HAZARDOUS SUBSTANCES LABELING ACT (PUBLIC LAW 86-613)

(New matter in italic; deleted matter in brackets)

* * * * * * *

DEFINITIONS

SEC. 2. For the purposes of this Act—

* * * * * * *

(f) * * *

2. The term "hazardous substance" shall not apply * * * to foods, drugs, and cosmetics subject to the Federal Food, Drug, and Cosmetic Act * * *.

* * * * * * *

REPEAL OF FEDERAL CAUSTIC POISON ACT

SEC. 18. The Federal Caustic Poison Act (44 Stat. 1406) is repealed effective at the close of the sixth calendar month after the month of enactment of this Act [except that the Federal Caustic Poison Act shall remain in full force and effect with respect to any "dangerous caustic or corrosive substance" (as defined by that Act) which is an article subject to the Federal Food, Drug, and Cosmetic Act and which is, by virtue of paragraph 2 of section 2(f) of this Act, excluded from the term "hazardous substance" as defined in this Act]: *Provided*, That, if the Secretary, pursuant to section 16(b) of this Act, prescribes an adidtional period or periods during which violations of this Act shall not be enforceable and if such additional period or periods are applicable to violations of this Act involving one or more substances defined as "dangerous caustic or corrosive substances" by the Federal Caustic Poison Act, that Act shall, with respect to such substance or substances, remain in full force and effect during such additional period or periods: *Provided further*, That, with respect to violations, liabilities incurred or appeals taken prior to the close of said sixth month or, if applicable, prior to the expiration of the additional period or periods referred to in the preceding proviso, all provisions of the Federal Caustic Poison Act shall be deemed to remain in full force for the purpose of sustaining any proper suit, action, or other proceeding with respect to any such violations, liabilities, and appeals.

U.S. DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., August 24, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H.R. 11582) Cosmetics and Therapeutic Devices Amendments of 1962.

The bill would make several amendments to the Federal Food, Drug, and Cosmetic Act. Cosmetics of such composition as to indicate doubt as to safety would be made subject to premarketing clearance requirements. Existing special exemptions for hair dyes would be repealed. Distribution of devices manufactured without adequate measures (as determined by the Secretary of Health, Education, and Welfare) taken to insure effectiveness, quality, safety, and proper lebeling would be prohibited. Devices of unestablished safety or efficacy would be made subject to premarketing clearance requirements. Provision would be made for protection against injuries resulting from foreseeable accidental or incidental handling or use of foods (limited to foods in gaseous propellant containers), drugs, and cosmetics. This would provide protection similar to that under the Hazardous Substances Labeling Act. Covered articles would be deemed misbranded unless adequate warnings are included on the labeling.

The Secretary would be authorized to exempt animal feeds from the special provisions of the food and color additives amendments regarding cancer causing agents (Delaney amendments) upon finding that no harm would result to the animals and no residue of the additives would be found in meat, milk, or eggs. Provision would also be made for removing an exception to the provisions of the act relating to food additives for substances sanctioned or approved under the act prior to enactment of the 1958 Food Additives Amendment, if the Secretary finds that there is doubt as to the safety of such substances.

The portions of the bill dealing with devices and cosmetics cover areas referred to by the President in his consumer message of March 15, 1962. The objectives of added consumer protection sought by the President will, it is believed, be effectively attained under these provisions and the Department recommends their enactment. It is also believed that the amendment providing protection against accidental injury from foods, drugs, and cosmetics will provide an important measure of consumer protection which is deserving of favorable consideration. The Department has no objection to the remaining portions of the bill.

The Bureau of the Budget has advised that the enactment of this legislation would be in accord with the program of the President.

Sincerely yours,

NICHOLAS DEB. KATZENBACH,
Deputy Attorney General.

The CHAIRMAN. We are glad to have the Secretary of Health, Education, and Welfare with us this morning.

We are hopeful that we can conclude the Secretary's presentation this morning, and, as a matter of fact, we hope we can conclude with the questions. If not, I will say for the benefit of our colleagues on the committee that we shall have to decide on a later date when he will be required to come back, because the committee cannot sit this afternoon, due to the program on the floor of the House.

Therefore, we should proceed as expeditiously as we can. As is the usual custom and procedure, Mr. Secretary, we want you to have such time as you need or desire to give a full and complete explanation, description, and analysis of these bills, because not only do the members of the committee need to know just what the Department desires in this field, but there are many questions that seem to be unanswered at this point, and we hope that in the presentation you will clear up some of those questions.

We are glad to have you with us this morning, and we will be glad to have your testimony.

STATEMENT OF HON. ABRAHAM RIBICOFF, SECRETARY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY GEORGE P. LARRICK, COMMISSIONER OF FOOD AND DRUG ADMINISTRATION; JOHN L. HARVEY, DEPUTY COMMISSIONER, FDA; WINTON B. RANKIN, ASSISTANT COMMISSIONER, FDA; WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL, FDA; AND THEODORE ELLENBOGEN, LEGISLATIVE ATTORNEY, HEW

Secretary RIBICOFF. Thank you, Mr. Chairman and members of the committee.

The CHAIRMAN. I am going to ask you to talk a little louder, too.

We have a big crowd here, and I am going to ask our guests who are here this morning to be as quiet as they can.

Secretary RIBICOFF. Thank you, Mr. Chairman and members of the committee.

With me are Mr. George Larrick, Commissioner of Food and Drug; John L. Harvey, Deputy Commissioner; Winton B. Rankin, Assistant Commissioner; William W. Goodrich, Assistant General Counsel, Food and Drug Division; and Theodore Ellenbogen, Legislative Attorney, Department of Health, Education, and Welfare.

Mr. Chairman and members of the committee, in his consumers protection message last March, President Kennedy outlined a broad program of consumer protection designed to close the serious gaps which exist in the food, drug, and cosmetic laws. In my judgment, the health and safety of the American people is in jeopardy today because of these gaps.

President Kennedy stated in his special message:

> In short, existing laws in the food, drug, and cosmetic area are inadequate to assure the necessary protection the American consumer deserves.

The bills under consideration today, H.R. 11581 and 11582, introduced by the chairman of this committee, carry forward fully the President's legislative program to provide consumers with better, safer, and less expensive drugs. Other members have proposed similar legislation to deal with one or more of the flaws to be corrected by the President's program (Mr. Boggs, Mr. Celler, Mr. Denton, Mr. Dingell, and Mrs. Sullivan).

The need for the proposals recommended by the President were underscored by the invaluable hearings that have been conducted by Senator Kefauver. In testifying on the Senator's bill last year, I told the Antitrust and Monopoly Subcommittee of the Senate Judiciary Committee that we supported the objectives of the Kefauver bill and believed its key provisions would do much to provide better consumer protection in the drug field. Our review of the situation during the year that has passed has only strengthened our determination to see a strong measure enacted. It is in that spirit that the President has recommended a program to Congress, and with that objective I appear before you today.

Among other things, the program embodied in H.R. 11581 and 11582 will, for the first time, give men, women, and children the same safeguards against worthless drugs that Congress has been giving hogs, sheep, and cattle since 1913.

There is a popular belief that the Nation's pure food and drug laws require all drugs to be produced in a manner that guarantees that they are safe, effective, and reliable. Unfortunately, this is not correct. After a drug has been produced and marketed, the Federal Government can take action to correct errors that may have occurred, but in many cases corrective action is possible only after the unfit drug has been placed in the hands of consumers and then only after the lapse of considerable time during which the Government is securing evidence to support corrective measures.

The amendments proposed by H.R. 11581 would make our drugs safer and more reliable by requiring the installation and maintenance of acceptable manufacturing and control procedures, in accordance with the standards of good pharmaceutical practice, and by requiring that new drugs be shown effective for their intended uses, as well as safe, before they may be marketed.

The bill would provide for the advance testing and certification as to both safety and effectiveness of all antibiotics—not just the few now covered by the certification procedures.

It would require basic improvement, in terms of simplification and usefulness, of drug nomenclature to eliminate confusion as to the identity and composition of drugs, and to facilitate the prescription of less expensive drugs for the sick.

It would strengthen the control of habit-forming barbiturates and stimulants, such as amphetamines.

It would improve the procedures employed in the advance approval of new drugs and would permit the prompt removal from the market of any such approved drugs just as soon as any substantial doubts about their safety or effectiveness should arise.

It would, by amending the Federal Trade Commission Act, require advertisements of prescription drugs to the medical profession to be more informative.

And, finally, it would provide the Food and Drug Administration with realistic inspection powers so that it can carry out its assigned responsibilities in the public interest.

H.R. 11582 would accomplish these same basic purposes in the areas of advance proof of safety of new cosmetics and the advance proof of both safety and effectiveness for new therapeutic devices. It would also extend cautionary warning labeling, similar to that provided in the recently enacted Federal Hazardous Substances Labeling Act, to hazardous substances and containers regulated under the Federal Food, Drug, and Cosmetic Act. And it would modify existing law to permit the approval of feed additives that may be carcinogens, provided they leave no residue in man's food and provided they do not injure the animals to which they are fed. As an essential safeguard, for this modification, the bill would also permit the withdrawal of any prior sanction or approval when a substantial doubt of safety arises.

ADEQUATE MANUFACTURING FACILITIES AND CONTROLS

Except for new drugs, the antibiotic and insulin products now subject to certification, and a few products subject to licensure as biologics, there are no basic requirements as to manufacturing facilties and control procedures that must be established before a person may enter the drug manufacturing business.

A totally untrained person, with little equipment, can open a place of business to make any of a great number of drugs—including some lifesaving prescription drugs—without installing the manufacturing facilities and controls that are so essential to assure the reliability of the packaged medicines he intends to offer to the public and to the medical profession.

If he wanted to open a drugstore, he would have to satisfy the Board of Pharmacy that he had the needed facilities and that he had a trained and licensed pharmacist. Indeed, if he wanted to open a slaughterhouse, he would have to satisfy the Meat Inspection Branch of the U.S. Department of Agriculture that he had installed the equipment needed to produce sound, wholesome, and healthful meat. And he would be subject to continuous inspection once he opened for business.

But no such initial requirements apply to manufacturers of many drugs. We have seen cases of extreme recklessness by firms producing drugs in backrooms, old store-front buildings, and similar inadequate facilities. And recently we discovered that one of the largest producers of tablets and capsules in this country had neglected his controls to such an extent that his calcium wafers actually contained dangerous amounts of another drug picked up from poorly cleaned equipment.

Certainly this kind of a situation cannot be squared with the present-day need for extreme care in the manufacture of the very potent products made available by modern drug technology. It is at least as important for drugs to be properly made and carefully controlled as it is for the pharmacist who dispenses the drug to have proper training and to use proper equipment.

Section 101 of H.R. 11581 would correct this situation by requiring a drug to be manufactured, processed, packed, and held under conditions that would insure that it had the proper identity, purity, quality, efficacy, potency, and labeling and that it would not be injurious to health when used in accordance with directions in the labeling. The Secretary would issue regulations setting forth the methods, facilities, and controls which, based on good manufacturing practice, should insure the production of safe and reliable drugs. If a manufacturer failed to abide by the regulations, the Government could take action immediately to prevent the distribution of the firm's questionable drugs and would not have to wait until a dangerous lot had been manufactured and placed in the hands of consumers or the medical profession.

Similarly, section 201 of H.R. 11582 would correct the situation with respect to therapeutic devices.

PREMARKETING SHOWING OF NEW DRUG EFFICACY; PREMARKETING CLEARANCE OF NEW DEVICES

The present law does not require the producer or distributor of a new drug or therapeutic device to determine that the product will accomplish the things claimed for it in its labeling. In a number of instances we have had to clear products for safety under the new drug section despite the fact that our medical officers had not been supplied any convincing evidence to support the therapeutic claims. We have had to tell the manufacturer that we regard his claims as unproved and believe that their use would violate the prohibition against false or misleading labeling. Nonetheless, we had to approve the new drug application.

Of course, we can take action later to remove the product from the market when we have accumulated the evidence necessary to prove the falsity of the claims. But this may take months or even years, and the drug meanwhile is being promoted to the unsuspecting public and to doctors on the basis of wholly unsupported therapeutic claims.

This state of affairs is indefensible. The manufacturer should be required to develop and to present in his new drug application proof that his product is effective for the purposes claimed before it is marketed.

The only issue is whether the claims for effectiveness should be reviewed before a product is put on the market or sometime later after the public's funds have been wasted and hopes for relief or cure have been cruelly disappointed.

Evaluating effectiveness is not a new concept in administration of the food and drug law. Proof of both safety and effectiveness are now required for certification of antibiotic and insulin preparations. Additionally, where a drug is offered for the treatment of a life-threatening disease such as cancer, we must consider the effectiveness of the product in order to reach a decision as to its safety. Under these provisions of existing law, worthwhile new discoveries have been cleared for use in medicine, and the public has been safeguarded from worthless products. These benefits should be available with respect to all drugs and devices.

By appropriate amendment of the Public Health Service Act, H.R. 11581 would also require human biological drugs to be proved effective as well as potent.

H.R. 11582 would require new therapeutic devices to be proved safe—a requirement new drugs have had to meet for almost 24 years—and, in addition, would require them to be shown effective for the conditions for which they are offered. Some of these important devices are used to mend broken bones, replace damaged arteries, and repair the heart. Plainly the same careful control is needed for devices as for new drugs.

RECORDS AND REPORTS OF CLINICAL EXPERIENCE WITH NEW DRUGS, ANTIBIOTICS, AND THERAPEUTIC DEVICES

Despite the care that goes into clearing a new drug, when it goes into general medical use, adverse reactions and side effects that did not show up in the early clinical testing frequently appear. This is understandable because the drug is administered to thousands or to millions of patients in general practice, thus revealing reactions which occur too infrequently to be disclosed in the testing program. For example, some of the newer drugs have proved to be the cause of liver damage to a limited number of people, and some have had to be recalled from the market completely because of this and similar untoward reactions.

When such a situation develops, it is essential that the Food and Drug Administration know of the adverse effects as soon as they are reported to the manufacturer. The physician's report to the manufacturer is often the very first sign of danger in the use of the drug. The present system is faulty because it does not require the manufacturer to report these adverse reactions; as a result, people have died because the Food and Drug Administration did not learn of the bad effects of drugs until much later than the manufacturer, and thus did not have a basis for requiring prompt recalls later found necessary.

The public has a right to the protection that would be afforded by requiring the shipper of a new drug, antibiotic, or therapeutic device to advise the Government of adverse reactions to a drug as soon as he receives reports of such reactions.

H.R. 11581 would require new drug applicants and antibiotic manufacturers to keep records and make reports to the Secretary of Health, Education, and Welfare of clinical experience and other information bearing on a new drug's safety or efficacy. It also provides that these records shall be made available to designated employees of the Department. Failure to establish or maintain such records, to make any required report, or to permit copying of such records, would constitute grounds for withdrawing approval of the new drug application or antibiotic petition to which the records applied.

H.R. 11582 would place similar requirements upon manufacturers of therapeutic devices.

PROCEDURAL CHANGES AS TO NEW DRUGS AND ADDITIONAL GROUNDS FOR WITHDRAWAL OR SUSPENSION OF APPROVAL OF NEW DRUG APPLICATIONS

Present law does not allow the suspension of a new drug application on the basis of substantial doubt even as to its safety. If we can prove that the applicant made false statements, we can suspend the application and thus stop distribution of the drug, and if new tests show that the drug is unsafe, we can suspend the application. But the product cannot be withdrawn from the market or its labeling suspended in part when the scientific evidence shows a substantial doubt as to safety and efficacy, convincing us that the drug should not have been approved in the first place.

H.R. 11581 would authorize the Secretary, when he finds that there is substantial doubt as to a new drug's effectiveness or safety, to withdraw approval of the application after giving the applicant due notice and opportunity for a hearing. Further, if the Secretary found an imminent public health hazard, he could suspend the approval of a new drug application immediately upon notice pending the opportunity for a hearing.

H.R. 11581 would also make certain desirable procedural changes in the handling of new drug applications. It would require affirmative approval of an application by the Secretary before a new drug could be marketed, rather than allowing the application to become effective automatically at the end of 60 or 180 days. If a hearing were demanded by the applicant, the time required for the hearing would not be taken away from the time allowed the Secretary for his decision. And in case of appeal to the courts from the Secretary's decision, the appeal would be heard by the court of appeals rather than the district court as at present; this would be consistent with other appeals under other sections of the law.

CERTIFICATION OF ALL ANTIBIOTICS

More than any other drugs, antibiotics are the drugs of first choice in treating life-threatening infections. It is essential that they be of proper strength and properly manufactured in all other respects to safeguard the lives of people who are acutely and seriously ill. At present, only five basic antibiotics and their derivatives are required to be tested and certified by the Government. This safeguard should be extended to 30 other antibiotics now being marketed without certifi-

cation and to additional antibiotics that may be expected to be discovered in the future.

Pharmaceutical manufacturers should not be the sole judges before marketing, of the safety and efficacy of individual batches of new antibiotics that are produced. Under the certification system, we have had to reject numerous batches which were submitted to us after the manufacturers tested them and concluded that they were suitable for distribution. We have had to withhold certification services with respect to certifiable antibiotics manufactured by some firms until their operations were brought into compliance with regulations designed to insure safety and efficacy of certified lots. We have had to suspend certification of a number of products that were shown to be unstable or otherwise unsuitable under the conditions of manufacture being employed.

Clearly certification of all antibiotic drugs as proposed in H.R. 11581 would be in the public interest.

STANDARDIZATION OF DRUG NAMES

Present law does not provide for any system to establish a simple and useful standard name for a drug. As a result, common names applied to drugs are frequently complex and confusing, and on occasion more than one common name has been applied to the same drug. This does not lead to good medical practice, and in effect it tends to force the practitioner to prescribe by brand name rather than common name.

H.R. 11581 would give the Secretary authority to standardize drug names. Additionally, it would require a drug label to give the standard name of the drug appropriate prominence and conspicuousness where a brand name is always used. This provision also would contribute to better knowledge about the composition of the drugs the physician prescribes and thus would facilitate prescribing less expensive, but equally safe and effective, drugs under their common names rather than highly promoted trade-named drugs.

SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

Present controls have proved inadequate to prevent the unsupervised nonmedical use of habit-forming barbiturate and stimulant drugs. Abusive use of these drugs presents serious public health problems leading to abnormal and antisocial behavior, to juvenile delinquency, to highway accidents, to broken homes. An extensive bootleg traffic in these drugs has developed along the highways and in places of entertainment in the United States.

In order to make regulation and protection of interstate commerce in these types of drugs effective, it will be necessary to regulate intrastate commerce; if adequate controls are not applied to intrastate commerce, then effective control of this menace on a nationwide basis will be impossible.

H.R. 11581 would permit much more effective regulation of this problem. It would require registration of manufacturers, compounders, and processsors, and would restrict manufacture, compounding, or processing of barbiturates and amphetamine-like stimulant drugs to regularly established firms which have registered with the Depart-

ment and to other individuals and firms which have legitimate use for the drugs. It would restrict possession of the drugs to those who have legitimate use for them. It would require adequate record-keeping to permit inspectors to determine the disposition of such drugs in commerce.

The bill would give the Secretary the authority to bring newly discovered habit-forming drugs under the same controls as is proposed for amphetamines.

CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

It is a deeply disturbing fact that all too often our inspectors are met with refusals to permit comprehensive and effective inspection in food, drug, device, and cosmetic manufacturing establishments. All too often inspectors are treated to a guided tour through the establishment. They are refused access to formula files, complaint files, shipping records, and a great deal more information than is absolutely essential for them to see in order to determine whether the products are being produced in compliance with law.

Over the years, this committee and the Congress have strengthened the protective features of the Nation's pure food and drug laws. This has expanded the Food and Drug Administration's responsibility in protecting the public health. In 1954 the pesticide chemicals amendment was passed. In 1958 the food additives amendment was enacted. In 1960 the color additives amendment and the Federal Hazardous Substances Labeling Act became law. These amendments added to an already broad statute which touches significantly upon vital health areas. We are required to establish and police safe tolerances for known poisons in our food supply. We are required to approve new drugs and to certify antibiotics from the standpoint of safety and to some extent efficacy. This bill would add additional responsibilities. Yet we are being denied access to the information in the manufacturing establishment to tell us whether our tolerances are being met, drugs are being properly prepared, and whether promotion excesses have grown up.

Every working day a food, drug, or cosmetic manufacturer refuses to give our inspectors access to information needed to safeguard the public. These refusals have not been restricted to the fly-by-night operator but extend to some of the very largest manufacturers in this country. We call upon the Congress to examine this situation. We hope that it will be corrected.

On my very first appearance before this committee as Secretary, I recall Congressman Paul Rogers saying that he had been perplexed by a letter which we had written to him answering an inquiry from one of his constituents. The constituent had bought a cosmetic and wanted to know whether it was safe to use. She wrote Congressman Rogers, and he inquired of us. We had to tell him that the firm refused inspection and would not tell us the composition of the cosmetic. Our reply to him was satisfactory neither to him nor to us. We think that the agency charged with overseeing the production of foods, drugs, devices, and cosmetics should be given the needed authority to observe what is going on, how products are being made, whether they are being properly labeled, whether they meet our safety requirements, and whether their use has resulted in consumer complaints.

H.R. 11581 would remedy this problem by granting the Food and Drug Administration authority to make complete inspection of all establishments producing foods, drugs, devices, or cosmetics. This provision would allow inspection of all records, files, papers, processes, controls, and facilities bearing on a product's compliance with the Food, Drug, and Cosmetic Act. It expressly authorizes inspection of independent consulting laboratories. It makes clear that establishments where products are processed or packed after introduction into interstate commerce are subject to inspection.

Also, it would permit inspection of drugstore prescription files. This authority is particularly important when it becomes necessary to remove stocks of dangerous drugs from the market or to trace illegal dispensing of hazardous prescription drugs.

The regulated industries need have no concern about the confidentiality of information obtained by factory inspection. In addition to safeguards already set up in the Food, Drug, and Cosmetic Act which prohibit disclosure of information entitled to protection as a trade secret, H.R. 11581 amends the act to reaffirm, with respect to employees administering it, the provisions of the general criminal code which afford criminal penalties for unauthorized disclosure of confidential information by any employee of the United States.

AMENDMENTS AS TO ADVERTISING

H.R. 11581 has an amendment to the Federal Trade Commission Act designed to eliminate false statements that have been appearing in drug advertisements directed to doctors and to require such advertisements to give physicians information that will permit them to do a better job of selecting drugs for use in their practice. We are in complete accord with the purpose of the amendment. We defer to the Federal Trade Commission for a more detailed statement on it.

PREMARKETING CLEARANCE OF COSMETICS FOR SAFETY

Federal law does not require cosmetics to be tested for safety before they are marketed. As a result over a period of years, untested or inadequately tested cosmetics have reached consumers and thousands of women have been injured. There have been a number of legal actions against cosmetics that contain poisonous or deleterious substances. There have been a number of recalls of dangerous cosmetics.

We believe that the cosmetic manufacturer has just as much responsibility to determine the safety of his products before they are released for use as does the drug manufacturer, the pesticide chemical manufacturer, the food additive manufacturer, and the color additive manufacturer. Of these groups only the cosmetic firms are not required today to test their wares and establish their safety in advance of marketing.

H.R. 11582 would correct this situation by requiring a cosmetic that is not already recognized as safe by appropriate experts to be tested for safety before it is marketed for general distribution. The test results would have to be submitted to our Department for evaluation by the Food and Drug Administration. And only after such

evaluation and approval of the application would a manufacturer be authorized to distribute his product in interstate commerce.

This requirement would apply to cosmetics already on the market which are not recognized as safe by experts, as well as to new cosmetics yet to be developed. It would not be in the public interest to exempt a questionable product now being sold just because it happened to be first produced before the bill were enacted.

The bill contains an anticancer clause that would ban the use of a chemical in cosmetics if it had been found to induce cancer in man or animal when tested by an appropriate procedure.

H.R. 11582 would repeal the exemption for coal-tar hair dyes that allows a dye to be marketed legally even though it contains a poisonous or deleterious ingredient that may render it injurious to users.

Some industry representatives have interpreted this proposal as a desire on the part of the Federal Government to outlaw all dyeing of hair. This is not true. Industry believes that its coal-tar hair dyes are safe when used as recommended in their labeling. If the facts support this belief, then these materials can pass the same safety requirements that apply to other cosmetics proposed in the bill. But if some of the hair dyes are not safe, then they should not be given special exemption that would allow them to remain on the market to the detriment of the public.

CAUTIONARY LABELING ON HAZARDOUS SUBSTANCES AND CONTAINERS REGULATED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

When the Federal Hazardous Substances Labeling Act was passed in 1960, foods, drugs, devices, and cosmetics were exempted. We believe the reason for this was the belief that this problem should more properly be dealt with under the Federal Food, Drug, and Cosmetic Act itself. H.R. 11582 proposes the necessary amendments.

As to foods, the cautionary information is required on pressurized containers only. As to drugs and cosmetics, more comprehensive warnings are required.

There is no doubt that drugs and cosmetics have been involved in a significant number of accidental household poisonings. These are preventable accidents. Warnings are needed to alert parents so that they will keep these items out of the reach of inquiring children and so that they will have the necessary information at hand in the event of accidental ingestion.

The Hazardous Substances Labeling Act is an important improvement in this area, but the amendments proposed in H.R. 11582 are necessary to round out this important consumer protection.

FEED ADDITIVES LEAVING NO RESIDUE IN FOOD FOR HUMANS

Finally, this bill would amend the anticancer clause of the food additives amendment to permit the use in animal feed of products that could not otherwise be approved. This may be done only when the additive does not injure the animal and leaves no residue in man's food. The amendments have procedural safeguards that fully protect the public health.

CONCLUSION

We wholeheartedly support the provisions of H.R. 11581 and H.R. 11582. We urge favorable action by the committee on these two bills.

The CHAIRMAN. Does that conclude your statement, Mr. Secretary?

Secretary RIBICOFF. Yes, it does, Mr. Chairman.

The CHAIRMAN. I would like to express my thanks to you on behalf of the committee for your clear and concise presentation, with reference to the position of the Department with regard to the amendments to the Federal Food, Drug, and Cosmetic Act.

Now, I am going to try to see if I can clear up one thing which was mentioned in your statement at the close.

I would like to turn to section 103, appearing on page 10 of H.R. 11582. That is the proposed amendment relating to hair dyes. Mr. Secretary, I know that you share the views that I and other members of this committee and many other people have that you do not want unnecessarily to interfere with our ladies' opportunity to become the most beautiful ladies in the world; do you?

Secretary RIBICOFF. I am all for beautiful women, and far be it for me to interfere with their use of cosmetics, but I think that I share with members of the committee, and I think the ladies themselves—since they are going to use these cosmetics—the desire that the cosmetics should be safe and not cause irritations, poisons, ill health, and sometimes possible death.

What we would like to do is have the woman still be beautiful and be healthy at the same time.

The CHAIRMAN. Two worthy objectives, I should think.

Does the Department have any information that certain hair dyes have been injurious to the health of some of our people?

Secretary RIBICOFF. The answer is "Yes."

The CHAIRMAN. Could you elaborate on that just a little bit?

Mr. LARRICK. If you will recall, Mr. Chairman, when the Food, Drug, and Cosmetic Act of 1938 was passed, all cosmetics were held to be adulterated if they consisted of a poisonous or deleterious substance. An exemption was made in the case of hair dyes.

The CHAIRMAN. All hair dyes?

Mr. LARRICK. Yes, sir; coal-tar hair dyes, predicated on the inclusion in labeling of a caution that the product might irritate the skin of some people, so that a preliminary test, a skin test, should be made before the cosmetic is applied to the hair, and further, that the product must not be used for dyeing the eyelashes or eyebrows; to do so might cause blindness.

You will recall, Mr. Chairman, we had at that time hair dyes that were used on the eyelashes and eyelids, and there were a number of very tragic cases of blindness.

Now, this caution grew out of that episode.

But hair dyes were exempted from the general safety requirements of the statute if they bore that warning, and over the years there have been a number of cases of injuries reported from the use of hair dyes, often because in applying the dye, it does run down and does get into the eyes, and also because women are sensitive.

Now, as the years have progressed, industry people and industry consultants in science have assured us that they have purified their dyes; they have perfected methods of application; and, based on that

premise, we are not proposing that hair dyes be eliminated, but we are proposing that they be subjected to tests that will require them to be certified like all other coal-tar colors, and that whatever tests are necessary be made.

So we would anticipate that the safe hair dyes would stay on the market, but that any that are dangerous would not stay on the market.

The CHAIRMAN. Doctor, have you had an opportunity to make any inspections to determine if they are harmful and injurious to any people?

Mr. LARRICK. Yes, we know; we know very definitely that there are many people who cannot tolerate the use of a coal-tar hair dye on their hair because they are sensitive to it, and in the case of those people they will get very ill; they will swell up and they get all sorts of bad symptoms.

Now, those can be eliminated.

The CHAIRMAN. There are certain people that are allergic to orange juice.

Mr. LARRICK. Yes.

The CHAIRMAN. Are you going to discontinue the use of orange juice completely because there are certain people allergic to it?

Mr. LARRICK. No, sir; but this is a much more serious type of allergy, and the industry has agreed with us that since there is a test known which can identify these people in advance, that that definitely should be done, and that is in the present law, but it is not observed sufficiently by the beauty shop operators.

The CHAIRMAN. Do I understand from what you say that the intention here, then, is to prevent the use of all coal-tar hair dyes?

Mr. LARRICK. It is not the purpose to prevent the use of all coal-tar hair dyes.

If anybody wants to put a coal-tar dye in a food or a drug or a cosmetic, they must now, under the statute that the Congress has enacted, submit these dyes to tests that will show that under the proposed use it is safe, and that each batch of the dye is of the same composition as the previous batch. Only hair dyes are exempted.

The CHAIRMAN. Well, now, right there, if the amendment were to be provided here as proposed in section 103, repealing the special exemption, then anyone who can show that a particular dye, coal tar or otherwise, is safe, would be permitted to put that dye on the market?

Mr. LARRICK. Correct.

The CHAIRMAN. Is that the intention of your proposal here?

Mr. LARRICK. Exactly.

The CHAIRMAN. Then the general information that seems to be out all over the country that this proposed amendment would prevent the use of hair dyes is not correct?

Mr. LARRICK. Your statement is 100 percent accurate.

The CHAIRMAN. Do you intend to encourage ladies to be more beautiful and more attractive?

Mr. LARRICK. I certainly do, Mr. Chairman.

The CHAIRMAN. I hope so; and we are going to try to hold you to it.

Of course, our American women are so beautiful and so attractive anyway, they do not necessarily need too much cosmetics.

Mr. LARRICK. That is right; they are beautiful by nature.

The CHAIRMAN. Now, Mr. Secretary, there are many questions that I wish I had time to go over with you. Perhaps I will get to some of them a little later.

In your statement you say that you are required to establish and police safe tolerances for known poisons in our food supply.

You are required to approve new drugs and to certify antibiotics from the standpoint of safety and to some extent efficacy. That is under present law?

Secretary RIBICOFF. Yes.

The CHAIRMAN. In those fields, are you authorized to look at the complaint files?

Secretary RIBICOFF. We are not.

The CHAIRMAN. Are you authorized to look at the shipping records?

Secretary RIBICOFF. No, sir.

The CHAIRMAN. Are you authorized to look at the formula files?

Secretary RIBICOFF. We are not.

The CHAIRMAN. Are you doing a good job in those fields, from your viewpoint?

Secretary RIBICOFF. I would say that we cannot do a good job with these restrictions. I mean we could submit to this committee a list of the manufacturers in this country in food, drugs, and cosmetics who have absolutely refused to allow us to make any of these inspections or to get this information, Mr. Chairman.

The CHAIRMAN. Yes; I know that, and I remember your very clear statement on that.

But you point to the pesticide chemical amendment, and you point out the color additive amendments of 1960, and the Federal Hazardous Substances Labeling Act.

Now, you point those out as examples.

Is your administration of those laws turning out fairly satisfactorily?

Secretary RIBICOFF. Mr. Larrick, who administers these, will answer that.

Mr. LARRICK. Yes; I would think those amendments have shown they have great value to the American public.

The CHAIRMAN. If you can administer those amendments satisfactorily without this additional authority you are seeking in these bills, why are you asking for authority to go into the intricacies of the operation of a particular business?

Mr. LARRICK. We can do a much more satisfactory job and a more efficient job in these areas that you refer to, Mr. Chairman, if we do have the authority that we seek in this amendment.

The CHAIRMAN. I am sure that you——

Mr. LARRICK. We would not admit that we are not doing a reasonably satisfactory job.

The CHAIRMAN. I would not feel, from your viewpoint, that you could not. I know that human nature being as it is, that you would like to have all of this additional authority. But do you not agree that there are also certain confidential things about the operation of a business that a competitor should not have?

Mr. LARRICK. I certainly do.

Mr. Chairman, may I say at this point that in the administration of the predecessor statute from 1906 to 1938 we had no power of inspection whatsoever, but the great majority of the American business in this country gave us the information that we needed freely and without restraint. And today, in spite of the limitations of the statute, the great bulk of American industry deals with us forthrightly and does not hesitate to give us that information.

The CHAIRMAN. Recently, a large company provided me with information that, in four different areas, wide and far apart, inspectors had asked for certain confidential information. They were not the same inspectors. They were operating in different areas altogether, which indicated there must be general instructions emanating from the Department here urging them to get this kind of information.

Why do you feel that you need the shipping records or the files of the industry?

Mr. LARRICK. Mr. Chairman, the simplest and most effective way to enforce this law is to do it in a manner that does not involve hide-and-go-seek.

If we go to a responsible firm in the food and drug field, when the inspector gets through, he does ask that firm to give him a representative list of their shipments in interstate commerce. He does that on instructions from Washington, Mr. Chairman.

The CHAIRMAN. Is there not a difference in a representative list and a list of their shipping records?

Secretary RIBICOFF. May I give you an example of what we are faced with here. I will read this. This is a case:

> Evidence obtained during inspections over a number of years has shown that some of the tomatoes of the King's Creek Canning Co., operating five canneries on Maryland's Eastern Shore were not fit for food. The firm has consistently refused to furnish full information about interstate shipments. Many shipments are made by the manufacturer's own trucks. In 1959 gross unsanitary conditions were encountered during inspection of the plants. We found fly eggs and maggots in the canned tomatoes. We were able to locate and seize only three shipments which probably represented less than 5 percent of the firm's output. Thus, the refusal of this canner to furnish complete shipping records resulted in the marketing and consumer consumption of large quantities of filthy, maggoty, canned tomatoes.

Now, our files show in case after case that when we run into a situation where a food product or a drug or a cosmetic is not proper or is not safe, and it is scattered distributively all over the United States in thousands and thousands of retail outlets, and we are trying to locate this product to take it off the market, if we cannot know who the customers are, it is impossible for us to protect the public and seize this adulterated and unsafe product.

I think it becomes very, very important, if we are to protect the American consumer, that when we run into a situation where we are dealing with unsafe substances, that we should know where to go and seize the unsafe substances, Mr. Chairman.

The CHAIRMAN. Do you know why a processor or manufacturer objects to his name being given to the Federal agency?

Secretary RIBICOFF. Why they do it?

I suppose many of them do it for purely selfish reasons. They realize if their goods are seized and not sold, that they will have a very large financial loss. It also may hurt their reputation. This is unfortunate.

The CHAIRMAN. Did you not know, Mr. Secretary, that in some instances in which the processor has told the manufacturer of these products that if they gave their names to your inspectors, that they would take their business somewhere else?

Secretary RIBICOFF. I do not know this to be a fact.

Mr. LARRICK. That is very rare, Mr. Harris.

The general food merchandisers in this country, the wholesalers and the retailers, are just as much interested in selling sound, good merchandise as anybody else, and they welcome our coming in and taking samples, and we have many of them who would be willing to come here and so state.

The CHAIRMAN. Well, I have used entirely too much time. Just one other question: Are you familiar with the letter the President sent to the chairman of the Judiciary Committee of the Senate?

Mr. LARRICK. We do not have that letter with us.

The CHAIRMAN. Are you familiar with it?

Secretary RIBICOFF. Yes, generally, we are.

The CHAIRMAN. Would you supply a copy of that so we can have it included in the record?

Secretary RIBICOFF. I will, sir.

(The letter requested was subsequently furnished for the record:)

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 2, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: When I appeared before the Committee on Interstate and Foreign Commerce on June 19, you requested that I supply you with a copy of the letter the President sent to the chairman of the Judiciary Committee of the Senate on April 10, 1962.

Enclosed is a copy of a release from the Office of the White House Press Secretary dated April 11, 1962, which reports the text of the letter in question.

Sincerely,

ABE RIBICOFF, *Secretary.*

[Immediate release, Apr. 11, 1962]

FOLLOWING IS THE TEXT OF A LETTER FROM THE PRESIDENT TO SENATOR JAMES O. EASTLAND

THE WHITE HOUSE,
OFFICE OF THE WHITE HOUSE PRESS SECRETARY,
April 10, 1962.

Hon. JAMES O. EASTLAND,
U.S. Senate, Washington, D.C.

DEAR SENATOR: In the message I sent to the Congress on March 14, I called attention to the need for new legislative authority to advance and protect the interests of consumers in the marketing of drugs.

S. 1552, which is now pending before your committee, incorporates the major recommendations I made. It will strengthen and broaden existing laws in the food and drug field, contribute toward better, safer and less expensive medicines, and establish a better system of enforcement. As you know, the bill is the outgrowth of 28 months of intensive investigation and hearings by your Subcommittee on Antitrust and Monopoly. I believe that early passage of this legislation will substantially improve the ability of the drug industry to serve the Nation and help provide consumers with quality drugs at low competitive prices.

I understand that the members of the Subcommittee on Patents have decided that the compulsory licensing feature of the legislation requires further study and consideration. I would hope that this would not, however, delay enactment of the other provisions of the bill—provisions which will establish neces-

sary safeguards to assure the reliability and effectiveness of drugs placed on the market, provide for standardization of drug names, and thereby encourage physicians to prescribe drugs by nonproprietary rather than by brand names, require disclosure of adverse as well as beneficial effects of drugs in drug promotion, and assure consideration of therapeutic effectiveness in the granting of patents for drugs that are modifications of other drugs.

The message I sent to the Congress made several other suggestions which, it would seem to me, might appropriately be included in the bill now before your committee. They are—

1. Drug manufacturers should be required to keep records on and report to the Department of Health, Education, and Welfare any indications of adverse effects from the use of a new drug or antibiotic.

2. The Department of Health, Education, and Welfare should be empowered to withdraw approval of a new drug on the basis of a substantial doubt of its efficacy or safety.

3. The provisions requiring drug manufacturers to maintain facilities and controls to assure the reliability of their product, and to institute more effective inspection to determine whether drugs are being manufactured in accordance with the law, cannot feasibly be limited to a particular class of drugs and should therefore be made applicable to over the counter as well as prescription drugs.

4. An enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines should be provided.

The need for these amendments is based upon the accumulated years of experience of the Food and Drug Administration, and they appear to be properly within the scope of the subject matter dealt with in the extensive hearings of the Subcommittee on Antitrust and Monopoly.

In addition, I recommend two minor procedural changes:

1. In the section having to do with the rendering of advisory opinions by the Department of Health, Education, and Welfare to the Patent Office on the therapeutic effect of modifications and combinations, I suggest that the requirement providing the applicant with an opportunity for a plenary hearing be deleted. Under the provisions of S. 1552 in its earlier form, the Secretary's finding was conclusive and therefore should have required a formal hearing. But since the bill in its present form requires no binding decision to be made by the Secretary, the requirement of the hearing seems inappropriate and would tend to unduly delay the rendition of the Secretary's purely advisory opinion to the Commissioner. The action of the Commissioner is, of course, subject to well established de novo judicial review.

2. The provision requiring the filing of patent agreements with the Commissioner of Patents should more properly be in the form of an amendment to the Patent Act rather than the Sherman Act.

I have asked the Department of Health, Education, and Welfare to transmit to you promptly any additional recommendations to strengthen, clarify, or improve the bill that it may have and that will not require additional hearings or substantially delay action on the bill.

It would not appear that the consideration of these proposed changes should occasion any further delay in the approval of this important measure.

With the above changes, S. 1552 adequately deals with the most pressing problems in the drug field, and it is my sincere wish that it be enacted during the current session of the Congress. Your cooperation and assistance to this end will be greatly appreciated.

Sincerely,

JOHN F. KENNEDY.

The CHAIRMAN. Can you state whether or not the amendments in H.R. 11581 and H.R. 11582 conform to the recommendations in the President's letter?

Secretary RIBICOFF. Yes, they do.

The testimony that has been given to you today and the bill before you are consistent with the recommendations of the President in his letter to Senator Eastland under date of April 10, 1962.

The CHAIRMAN. Are you familiar with the several amendments that have been adopted by the Senate Judiciary Committee and the four or five other amendments that are pending for consideration?

Secretary RIBICOFF. My understanding is that they have not come out of the committee as yet, sir; that they have been discussed in the committee, but they have not actually been voted out. Six have been approved but they have not been voted out of the committee.

The CHAIRMAN. Yes, I understand that is true.

Six have been approved according to the information I received out of the record. Some are still pending.

Are you familiar with those amendments?

Secretary RIBICOFF. Yes, we are, but, basically, I do not think that these amendments conform with the President's recommendations.

The CHAIRMAN. Do they substantially differ from what you have recommended here today?

Secretary RIBICOFF. I think they differ substantially enough to make us quite unhappy about them.

The CHAIRMAN. Mr. Springer?

Mr. SPRINGER. Mr. Secretary, if we have a drug today, we will say, manufactured by Eli Lilly, and it is submitted to you, what procedure do you go through now?

How much time do you have to determine whether or not it is a safe drug to put on the market?

Secretary RIBICOFF. Mr. Larrick will explain how that is worked.

Mr. LARRICK. Under the statute as passed in 1938, a firm submits to us an application with respect to a new drug. We file that application and serve them notice that we have filed it.

We have 60 days within which to act. That period of time within which we can act can be extended by ourselves to a period of 180 days.

The CHAIRMAN. Additional?

Mr. LARRICK. Total.

Within that period of 180 days, we would have to give consideration to the chemistry, the pharmacology, the clinical medicine, and all aspects of whether or not that drug is safe for use.

If we did not agree that the application should be made effective, we would have to serve notice on the firm and hold a public hearing within that period of 180 days. In most instances where the firms and we agree that the drug is safe to go on the market, the time has been sufficient, but as the drugs become more complex and there are more problems of safety, we have learned by experience that the 180 days is not enough time.

Mr. SPRINGER. Suppose at the end of 180 days you say that drug is not safe to be put on the market. What do you do?

Mr. LARRICK. Well, in practice, Mr. Springer, ordinarily if we reach that conclusion, we get in touch with the firm informally and state our views informally, and 9 times out of 10 our scientists and theirs get together and agree that further work needs to be done before final action is taken on our part, and they withdraw their application.

But they are not required to do that.

If they say, "No, we want to stand on our position," we must serve notice on them and set a date for a hearing, at which hearing they put on their evidence as to why they think the drug is safe and should go on the market; we put on our evidence as to why we think the drug is either unsafe or sufficient evidence has not been presented to show whether or not it is safe.

Then on the basis of that record, which is taken down, the Secretary reaches his decision as to whether or not the drug should be permitted to go on the market.

If he reaches a decision that it should not go on the market, the firm then can appeal on the basis of that record to the district court, where the matter is settled on the basis of that record.

Mr. SPRINGER. That is the present system?

Mr. LARRICK. That is the present procedure.

Mr. SPRINGER. Now, tell us just exactly what you propose to change in that existing law?

Mr. LARRICK. The change, as proposed in this law, would (1) provide for an appeal by the applicant from an adverse decision of the Department directly to the U.S. court of appeals to make it consistent with other appeals provisions under the act.

It would remove the provision which now prevails that if we do not act one way or the other within 180 days, the application would become automatically effective. This is too important to make it automatically effective.

Mr. SPRINGER. Just a moment.

You said it would do what, now, in 180 days?

Mr. LARRICK. If we do nothing, under present law at the end of 180 days the application to put the drug on the market automatically becomes effective, just as though the Secretary had affirmatively held that it was safe.

In other words, a clerical error could under the present circumstances put a dangerous drug on the market—I am not anticipating clerical errors, but we all have them—and we do not think that 180 days is a sufficient period of time.

We just had an episode that happened in Europe.

Mr. SPRINGER. Wait a minute.

I want to stay on this, because this is not clear, Mr. Larrick. I do not understand what the change is, and that is what I want to know.

Mr. LARRICK. We would no longer have to conclude the hearing within 180 days from the filing date of the application, and the application would not become automatically effective if we did not act within 180 days. We would not be held to a time limit within which to act, so far as the hearing stage is concerned.

Mr. SPRINGER. What is going to happen at the end of that time? Is the petition going to be approved and put it on the market?

Mr. LARRICK. No, sir.

There would have to be an affirmative action by the Secretary rather than an action by default.

Mr. SPRINGER. I still do not understand what you intend to do.

This is the crux, one of the cruxes of this bill.

Mr. LARRICK. Right.

Mr. SPRINGER. And I want to be sure this committee understands it.

You have 60 days at the present time, and you may extend that to 6 months, is that correct?

Mr. LARRICK. 180 days is the sum total time limit to which we can extend the period within which we can issue a stopover. We start with 60 days.

Mr. SPRINGER. 180 days is 6 months, is it not?

Mr. LARRICK. Right.

Mr. SPRINGER. You start with 60 days and it can go to 6 months?

Mr. LARRICK. Right.

Mr. SPRINGER. Now, at the end of 180 days, can you still extend it for 6 months?

Mr. LARRICK. No, sir.

That is the end.

Mr. SPRINGER. Now, if you do not say anything, does it automatically go on the market?

Mr. LARRICK. Today?

Mr. SPRINGER. No, under this proposed legislation.

Mr. LARRICK. No.

Mr. SPRINGER. You mean because you do not do anything, it could not go on the market?

Mr. LARRICK. Right.

Mr. SPRINGER. All right, that is the first point.

Mr. LARRICK. Right.

Mr. SPRINGER. And then the only recourse they have in the meantime, they cannot put it on the market, they have to take an appeal to the U.S. circuit court of appeals, is that correct?

Mr. LARRICK. Mr. Goodrich, would you answer that?

Mr. GOODRICH. They would be expected to give more evidence there.

The CHAIRMAN. Will you identify yourself for the record?

Mr. GOODRICH. My name is William W. Goodrich, Assistant General Counsel.

Under the present law there is a provision that the application becomes effective at the end of 180 days unless, prior to that time, after notice and opportunity of hearing, it has been turned down.

Under this bill the application would not become effective until safety were proved.

If we delayed a decision on a hearing inordinately, you know, just failed to act, we could be mandamused to act, but there would be no automatic time limit within which we would have to complete the hearing or make a decision based on the hearing.

Mr. SPRINGER. Then you would have a mandamus through the U.S. circuit court of appeals?

Mr. GOODRICH. That would be in the U.S. district court.

Mr. SPRINGER. U.S. district court?

Mr. GOODRICH. Yes.

Mr. SPRINGER. Would you try that de novo?

Mr. GOODRICH. No.

The issue there would be whether we had delayed the matter inordinately, whether he had refused to act when we were dutybound to act, where there was undue delay.

Mr. SPRINGER. Upon whom at that point is the burden of proof?

Mr. GOODRICH. The burden of proof would be on the applicant to show that we had acted with undue delay.

Mr. SPRINGER. Now, today, before the end of the 180 days, on whom is the proof?

Mr. GOODRICH. If we do nothing within 180 days, that is all there is to it. It is effective.

Mr. SPRINGER. At the present time?

Mr. GOODRICH. Yes, sir.

Mr. SPRINGER. The burden of proof then is upon whom under the present law?

Mr. GOODRICH. The burden of proof of safety is still on the applicant, but we have to act to prevent that drug from becoming effective, to hold a hearing and issue a decision on the basis of the hearing within those 180 days.

He still has the burden, but the point is that the hearing has to be noticed and completed, all the scientific review completed, within 180 days, which we are suggesting is too short a time.

Mr. SPRINGER. Unless you, by affirmative action under present law, extend it for 6 months, am I correct?

Mr. GOODRICH. 180 days is the 6 months. You see, we start with the 60 days.

Mr. SPRINGER. I beg your pardon, you are correct.

Mr. GOODRICH. We start with the 60 days and then we are allowed up to 6 months by extension, but at the end of those 6 months, which includes the time required for hearing, our time is out.

Mr. SPRINGER. All right.

Now, at the present time, what you are, in effect, doing is extending that indefinitely until proved in the U.S. circuit court?

Mr. GOODRICH. Under this bill, yes, we are excluding the hearing time from the statutory time limit, and judicial review will be in the U.S. courts of appeals.

Mr. SPRINGER. You are not shifting the burden of proof?

Mr. GOODRICH. No, sir.

Mr. SPRINGER. Now, Mr. Larrick, one further thing. I understood—I will direct this to the Governor. Governor, somewhere in this statement it is my understanding that you said that anyone involved in this, such as one producing drugs, need have no fear of the confidentiality of this information which might be supplied.

Secretary RIBICOFF. That is correct, sir.

Mr. SPRINGER. I do not know what you have in mind, and I can only think of one other agency as the perfect example of what frightens people affected by this legislation, and that is the Federal Trade Commission's *Indianapolis* case a few months ago, in which they subpenaed every record of a number of companies and laid it out on the top of the table.

It was evidence and it was open to the public, at least it was open to such that it could be leaked to any newspaper and become a matter of public print.

Secretary RIBICOFF. We have no subpena power.

We have no right to give it to the public. It would be a criminal offense.

Has there ever been an example in this Department, Mr. Larrick, of any inspector ever having given any information to any competitor or rivals or anyone else?

Mr. LARRICK. No, sir.

Secretary RIBICOFF. Basically, Mr. Larrick, who has been with this Agency for this entire period of time, never recalls one.

Mr. SPRINGER. There is a word which is used in one of these bills called "efficacy."

Could you, Governor, tell me what "efficacy" means?

Secretary RIBICOFF. I would say "efficacy" means that it is effective to do the job that it is represented to do. If it is represented to effect a cure, it will effect such a cure. If it is represented to clear up a condition, it will clear up a condition.

Many drugs on the market might be safe but absolutely useless to effect what they are represented to accomplish.

Mr. SPRINGER. Efficacy, power to produce effects, the efficacy or power of medicine.

Are you using that word as a term to determine whether or not the drug used will produce the effect it says it has, is that your thought about that?

Secretary RIBICOFF. That is right.

Mr. SPRINGER. Are you familiar with the polio situation in this country of 1953?

Secretary RIBICOFF. I am sorry, sir?

Mr. SPRINGER. You are familiar, Mr. Larrick, with the polio situation in 1953, when we had the hearings, and sitting there heard the 15 experts in the world, probably, on this problem?

Mr. LARRICK. The problem was not a problem of the Food and Drug Administration. It was the Public Health Service. But I was on the fringes of it and had some information.

Mr. SPRINGER. You do have jurisdiction of polio vaccine, do not not?

Mr. LARRICK. No, sir; we do not license it.

That is the jurisdiction of the National Institutes of Health under the Surgeon General of the Public Health Service and Secretary Ribicoff, but not of the Food and Drug Administration.

Mr. SPRINGER. Then you do not have any supervision over that kind of a drug?

Mr. LARRICK. It is, predominantly, under the old Virus, Serum, and Toxin Act, now embodied in the Public Health Service Act.

Mr. SPRINGER. I beg your pardon, I could not hear.

Mr. LARRICK. It is regulated under a statute enforced by the Public Health Service.

Mr. SPRINGER. And the Public Health Service alone has jurisdiction?

Mr. LARRICK. No; that is the reason I answered as I did. To the extent that the Public Health Service Act covers it, we do not have jurisdiction.

Mr. SPRINGER. Did you have any inspection in the polio situation?

Mr. LARRICK. No.

Mr. SPRINGER. Do you have it over streptomycin and sulfa drugs?

Mr. LARRICK. Yes, sir.

Mr. SPRINGER. Suppose that they wanted you to approve a new sulfa drug or a new mycin of some kind. In those instances where it may or may not be clear as to whether or not this has some danger for some people, do you still approve it?

Mr. LARRICK. In determining whether or not a new drug is safe or in determining whether or not a derivative of some antibiotics can go on the market, we try to learn what the probable side effects and harm to be produced by the drug are.

We try to learn what good it will do.

Then we balance one against the other, and if the good outweighs the harm, we pass it. There are few drugs that are absolutely 100 percent safe.

So it becomes a relative proposition.

The answer to your question is yes on that basis.

Mr. SPRINGER. Are you in the same situation today with reference to hair dye?

Mr. LARRICK. No, we are not.

We do not have the power to pass on the hair dye. Hair dye is not subject to the same type of regulation.

Mr. SPRINGER. Would you submit all drugs to that test that it is relatively safe?

Mr. LARRICK. All drugs now, all new drugs, are subject to the test of safety.

We would recommend that all drugs be subjected to the test of safety, and that the manufacturer be required to prove, before they are put on the market, that they will do what is claimed for them.

Mr. SPRINGER. You are asking that the person who puts it on the market prove that?

Mr. LARRICK. That is right.

Mr. SPRINGER. Is that correct?

Mr. LARRICK. The burden of proof would be on him, to use your terminology.

Mr. SPRINGER. Now, in effect, by this procedure, are you forcing the drug manufacturer to go to the U.S. circuit court in order to prove his case?

Mr. LARRICK. No, sir.

In the whole administration of the statute that you gentlemen passed back in 1938, we have handled the problems that have arisen on safety on a scientific basis and only about two or three of them have gone to the Federal courts during that whole period of time.

We would hope that the same situation would prevail with respect to these new proposals.

Mr. SPRINGER. All right.

Now, if that is true, Mr. Larrick, then why are you asking that this time be extended from 180 days?

Mr. LARRICK. Because, as drugs have gotten more and more complex, as the problems that we have to decide have gotten greater and greater and greater, we have found that we cannot give the public the protection that they expect with that time limitation placed on us.

Mr. SPRINGER. How many cases, roughly, in the last 5 years has your agency had up for determination?

Mr. LARRICK. Had what?

Mr. SPRINGER. Drugs, how many in the last 5 years, 130, 1,000?

Mr. LARRICK. There would be, on the average, of new drugs, somewhere around 300 or 400 a year.

Mr. SPRINGER. Now, out of those 300 or 400, how many have you turned down?

Mr. LARRICK. I would like to supply those data with accuracy, but they would be relatively few.

Mr. SPRINGER. Three percent?

Mr. LARRICK. It would be larger than that.

If you count in the turndowns the ones that did not go to court, where we agreed between us that they would be withdrawn, it would be much higher than that.

I would say that the average on a brand new drug, where it comes along for treatment of a serious disease and it is a very complex thing, that more than 50 percent of them, we would not approve in the first 180-day period.

Mr. SPRINGER. All right.

Now, do you mean to say, then, that you allowed them to go on the market?

Mr. LARRICK. We have said to the manufacturer, "For this reason we are not prepared at this time to tell the American public and the physicians of this country that this drug is safe. We think you need to do 6 months more work in this area or 6 months more work here."

If they say, "OK, we agree," or, "We will do it," they withdraw their application, and it starts all over again.

Mr. SPRINGER. Now, how many have passed the 180 days and have gone ahead and put the drug on the market over your objection?

Mr. LARRICK. They cannot do that.

Mr. SPRINGER. They cannot put it on the market over your objection?

Mr. LARRICK. No, they cannot put it on over our objection without going through the district court of appeals procedure, sir.

Mr. SPRINGER. Then how many have appealed to the district court of appeals or to the U.S. circuit court?

Mr. LARRICK. My recollection is it is two or three, is that right, Mr. Goodrich?

Mr. GOODRICH. Only two on appeal.

Mr. LARRICK. Two on appeal in the last 20-odd years.

Mr. SPRINGER. What I am trying to get, Mr. Larrick, is:

If you tell them not to put it on the market, they cannot put it on the market, and, yet, you say there have been only two or three that have seen fit to go to the U.S. circuit court of appeals, over your objection. Am I stating this correctly?

Mr. LARRICK. I think that is correct.

Mr. SPRINGER. Then I do not understand why you are asking for this revised procedure, when, as a matter of fact, you have said to them, "No, I do not want you to put it on the market," and nobody has gone around you.

They have backed up and started over.

Mr. LARRICK. We think that the safety of drugs for the American public, lifesaving drugs, is too important to leave to a matter of arrangements between us and the industry.

We think it should be a matter of law, and that you gentlemen should lay down the rules for us to follow.

Mr. SPRINGER. Have we not laid down the rules for you to follow?

Mr. LARRICK. You have, and each time that we have come forward with a request for amendment as circumstances and technological advances have required, you have laid down new and improved rules, and, once again, we are coming to you to take into account the very significant technological changes that have gone on in this drug field, and to bring the law up to date.

Mr. SPRINGER. I do not want to take any more time asking questions, but I think this is the other crux of this, and that is the necessity of what you are trying to put forward, and this committee will give it to you if you can prove that you need it.

But I find in my examination of you—and I take it that what you have said is true—that you have had only two or three people who have persisted in saying, "I am going to go ahead over your objection," and have gone to the U.S. circuit court for a trial.

I take it that the rest of them, those that you felt were dangerous, you have said, "No, you are going to have to go back for more testing," or they have put it on the market and you have come forward with those and you may have come forward with others after you have had a retesting?

Mr. LARRICK. Right.

But this business of including the necessity of having this hearing within that 180 days is just not realistic at all.

A hearing may take 30 or 40 days in itself, and the possibility that the firms may call for this procedure pushes the hands of our scientists too much, so that actually they do not have 180 days to consider this tremendously important matter.

They have to conclude their consideration far enough in advance of the 180-day time limitation so that we can serve a formal, legal notice on the firm, and so that we can set a time for a hearing and have a hearing, and then go through all the rigmarole that follows the hearing.

That is the most important part of our proposal.

Mr. SPRINGER. Mr. Larrick, this is just one reason why the 180 days was put in there. It was to force your hand in order that you would allow and to get the drugs on the market.

I know bureaucracy, what they are going to do. The least little thing, they are not going to do anything about it. They are just going to say, "Let the 180 days ride," as long as they want to.

But this is the reason that the time limitation was put in this act, in order that you would expedite it and put forward first the examination of these drugs in order that they might come on the market.

Mr. LARRICK. All right.

But in your broad consideration of this public problem, at least give very careful consideration to adding whatever amount of time the hearing takes to the 180 days.

The pressures that we are under on occasion to make these drug applications effective is very great.

Mr. SPRINGER. Now, let us just take it this way, Mr. Larrick.

I am not so sure that this ought to be still on your back, should this be extended another 90 days, but this idea of leaving this thing wide open that these people down here can just dictate to any industry, "I am sorry, but your drug is not going to go on the market, we do not have any evidence yet"——

Mr. LARRICK. We will not argue. The Secretary just told me to point this out to you.

If you were to add to the 180 days whatever length of time it takes to proceed with this hearing and to conclude it, then we probably would have enough relief.

Mr. SPRINGER. All right, now let me ask you this.

Do you have an opinion, you and the Secretary, today, how much additional time that ought to be?

Mr. LARRICK. Do you mind if I ask Mr. Goodrich? Would you want to state a time?

Mr. GOODRICH. It would be impossible to do that, Mr. Springer.

The only two hearings we have had have run into records of about 4,000 pages. We were able to persuade the people in those two cases to pull these drugs back off the market while the hearing was going on, but there was not any requirement that they do so.

The more complex the drug is, the more involved the hearing.

Mr. SPRINGER. I think that this committee is sympathetic, but I do not think they are sympathetic to leaving this record wide open so that the Pure Food and Drug can extend this thing indefinitely when someone is trying to get a drug on the market.

Mr. LARRICK. I do not think we would debate that with you, Mr. Springer.

Mr. SPRINGER. Mr. Chairman, that is all.

The CHAIRMAN. Mr. Williams, any questions?

Mr. WILLIAMS. No questions.

The CHAIRMAN. Mr. Macdonald, questions?

Mr. MACDONALD. Yes, sir; I have just two.

One thing, I think most of the committee is in sympathy with the plan.

I take it, Mr. Larrick, you were consulted about the bill before it came up to the committee?

Mr. LARRICK. Oh, yes, sir.

Mr. MACDONALD. One thing that bothers me is that some of the abuses—and I suppose that is what you are trying to cure, the abuses—it seems to me that a pill, and I will not name it because there is no point to prejudice a certain pill, but it will be cleared for sale by you or your group, your Commission, and then you will see an ad on TV, for concrete example, about this very pill that it perhaps is not harmful, and, yet, the inference left by the advertisement would lead one to believe, a layman at least, that it could cure something that you would not clear it for sale, is that not correct?

Mr. LARRICK. Well, I think on occasion that has occurred. My hesitancy is occasioned by the fact that, as this committee very well knows, advertising is subject to the jurisdiction of our companion agency, the Federal Trade Commission, and we are working energetically to bring our two types of actions as close together as we can.

(The following letter was supplied for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 11, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: When I appeared before your committee on June 19, 1962, to testify on H.R. 11581 and H.R. 11582, Congressman MacDonald had some question about the regulation of drug advertising (at pp. 59–62 of the transcript).

To make the record clear, I would like to point out that there is nothing in either of the bills that would change the present plan of drug control under

which the Federal Trade Commission has jurisdiction over advertising claims and this Department has jurisdiction, under the Food, Drug, and Cosmetic Act, over the labeling and purity of drugs.

Section 131 of H.R. 11581 would give the Federal Trade Commission stronger provisions with which to deal with the advertising of prescription drugs.

I would appreciate it if you would include this letter in the record of the hearings as a further response to the questions raised by Congressman MacDonald.

Sincerely,

ABE RIBICOFF, *Secretary.*

Mr. MACDONALD. For a concrete example, a man will come out of an office, and he will hit his stomach, and he will say, "Well, thank God I do not have an ulcer. I am going to take one of those pills," which would lead you to think that the pill cured the ulcer.

Now, do you not think that some people can fall into the trap of buying that drug to avoid an ulcer, or to cure an ulcer?

Secretary RIBICOFF. Without a question.

I mean we have a list here, which we would be pleased to leave with you, Mr. Chairman, of many, many drugs that we have had to clear because they are safe, but whose claims, as you point out, Congressman Macdonald, are most questionable, to say the least, and will not accomplish what they say they will accomplish, and, yet, people go out and buy them, and they are represented to do certain things that they cannot do. However, they are safe; they will not do any harm.

The list is a long one, and we will be pleased to submit this for the record, Mr. Chairman.

(The list mentioned by Secretary Ribicoff follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 19, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: When Secretary Ribicoff appeared before your committee on June 19, 1962, to testify on H.R. 11581 and H.R. 11582, he indicated that we would submit for the record a list of drugs that we have had to clear because they are safe, but which have one or more questionable claims for effectiveness in their labeling.

We herewith enclose a copy of the list to which the Secretary referred. We would have no objection if you should wish to make this list of drugs a part of the record in connection with the Secretary's testimony.

Sincerely yours,

WILBUR J. COHEN,
Assistant Secretary.

EXAMPLES OF NEW DRUG APPLICATIONS THAT HAVE BECOME EFFECTIVE EVEN THOUGH SOME CLAIMS FOR EFFECTIVENESS OF THE PRODUCTS ARE QUESTIONABLE

Some of these drugs have some recognized usefulness. All of them were allowed effective new drug applications on the basis that the product was safe despite the fact that the data submitted did not support a burden of proof of efficiency for one or more of the claims. Each product listed under its trade name contains the drug listed under its common name, but the trade-name product may also contain other ingredients.

PRESCRIPTION DRUGS

Common name	Trade name	Firm that filed new drug application	Questionable claims
Carisoprodol	Soma tablets	Wallace Laboratories, division of Carter Products, Inc.	Relieves pain as a primary or direct analgesic.
	Rela tablets	Schering Corp.	
Conjugated estrogenic substance	Premarin intravenous	Ayerst Laboratories, division of American Home Products Corp.	Control of hemorrhage from nosebleeds and bleeding associated with surgical procedures such as tonsillectomies, dental extractions, prostatectomies, and adenoidectomies. Useful in control of gastrointestinal hemorrhage.
Edathamil disodium	Endrate disodium	Abbott Laboratories	Will remove calcium from pathological deposits, such as calcified heart valves, calcific deposits on the skin and joints, calcified deposits in the kidney, and otosclerosis. Has a beneficial effect in angina pectoris, peripheral vascular disease, scleroderma and porphyria.
Hydroxyzine hydrochloride or pamoate salts.	Atarax	J. B. Roerig & Co., division of Charles Pfizer & Co., Inc.	Useful in treating cardiac arrythmias of ventricular origin.
	Vistaril	Pfizer Laboratories, division of Charles Pfizer & Co., Inc.	
Nylidrin hydrochloride	Arlidin	Arlington Funk Laboratories, division of U.S. Vitamin Corp.	Useful in cerebrovascular disorders, including arteriosclerosis of cerebral vessels; circulation disturbances of the inner ear, and eye conditions in which vasospasm and impaired circulation are factors.
Papain	Papase buccal tablets	Warner-Chilcott Laboratories, division of Warner Lambert Pharmaceutical Co.	Enhances normal physiological responses in reducing inflammation, reducing edema, restoring normal circulation, resolving extravasated blood and lymph, reducing pain and promoting healing. Recommended in treatment of injuries, infections, inflammations, allergies, respiratory disorders and surgical, obstetrical, and dental trauma. Recommended in treatment programs for sprains, abscesses, thrombophlebitis, hemorrhoids, bursitis, bronchial asthma, tonsillitis, laryngitis, and sinusitis.
Piperidolate hydrochloride, ascorbic acid, and hesperidin complex.	Dactil-OB	Lakeside Laboratories, Inc.	Prevention of premature delivery in pregnancy.
Polyunsaturated fatty acids	Lenic capsules	Crookes-Barnes Laboratories, Inc.	Useful in lowering elevated blood cholesterol levels.
Potassium and magnesium aspartate	Spartase	Wyeth Laboratories, division of American Home Products Corp.	Treatment of fatigue.

NONPRESCRIPTION DRUGS

Dequalinium acetate, cetyl pyridinium chloride, oil of peppermint, menthol.	Micrin	Johnson & Johnson	Promotes healing of raw inflamed tissue.
Pregnenolone acetate, in an ointment cream base.	Eterna 27	Revlon, Inc.	Will show dramatic results on the skin of 6 out of every 10 women, and will do more for your skin than any other cosmetic cream.

Mr. MACDONALD. The point is, Mr. Secretary, I appreciate your submitting the list, but do you not think that if we are going into this field, that this might be an opportune time to try to clear up the lack of jurisdiction that exist in this area?

Do you not think that it would be advisable to include in such an omnibus bill as this, to pinpoint the responsibility for this false advertising?

Secretary RIBICOFF. I think it would be fine.

Mr. WILLIAMS. Will the gentleman yield at that point for a question?

Mr. MACDONALD. I will be happy to yield.

Mr. WILLIAMS. It is my understanding that this legislation applies only to those drugs which are dispensed by a physician, is that not right?

Mr. LARRICK. No, Mr. Williams.

Mr. WILLIAMS. Does this go so far as to cover over-the-counter drugs, aspirin, for example?

Mr. LARRICK. Very definitely. Part of the Kefauver bill, S. 1552, originally did not.

Mr. MACDONALD. Would I be going too far to ask that you send up recommendations in this field to be included?

I, for one, would be happy to put in such an amendment.

Secretary RIBICOFF. I would say what you have got involved is the ordinary jurisdictional problem, but it will certainly be submitted.

I think it makes a lot of commonsense, and I never could be very patient with which agency has jurisdiction if you have got a public interest involved.

I think that your request is a fair one, and we will make the request accordingly to see whether something that does not come within our Department can be called to the attention of another agency to supply this phase of it to you.

Mr. MACDONALD. I would appreciate it, that it come up in time, so that it can be included in such a bill.

Now, the second thing is this. I do not know anything about this, and I do not suppose any of my colleagues do either, but I have been inundated with mail from hairdressers saying that if this bill passes, that they will be put out of business; that it is an unwarranted intrusion into the affairs of hairdressers; and I would like for the record some statement from somebody in authority, perhaps Mr. Larrick, saying what will be the result.

No. 1, will it put professional hairdressers out of business?

Secretary RIBICOFF. I would say the first question the chairman asked covered this particular field.

He wanted to know whether we were interested in interfering with the beauty of American women, and the answer we gave the chairman was that we were all for beautiful women but we wanted to make sure they are healthy at the same time.

Mr. MACDONALD. That is a very good answer, Mr. Secretary, and all of us share the same feeling, but will this interfere with the hairdressing business, as such?

Secretary RIBICOFF. Not at all.

Mr. MACDONALD. If you have answered these questions, just say so.

Secretary RIBICOFF. I do not mind answering them. I would rather have the chairman's statement whether I have or have not.

The CHAIRMAN. Yes, so far as the record is concerned, he has made a very clear and concise statement on it, but, for the gentleman's information, if he wants to repeat it, why, he is entitled to.

Mr. COLLIER. It was a very uncontroversial issue.

Mr. MACDONALD. You mean we are all for beauty and health?

I have no further questions. Thank you very much, Mr. Chairman.

The CHAIRMAN. Now that that issue is firmly established, we will proceed.

Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

Is it not true that the Federal Trade Commission has full power to control the false advertising?

Secretary RIBICOFF. Yes, they do.

Mr. YOUNGER. So that if these drugs are falsely advertised, the Federal Trade Commission can step in and stop that?

Secretary RIBICOFF. They are limited. They do not have adequate power over advertising of prescription drugs. They do not have the full power over prescription drugs, but I think, as you do, that the importance of the health of our Nation is such that you just should not rely merely upon the Federal Trade Commission waiting for someone to have a piece of false advertising as to a drug's efficacy while we are examining these drugs only for their safety factor.

We certainly should be able at the same time to determine whether they are effective for the claims.

I think it is wrong to allow these drugs to get widespread throughout the Nation, to start your advertising campaign, then start your procedures to declare this advertising false and misleading, which consumes much time, and during this period many ineffective drugs are on the market instead, even if not doing physical harm to the people of this country.

I think the basic thing that we are concerned with is that at the same time that we are determining the safety of drugs, we can also determine the effectiveness of the same drug that we are declaring safe.

Mr. YOUNGER. As I understood the answers to Mr. Macdonald's question, which was in regard to the advertising of drugs over television and in the papers, a drug that you have declared safe, but it has false advertising?

Secretary RIBICOFF. The drug may be safe, but not effective as represented.

In other words, they cannot do you any physical harm, but neither can they do you any good.

I think this is the problem that Mr. Macdonald was raising.

Now, we feel that the person who reads a pamphlet or believes that he is effecting a cure by a drug should have more than the assurance that they will not do him any harm, but will they be a plus factor, will they do some good as represented?

Mr. YOUNGER. Just how much further are you going in this bill than you do now in regard to declaring a new drug safe?

Secretary RIBICOFF. If a drug is safe, it will not do any harm, the manufacturer is entitled to clearance. However, many claims are made which we know not to be true concerning what they are represented to cure, their effectiveness.

We have an entire list of these that we could leave with this committee of drugs that might be safe, but might not be effective.

Mr. YOUNGER. Do you propose in this legislation to govern the advertisement of the drug after it has been declared safe?

Secretary RIBICOFF. Concerning prescription drug advertising, yes.

Basically, whatever is represented concerning the effectiveness should be truthful in the package that goes to the doctor and the advertising to the doctor and the druggist, sir.

Mr. YOUNGER. You say it is not going to be done in regard to prescription drugs, is that right?

Secretary RIBICOFF. Oh, yes.

Mr. YOUNGER. It will be done?

Secretary RIBICOFF. Effectiveness.

Mr. YOUNGER. Then you are removing from the Federal Trade Commission the supervision of false advertising on all drugs, is that right?

Mr. LARRICK. Mr. Younger, (1) so far as drugs that are sold to the lay public are concerned——

Mr. YOUNGER. Those are not prescription drugs?

Mr. LARRICK. Those are not prescription drugs.

Mr. YOUNGER. OK.

Mr. LARRICK. We are not seeking to transfer the authority to regulate the advertising from the Federal Trade Commission to the Food and Drug Administration.

(2) On prescription drugs the Secretary is not advocating a transfer of power from the Federal Trade Commission to the Food and Drug Administration either.

Instead, he has said on page 15 of his prepared statement, under the heading "Amendments as to Advertising," that he thinks that there is a weakness in the language of the statute of the Federal Trade Commission to regulate advertising to doctors as to safety.

Secretary RIBICOFF. If you will look on page 29 of the bill, section 131?

Mr. YOUNGER. Which bill?

Secretary RIBICOFF. H.R. 11581.

Mr. YOUNGER. What page?

Secretary RIBICOFF. That is on page 29, sir.

In our testimony we mentioned the fact, we called it to your attention, that the bill contains an amendment to the Federal Trade Commission Act to require that prescription drug advertising be more informative, and we said the Federal Trade Commission would be here and cover it more fully.

We did not go itnnto this completely in our testimony. We stated in our testimony that we were deferring to the Federal Trade Commission to come here and testify more fully, but this is what the amendment seeks to do on page 29.

Mr. YOUNGER. In your testimony, as I recall, you stated that the prescription drugs do not now always state the full information in regard to the drug, and you were going to supervise what goes on the

bottle, or the package, which the druggist puts out in a prescription drug, is that correct?

Secretary RIBICOFF. That is right.

Mr. YOUNGER. But you are not going to interfere or take from the FTC the supervision of the general advertisement of the drug, is that correct?

Secretary RIBICOFF. That is correct.

Mr. YOUNGER. You mentioned a case a while ago about a canner over in Maryland. First, does Maryland have a Pure Food and Drug Act within the State?

Mr. LARRICK. Yes, they do. We work very closely with them.

Mr. YOUNGER. How many inspectors do they have, do you know?

Mr. LARRICK. Mr. Younger, I can get that, but I don't know. They have a very good food and drug setup in Maryland.

Mr. YOUNGER. How many States have pure food and drug laws?

Mr. LARRICK. I believe all but one, and I am meeting with them if this hearing does not last too long; I am meeting with them in Florida immediately after this hearing.

Mr. YOUNGER. You would not propose that we shorten this hearing?

Mr. LARRICK. No, Lord forbid.

Mr. YOUNGER. And fail to get the information that we need to reach a decision, are you?

Mr. LARRICK. No, no.

I was simply trying to make the point that we do work very closely with the States. This hearing is most important business.

Mr. YOUNGER. I, for one, want to put in plenty of time on this bill before I decide what to do.

Mr. LARRICK. That is right.

Mr. YOUNGER. What happened to that canner over in Maryland?

Mr. LARRICK. We seized about 3 percent of his output. He is still in business.

Mr. YOUNGER. He is still in business?

Mr. LARRICK. That is right.

Mr. YOUNGER. Is he still putting out maggots in his cans?

Mr. LARRICK. I think not.

Mr. YOUNGER. What did the State inspection do in that case?

Mr. LARRICK. I do not know what they did in that case. You see, the State could not do anything. This man is an interstate seller and the State could not do anything about the material that he shipped in interstate commerce. That is our jurisdiction.

Mr. YOUNGER. Whatever he shipped in the State, they could control?

Mr. LARRICK. That is right.

But this man was doing business in interstate commerce predominantly, apparently.

Mr. YOUNGER. But under this bill you are proposing here to go into intrastate shipment also?

Mr. LARRICK. Mr. Younger, no.

We are proposing to go into intrastate commerce only with respect to the sleeping pills and the amphetamines, which are used for nonmedical purposes, and they are today, in my opinion, as much of a public health problem as are the narcotics.

That is the only place that we are proposing to move into intrastate commerce, on the theory that it is a great burden on interstate commerce.

Mr. YOUNGER. Doctor, when you go into intrastate commerce, you always go in first on a sliding scale.

You never go in on a broad scale.

You get your foot in the door first?

Mr. LARRICK. Mr. Younger, we have been doing business with this committee now since 1906, and we have not gone very far into intrastate commerce. The only place that I know of is on margarine, and that was not of our doing.

Mr. YOUNGER. That is true. But now you are asking permission to do something, to go in, and then you will have that right.

Mr. LARRICK. Only in the case of these drugs where you find tremendous quantities in the backroom of a bar or you find them bootlegging at a truck stop where they sell them to the truckdrivers and the truckdrivers get high on them, and we have cases like the case out west where the truckdriver got high on these stimulant pills and drove on the wrong side of the road and killed nine people.

You just cannot handle the enforcement of the amphetamines and the barbiturate problem where you are dealing with a bootleg deal, where you cannot take any Federal action in court unless you can prove that this material that you found moved in interstate commerce. We just cannot prove it when you find large quantities in the backroom of a bar or at a truck stop.

Mr. WILLIAMS. Will the gentleman yield?

Mr. YOUNGER. Yes; I will be glad to.

Mr. WILLIAMS. With respect to this invasion of the States' field of jurisdiction, I guess you are familiar with the preemption doctrine that has been adopted, that has been followed by the Supreme Court in a recent decision?

Mr. LARRICK. As a layman, Mr. Williams, I am, but not as a lawyer.

Mr. WILLIAMS. The Supreme Court has ruled that where the Federal Government invades the State's field of jurisdiction, it automatically preempts State jurisdiction in that field. Is it your purpose here to put all of the food and drug people of the States out of business?

Mr. LARRICK. Mr. Williams, I think I can say that we would be very happy to have you specifically provide that we do not preempt this field; that the States would come in and continue to work with us on this very important problem.

Mr. WILLIAMS. Would you be willing to submit language that would protect the sovereignty and the jurisdiction of the States in respect to this legislation?

Mr. LARRICK. As the bill is now drafted, it is intended to do that, and I will be very glad to point out to the committee what language we think would accomplish what you are driving at.

Mr. WILLIAMS. I will not push that at the moment.

Secretary RIBICOFF. This is on page 28.

Mr. WILLIAMS. I will give you plenty of time to push that.

Secretary RIBICOFF. This is on page 28 of the bill.

Mr. LARRICK. Mr. Williams, we had you in mind when we wrote this in the bill.

Secretary RIBICOFF. Section 125.

Mr. WILLIAMS. I would prefer that you had the Constitution in mind.

The CHAIRMAN. I think this would be a good place to conclude the hearing today.

It is almost 12 o'clock and the House goes into session and we will have an important vote immediately upon the convening of the House.

Several members, of course, including Mr. Younger, who has not concluded his interrogation, have questions.

Mr. Secretary, I think possibly we will confer with you at a later date and arrange for a convenient time for your return, after we proceed with some of the other witnesses who have already been scheduled.

The committee will adjourn until 10 o'clock in the morning, at which time we will have sponsors of the bills to present their interest in this program.

(Whereupon, at 12 noon, the hearing was adjourned, to reconvene at 10 a.m., Wednesday, June 20, 1962.)

DRUG INDUSTRY ACT OF 1962

WEDNESDAY, JUNE 20, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

Today had been set aside for Members of the Congress who are sponsoring bills in this field. We are glad to have our colleague from Missouri, Mrs. Sullivan, who has been tremendously interested in, and concerned with, the problem over a period of years.

She has a bill which is pending before this committee, and even though yesterday the Secretary of Health, Education, and Welfare referred only to the two bills they are sponsoring, the entire subject matter is before the committee for consideration during these hearings.

Mrs. Sullivan, we are glad to welcome you to the committee and we shall be glad to hear you at this time, particularly with reference to your bill, H.R. 1235.

STATEMENT OF HON. LEONOR K. SULLIVAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mrs. SULLIVAN. Thank you, Mr. Chairman and members of the committee.

In order to save the time of the committee I would like to read only parts of my testimony and ask permission to have the entire statement made part of the record.

The CHAIRMAN. You may include your entire statement in the record and proceed as you desire.

Mrs. SULLIVAN. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, it is certainly no criticism of this committee when I say that this is a moment I have been waiting for—impatiently—for a year and a half, or at least since the opening day of the 87th Congress on January 3, 1961, when I introduced H.R. 1235, an omnibus bill to rewrite the Food, Drug, and Cosmetic Act to bring it up to date in terms of today's needs and problems in protecting the American consumer. It is still the only measure pending in either House which would combine in one bill provisions for closing all of the major loopholes in consumer protections under the Food, Drug, and Cosmetic Act.

Chairman Harris and I discussed the importance of having the formal departmental reports from the Department of Health, Education, and Welfare and other Government agencies affected by, or

interested in, the many complex and technical provisions of the bill before hearings could be scheduled.

Unfortunately, except for a "no comment" report from the Federal Trade Commission—subsequently clarified in an exchange of correspondence between me and FTC Chairman Dixon—none of the executive departments or agencies directly or indirectly affected by H.R. 1235 ever did file the requested reports to this committee on the specific provisions of the bill.

PRESIDENT ENDORSES MANY PROVISIONS INCLUDED IN H.R. 1235

On March 15, however, the President sent his comprehensive consumer message to the Congress which contained a formal endorsement on behalf of the administration of many of the changes in the law which are contained in H.R. 1235; and last month, as you know, Chairman Harris on behalf of the administration introduced two separate bills directed to those recommendations—H.R. 11581 dealing with drugs, and H.R. 11582, dealing with cosmetics and therapeutic devices. Together, these bills contain many of the features of H.R. 1235, but not all of them, and also contain some provisions not in H.R. 1235.

I suppose I wouldn't have minded the long delay nearly as much if, after all this time, the administration had reported that the approach in H.R. 1235 was completely wrong and impractical. However, now that most of the provisions of the administration bills are shown to be identical to, or at least very similar to, H.R. 1235, I am indeed sorry we couldn't have gotten to this matter a year or more ago, and thus with a better chance of final action in this Congress.

On Monday, I placed in the Congressional Record a detailed breakdown prepared for me by Mr. Raymond J. Celada of the American Law Division of the Legislative Reference Service in the Library of Congress showing in comparative tabular form all of the similarities and all of the differences when comparing H.R. 1235 with the two Harris bills, and also as compared with the widely discussed Kefauver-Celler bill. I felt it would be helpful to the committee and to all of your witnesses to have this material available prior to the start of the hearings for a better understanding of the technical points in the various bills. All of the bills share the one common objective of protecting the American consumer; all differ, however, in some significant respects.

The Kefauver-Celler bill is not before this committee, of course, since, as introduced, it is directed primarily at changes in the antitrust laws and the patent laws applying to drugs, and thus comes within the jurisdiction of the Judiciary Committee, even though it also contains many provisions amending the drug provisions of the Food, Drug, and Cosmetic Act. But I thought it would be useful to have the comparative breakdown of the various bills include this one, too, even though it is not officially before you.

GREAT CHANGES IN FOOD, DRUG, AND COSMETIC TECHNOLOGY

You are faced here in this committee with an assignment of great magnitude, in an area of supreme importance to the lives and health and safety and well-being of the American people, in connection with

the purchase and use of the most personal and intimate of products—all of the foods we eat, all of the drugs and devices we use for health purposes, all of the cosmetics used not only by women but in increasing numbers by men, as well. In many respects, you are facing the same problem which confronted your predecessors on this committee a quarter century ago when it became obvious that the Wiley Act of 1906—a great legislative achievement in its time—was woefully out of date and replete with loopholes permitting practices which visited fraud, deceit, poisoning, blinding, and death upon untold numbers of trusting American consumers.

From 1906 to 1938—a period of 32 years—Congress amended the Wiley law in a number of very important respects to protect consumers but never quite succeeded in making the law as effective as we know it should have been. Congress in 1912, 1913, 1919, 1923, 1930, and 1934 closed loopholes as they became glaringly evident—just as this committee since 1938 has initiated many, tremendously important improvements in the 1938 act—the factory inspection bill, the pesticides bill, the food additives bill, et cetera. But the time has come now, just as it did in 1938, for a complete rewriting of outmoded provisions—a modernization and updating of the whole statute based on far-reaching changes in food, drug, and cosmetic technology and the dangers created for consumers by omissions in the law, or by court decisions, or by studied evasions and easy violations which are often almost impossible to prevent because of shortcomings in the law.

CATASTROPHE SHOULD NOT BE ONLY SPUR TO ACTION

So it is my hope, as I know it is the hope of every American consumer concerned about the health and safety of our people, that you will now do what was done in 1938—rewrite the statute from beginning to end, keeping what is good but replacing what is obsolete or ineffective. It required a series of horrible episodes to stir the 75th Congress finally to pass the basic statute now on the books, after the 73d and 74th Congresses had extensively discussed and debated similar legislation but let it die in squabbles over special interest amendments and exemptions. By the time the 75th Congress finally acted, it had before it a sickening parade of horror cases—of young women blinded by eyelash blackeners; of many Americans paralyzed by a poisonous substance in jamaica ginger—the infamous "Ginger Jake" scandal; of at least 73 Americans dying from the use of a new prescription drug, Elixer Sulfanilamide, at first considered a great medical breakthrough until horrified doctors watched many of their patients die in prolonged agony from its use.

No such mass poisoning or blinding or paralyzing or killing episodes have occurred, thank God, in recent years. I hope it never again requires such incidents to persuade Congress to act on a broad level to improve the Food, Drug, and Cosmetic Act. However, as we all here know, most of the changes and improvements in the act since 1938 have been on a piecemeal, limited approach basis. I complained of this in 1960 when the color additives bill was being considered. I felt if we were going to "bail out" the lipstick makers on the use of other than "harmless" colors, we should insist on something for something—that is, on a requirement for pretesting for safety of all in-

gredients used in cosmetics, not just the coloring matter. In fact, I felt so strongly about that aspect of it that even after you agreed to amend the hastily passed Senate bill to include an anticancer clause, I voted against the bill in the House.

COSMETICS NOT PRETESTED FOR SAFETY

Since 1938, when it first came under Government regulation, the cosmetic industry has had comparatively gentle treatment. Unlike drug manufacturers marketing a new product, or food manufacturers using a new ingredient, the cosmetic industry does not have to prove safety of a new product prior to marketing. If the product is believed unsafe, furthermore, the Government must furnish legal proof of danger to the consumer in order to force the item off the market. This is the situation which previously existed in connection with the use of food additives, and which we changed in 1958—relieving the Government of the obligation of proving a product dangerous in order to take it off the market. We now require, instead, that the manufacturer prove his additive is safe before putting in on the market.

As a result of our lax cosmetics controls there have been occasional cases of extremely painful injury to cosmetic users, and frequent cases of allergic reaction, because the cosmetic manufacturer is not required to pretest the product for safety or even to identify the ingredients in the product.

Of course, I do not maintain or believe that major cosmetic manufacturers are anxious to poison, or disfigure, or denail, or scalp, or burn, or otherwise injure the American consumer. Certainly, there is no profit in that, and these are firms anxious to make a profit by pleasing, not harming, the customer. But the competitive situation in the cosmetic industry is such, and the ease of entry of new firms into the field of processing cosmetics is such, that new products hit the market accompanied by a wave of high-pressure advertising and promotion. and each firm tries to beat the other to the drugstore or department store counter or supermarket shelf with the latest magic potion for making us attractive.

Cosmetics are as old as history, and the basic ingredients used are well known in the trade. So sales spurts must often depend upon mysterious "gimmick" additives—turtle oil to promote skin rejuvenation or tighten chin muscles (but did you ever see a turtle's skin?); shark oil, queen bee royal jelly; chick embryo extract; horse blood serum; pigskin extracts—yes, these are all ingredients which have been introduced in face and skin creams to form the basis for extravagant claims of beauty in a jar.

INGREDIENTS NOT DISCLOSED EVEN TO FDA

They are seldom dangerous—but if they are, we never know about it until a lot of gullible consumers—or consumers who have assumed the product must be safe or it couldn't be sold—have been hurt. That has been the situation in cosmetic regulation for 24 years.

Since the 1938 act does not even require cosmetic manufacturers to identify ingredients in their products, the Food and Drug Administration must analyze new products to determine their content, in case it suspects the presence of a dangerous ingredient. It cannot even go

to the firm and legally demand to know what is in the product. Consequently, the consumer never knows—has no way of knowing except by painful trial and error—whether an attractive cosmetic product contains an ingredient to which she knows she is allergic. And, even worse, if a child swallows a cosmetic, the parents and doctor have no way of knowing for sure what ingredients it contained and what antidote may be necessary.

These loopholes in the law applying to cosmetics should have been closed when we rescued the cosmetic industry from the color crisis in 1960. But we didn't do it then. We just dealt with color additives and nothing else.

It was after that experience—of seeing another blowout patch being placed on the old Food, Drug, and Cosmetic Act to meet only a limited problem situation, just as we previously passed the factory inspection bill and the pesticides bill and the food additives bill and the citrus red bill and so on—that I decided late in 1960 to draft a single bill to rewrite all of the obsolete provisions of the basic law. That resolve resulted in the introduction of H.R. 1235 the following January.

Mr. Chairman, let us turn now to the provisions of that bill and of the administration bills. Secretary Ribicoff covered some of these points yesterday, as did the report from the Library of Congress. Of course, the items in the Harris bills that are also in my bill I approve of 100 percent, and also, as I shall point out further on, I endorse some of the technical provisions of the administration bills which are not in my bill. But there are things in my bill which are not in the others, and I want to discuss those, too.

WHILE DIFFERING, HARRIS AND SULLIVAN BILLS COVER SIMILAR GROUND

As the Legislative Reference Service report points out, the two administration bills, H.R. 11581 and H.R. 11582, and my bill, H.R. 1235, cover substantially similar ground, while differing to some extent in language, approach, or, in a few instances, in content.

For instance, H.R. 1235 and H.R. 11581 both require more adequate controls over drug manufacturing to assure the quality of the product output, thus, for one thing, making it more likely that physicians would feel safe in prescribing by common names instead of the often more expensive trademark names; both require new drugs to be proved efficacious as well as safe for the purposes intended; both permit recall of previously approved drugs in case of substantial doubt of their safety; both require batch-by-batch testing and certification of all of the 30 or more groups of antibiotic drugs other than just the 5 so-called wonder drugs in existence a dozen years ago; both call for extensive controls over the manufacture, distribution, sale, and possession of habit-forming barbiturates and stimulant drugs to curb the flagrant bootlegging of these powerful and dangerous and death-dealing drugs; both clarify the existing factory inspection laws as they apply not only to drugs but also to foods and cosmetics.

Similarly, H.R. 1235 and the other Harris bill, H.R. 11582, both require pretesting of cosmetics for safety before marketing, including a Delaney anticancer clause; both require that therapeutic devices be proved safe—closing a serious and dangerous loophole—and also that therapeutic devices be proved effective for the purposes for which they are offered for sale; both bills repeal the provision in the present

law which permits the sale of coal tar hair dyes containing poisonous or deleterious ingredients which may be injurious to the user (the present law merely requires a label warning of possible danger).

H.R. 11581 and H.R. 11582 have some other provisions in them which are not contained in H.R. 1235 and which are worthwhile. For instance, there is a tighter provision in H.R. 11582 than in H.R. 1235 on the recordkeeping requirements for cosmetic manufacturers after a new product has already been approved for sale, and in case consumer complaints or experience should indicate the existence of danger in the use of the product. H.R. 1235 contains such reporting and recordkeeping requirements on drugs and should have included cosmetics. cosmetics.

H.R. 11581 has a provision amending the Public Health Service Act requiring tests for efficacy of biological drugs—the provision the President referred to when he said hogs, sheep, and cattle receive somewhat greater protection in this respect than humans.

The same bill also proposes the assignment of standardized names by the Secretary of Health, Education, and Welfare in cases where such names do not already exist or there is a dispute over a particular name. Of course, as I said earlier, many doctors will not use generic names in prescriptions unless and until factory inspection authority is so strong that there is no chance of fly-by-night operators turning out inferior drugs for sale in the prescription departments of pharmacies.

However, I have strong doubts, I must admit, over the retreat on the Delaney anticancer clause on feed additives, as contained in H.R. 11582, particularly in view of the Government's experience several years ago with the hormone-treated chickens. It cost us $10 million to remove from the market the fowl treated with a drug considered safe for the purpose—after it was learned that there were residues of the cancer-inducing substance in the skin of the chickens. Too often for complacency, new testing methods disclose the existence of harmful residues which had not shown up in earlier tests, but by then the damage is done.

ADDITIONAL FEATURES OF H.R. 1235

Now, I would like to discuss some of the provisions of H.R. 1235 which are not in either of the administration bills, and which I strongly believe should be made part of the Food, Drug, and Cosmetic Act.

First of all, there are the sections dealing with fake cancer remedies and useless dietary ingredients. If the law were strengthened in all other respects, as has been recommended, perhaps the FDA would then be able to reach the cancer quacks and put them out of business quickly. But I think the provisions of H.R. 1235 would be of invaluable assistance in this respect. As to the special dietary food section of H.R. 1235, it does not aim at legitimate dealers but at the charlatan who evades the law by making oral claims of special benefits to be derived from the inclusion of some exotic or unusual ingredient with no known nutritional value whatsoever.

H.R. 1235 also gets at an exemption in the law for common carriers responsible for causing an article in commerce to become misbranded or adulterated. Carriers should be held accountable, I believe, for violations of the law for which they are responsible. Under present law, they are apparently exempt from responsibility for

adulterated products in transit, even if the carrier's own neglect caused the violation.

A very important provision of H.R. 1235 which is not included in either administration bill would facilitate oversea inspection by U.S. officials of factories shipping substantial quantities of foods, drugs, or cosmetics into the United States. Importation could be refused any product from a manufacturer who would not permit reasonable inspection of his facilities on request. According to the testimony of Commissioner Larrick on the FDA appropriation bill, we import about $6 billion worth of foods, drugs, and cosmetics a year, of which only a fraction can be inspected on arrival. It is significant that nearly one out of every three sample analyses and wharf examinations uncovered violations of the Food, Drug, and Cosmetic Act. Mr. Larrick acknowledged that this high rate of violations results from the selective nature of the inspection work—in other words, the inspectors pick out those shipments they suspect of violations, rather than depending upon a random sample. While there are at present no elaborate plans for sending inspectors overseas, yet it seems to me the authority should be there to require those foreign firms which ship substantial amounts of food, drug, or cosmetic items to the United States to give our inspectors the same right of entry on request as an American firm is required to do.

SPECIAL INTEREST LOOPHOLES ADOPTED IN 1938

Another loophole which H.R. 1235 alone among the pending bills would close involves the label exemption under the present law for butter, cheese, and ice cream in revealing the presence of artificial color. This was a deliberate special interest provision written into the law in 1938 to quiet protests from the dairy interests, even though some Members of Congress said at the time there was no good reason for it. By law, coloring matter cannot be used unless it is safe, so why not let the consumer have this information if it means anything to him? Some people just don't like to buy artifically colored butter or cheese or ice cream—but, at the present time, they have no way of indulging their wishes in this regard. All other food items must acknowledge on the label the existence of artificial coloring. So why not ice cream, butter, and cheese, too?

Another special interest exemption written into the 1938 act, and which H.R. 1235 would repeal, is the provision which declares that soap is not a cosmetic.

It is not a food, of course. Except in the relatively few instances in which certain therapeutic values are manufactured into—or claimed for—a soap product, it is not a drug either. The law defines cosmetics as, among other things—

> articles, including components of any such articles, intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance. * * *

Soap is certainly intended for cleansing, and it is used by most of us also, if not consciously for beautifying, at least for promoting attractiveness in the removal of dirt from face and hands. Some soaps presumably will do far more for our appearance than that. Nevertheless, by law, soap is not a cosmetic. Under the Food, Drug, and

Cosmetic Act of 1938, then, it is a nothing—it is not subject to the law in any way unless therapeutic values are claimed for it as a drug.

I am not so much concerned over the money spent trustingly and hopefully by women who are led to expect beauty miracles from the soap they buy, although the economic waste may perhaps be significant. What I am concerned about is that a complexion soap can be adulterated with unsafe chemicals or unsafe color additives, and the Food, Drug, and Cosmetic Act cannot touch it. And regardless of how fraudulently it might be packaged, there is not even a requirement that the size or net weight or anything else of an informational nature be printed on the label for the consumer's guidance. Why should soap be above the law?

READ THE LABEL—IF YOU CAN FIND IT

Unlike soap, products subject to the Food, Drug, and Cosmetic Act must carry certain label information, but the language of the law, and the rulings of the courts, are such that this information is often almost impossible to find. Just the other day, the FDA seized 16,000 plastic tubes of a well-known firm's deodorant product because, while the required information was printed somewhere on the product, the printed matter was the same color as the plastic container and was almost impossible to find and read.

H.R. 1235 provides for an effective attack on the labeling problem in foods, drugs, and cosmetics by providing the Government with authority to spell out, in regulations, the degree of prominence required for certain label statements, including statements of the quantity of contents of foods, drugs, and cosmetics, the common or usual names of drugs, and the ingredients in foods and cosmetics.

The present law prohibits labeling which is—

> not prominently displayed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

But, as the Senate Antitrust Subcommittee hearings brought out last year, you often need a magnifying glass to find the required label information on quantity and contents—before you get out the slide rule to figure the cost per ounce. As a nonlawyer, the present law seems very strong, to me, but apparently the courts have held it to be vague. That is why we now need the same authority in the Food, Drug, and Cosmetic Act to specify size and location of labeling information as you provided in the Hazardous Substances Labeling Act.

PREFERENCE FOR A SINGLE OMNIBUS BILL

If we are going to change the law on food, drugs, and cosmetics, then let us write a model law and close all of these loopholes.

I believe H.R. 1235, or a similar omnibus bill, would best serve as the vehicle for accomplishing this purpose. I see no valid reason for having two separate bills, one on drugs and the other on cosmetics and devices. They are part of the same overall problem and under the jurisdiction of one agency. If there are omissions in H.R. 1235 based on the administration's 18-month study of the issue since

I introduced that bill, it should be an easy matter to incorporate them into a single omnibus measure along the lines of H.R. 1235.

For instance, while H.R. 11581 provides for requiring proof of the efficacy as well as the safety of all new drugs, a similar provision dealing with therapeutic devices is contained in the different Harris bill, H.R. 11582. Since the pretesting requirements for both drugs and devices would be similar, and are often intended for the same people, why not cover them in one piece of legislation? If you go through the detailed breakdown of H.R. 11581 and H.R. 11582, you find that substantially similar provisions in those two bills deal separately with drugs and devices. I am not a lawyer, but I suspect lawyers would have a field day over the years finding hidden meanings and significance in the fact that Congress used duplicate wording, but in separate bills applying to different products, in providing for pretesting for efficacy as well as safety of drugs and therapeutic devices. Obviously, some lawyer, some day, will argue, and perhaps successfully, that Congress didn't really mean to have these products treated alike in their safety requirements, or it would have placed them in the same bill rather than passing separate bills. Do I just imagine this?

Furthermore, while H.R. 11581 applies primarily to drugs—every specific provision applies only to drugs—yet, it also would have the effect of amending the factory inspection laws applying to "any articles subject to" the Food, Drug, and Cosmetic Act, including, of course, food and cosmetic products. I think this is to the good—our factory inspection laws need strengthening, for food products and cosmetics as well as drugs, and H.R. 1235 so provides. But why put a food inspection provision in what is exclusively a drug law, as is done in H.R. 11581? Why put a cosmetic inspection provision in a drug law, as is done in H.R. 11581 but leave it out of the proposed new cosmetic law proposed in H.R. 11582? Obviously, there must be some rhyme or reason for dividing up the proposed improvements in the law in separate bills in this fashion, but I do not understand the value of it.

The use of H.R. 11582, primarily a bill dealing with pretesting of cosmetics and therapeutic devices, as a vehicle for amending the Hazardous Products Labeling Act dealing with household products, and also to amend the animal feed additives law and the food additives law is, I beieve, further evidence that we should have a single omnibus bill and not two separate bills, each covering one major area and a variety of unrelated ones.

Mr. Chairman and members of the committee, I appreciate your courtesy in hearing me. The subject matter of these hearings is of paramount importance to me from a legislative standpoint and has been ever since I came to Congress in 1953 and introduced a safe cosmetic bill to carry out the recommendations of the Delaney investigation. I have introduced safe cosmetics bills in every Congress since then. I have supported this committee in every proposal it has made to strengthen the Food, Drug, and Cosmetic Act, and have opposed it in the few instances I thought the legislation would weaken consumer protections.

It would be a relatively simple matter for the committee at this late date in the final months of the life of the 87th Congress to pick out one of the many major areas of inadequacy in the law and recom-

mend another blowout patch to tide us over temporarily. I hope you will not do that—that you will recommend legislation to close all of the major loopholes in the act.

In 1938, after attempts in two previous Congresses to replace the 1906 act had failed, the House Committee on Interstate and Foreign Commerce, in a report filed in the House on April 14, 1938, said of the Wiley law of 1906:

> While the old law has been of incalculable benefit to American consumers, it contains serious loopholes and is not sufficiently broad in its scope to meet the requirements of consumer protection under modern conditions.

After 2 dozen years, the same words are exactly applicable today to the law passed in 1938. I hope this same committee will shortly file a report with the House containing those words, or similar words, in connection with a legislative accomplishment in 1962 as far reaching as that of 1938 in the field of consumer protection.

That is the end of my statement, Mr. Chairman.

Mr. ROBERTS. I would like to thank the young lady from Missouri for a very interesting and a very valuable statement.

The Chair and members of this committee know of your long and active interest in this subject and the fine contributions you have made in this field.

I am sure that I speak for the sentiment of the committee in saying that we are grateful to you for this statement and for your appearance here today.

I have one or two questions.

Back on page 6, in the second paragraph of your statement, with reference to the fact that soap is not a cosmetic under the act, do you know of any instances of damage that has resulted from the use of various soaps?

Mrs. SULLIVAN. I cannot cite you any cases on that, Mr. Chairman.

Mr. ROBERTS. I have in mind that there are some bubble-bath products that are damaging to people who are allergic to certain ingredients, but I do not believe that I have heard of any serious illnesses or damage that resulted from the use of these products, but I do think there should perhaps be testing of these things to find out about the article.

Mrs. SULLIVAN. I am sure the FDA itself could give you any evidence there is of harm to the public, but I do not have that information. Most soaps, I am sure, are generally safe. But the question of allergies is different. I know it is discussed often, especially among women—that they cannot use this or that soap because of being allergic to it. What causes it no one knows, because the ingredients are not listed on the label. I think they should be.

Mr. ROBERTS. Now, another place where I wanted to ask a question is on page 5, paragraph 3.

You speak of the fact that there is an exemption in the law for common carriers from responsibility for adulterated products in transit.

I would like to know if you know of any specific examples of where a carrier has, in fact, caused a violation. I do not understand what you are driving at there.

Mrs. SULLIVAN. There is a provision in the present law that generally exempts common carriers from the requirements of the law, except that—

They furnish upon proper request access to, and allow copying of, records showing interstate movement of food, drugs, devices, and cosmetics.

This was inserted to excuse carriers from liability for the misbranding or adulterations caused by others, even though the illegal merchandise might be temporarily in possession of a carrier when discovered.

However, the wording of this exemption raises some questions to the liability of a carrier for himself causing an article subject to the act to become misbranded or adulterated.

For example, there have been a number of instances in which food became filthy while in possession of a carrier because he neglected to exercise reasonable sanitary precautions. Carriers should be held accountable for such violations which they cause.

The amendment is suggested to accomplish this.

For instance, in shipping of grain, if the grain becomes unsanitary while it is being shipped, the carrier is not held responsible. The man who owned the grain when it was shipped is held responsible.

And there are other incidents that have been reported by the Food and Drug Administration.

I would rather have them cite the examples. The FDA has actual cases of food adulteration, and so on, in which the damage has been done while the item is being transported. It has been the carrier's fault, but he is exempt from any legal responsibilty as far as FDA is concerned.

Mr. ROBERTS. The reason I raised that, I think in the case of damaged articles, spoiled foods, and so forth, the consignee has the right to refuse to accept those articles, which, it seems to me, would give some protection.

I was wondering if the carriers should be required to actually inspect an article that is packaged, unless he has some way by smell, odor, or some way of knowing it is not safe.

That is about all I have, Mrs. Sullivan, and, again, I would like to thank you for your long-time interest in this subject.

I think you have made a really fine contribution throughout the years, and I am sure the members of the committee feel the same way.

The gentleman from Massachusetts?

Mr. KEITH. Mr. Chairman, I, too, would like to join you in complimenting our colleague on the good points she has made and I am grateful to her for her analysis of this problem.

Thank you.

Mrs. SULLIVAN. Thank you.

Mr. ROBERTS. The gentleman from California?

Mr. MOSS. Mr. Chairman, I have no questions, but I want to join also in complimenting our colleague for a most excellent statement and one consistent with the views she has expressed on numerous occasions in the House during her 10 years of service here.

Mrs. SULLIVAN. Thank you, Mr. Moss.

Mr. ROBERTS. The gentleman from Pennsylvania?

Mr. CURTIN. Mr. Chairman, I, too have no questions, but I would like to add my thanks for a very enlightened statement.

Mrs. SULLIVAN. This is a mutual admiration society.

Mr. HEMPHILL. I want to join the mutual admiration society with great enthusiasm. I have noticed that not only by her activities, in the legislative field, but by her personal charm and grace, that she had added much to this crusade. I might ask one question which concerns me.

I have received about 1,000 letters, I suppose, from the cosmetologists of my State and adjacent areas who have been given some reason to believe that the enactment of this legislation will work irreparable harm to their profession, especially in the field of hair dye with which I am not familiar as yet but for which I have great appreciation, because I think a beautiful woman is one of the greatest gifts to mankind so far.

But I just wondered if the lady, because of her familiarity with the matter, feels that we can enact this legislation and at the same time preserve all the rights, functions, and freedoms of the cosmetologists?

Mrs. SULLIVAN. May I answer my colleague in this manner:

Women are not going to stop using cosmetics to make them more attractive. The thing she wants—and deserves—is the knowledge and complete assurance that those cosmetics are safe to use. Most women whom I have talked to—and I have talked to many and many and many a group of women—are usually under the impression such proof is already required. And may I say that I have had no letters from St. Louis on the hair dye issue, although they know of my deep interest in this and the fact that I have been pushing for this kind of legislation over the years. I have had not one letter from St. Louis, where there are many, many beauty shops and hairdressers, on the subject. They know from my record that I would not sponsor legislation to put the beauty shops out of business.

But I would say this:

Most women now take it for granted that if an item is on that shelf in the store, it is pure, and that the FDA protects us from any unsafe product. Therefore, they feel they can safely buy any product knowing it is safe or else it would not be allowed to be offered for sale. But as the members of this committee know, this is not true. Cosmetics do not have to be proved safe in advance of marketing.

It is only after the FDA finds that something is wrong, either through complaints or through their own tests, or otherwise has been informed that a product is dangerous, that they seize it and take it off the market. But FDA must be able to prove it is dangerous or unsafe for use. The manufacturer, on the other hand, should be required in advance to prove the product is safe. As it is now, there is no one to stop the manufacturer from marketing an unsafe product except himself—by wanting to protect his good reputation. Otherwise there is no way to stop this product from being marketed before it is tested.

At present, it is tested as you use it—we are the guinea pigs.

Mr. HEMPHILL. I think that we have some problem of education to tell the cosmetologists and others who are interested that our purpose here is only to insure safety and not to hurt or change the trade.

Mrs. SULLIVAN. That is right.

Mr. MOSS. Would the gentleman yield at that point?

Mr. HEMPHILL. As soon as the lady finishes her statement, I will be glad to yield.

Mrs. SULLIVAN. I was just going to say that, of course, the beauty shop operator also wants to use safe products only. She has confidence in the good faith of the company from which she buys the product. But what would happen in a lawsuit if a customer lost her hair through use of an unsafe dye, or her scalp was burned, or for some reason something happened to her? I do not know who would be liable; that is whether it would be the beauty operator or the manufacturer, but I think that beauty shop's reputation would be harmed, and in such instances, it has been harmed.

I remember a great deal about the eyelash blackeners back before passage of the present act in 1938, because I had my eyelashes dyed and it was the last time I ever did, after that experiment, because of what I suffered.

But while some of these unsafe products are not going to kill you, and I do not think they blinded many people, there was much harm done until the law was corrected in 1938 to outlaw the use of any unsafe coal tar colors except in hair dyes. Women want these dyes, too, to be safe. That is all it does. Take the case of the eye-liners that women use to put color behind their lashes, on their eyelids. Many of those eye liners were taken off the market because they were discovered to contain coloring matter not approved as safe to use near the eye. The requirements are very strict for cosmetics used around the eyes. But a poisonous hair dye could drip into the eyes.

I know that the legitimate cosmetic people try to test and police their own products to make sure they are all right, but there is no reason why we customers cannot be assured, before that product is put on the market, that it has been tested properly and thoroughly. As I said before most people today already believe that if it is on the shelf, it is safe because FDA is behind it. This is a misunderstanding. It is unfortunately, just not true in many instances, that products have been pretested for safety.

Mr. HEMPHILL. I want to thank you.

Before I make a comment, I will yield to the distinguished gentleman from California.

Mr. Moss. The gentleman from California merely wanted to observe that in the past few days his mail has accumulated to the point of about 2,000 letters, and after carefully reading the letters, the only thing the gentleman can conclude from their content is that someone pressed the panic button, and that they reflect fears without any understanding or any effort to become acquainted with the content of any of the legislative proposals before this committee.

I would observe personally that this type of mail is rarely helpful to Congress.

It only indicates that someone has told someone that they had better get busy and contact us because we are set to take them out of business, which, of course, is not the intent.

Mr. HEMPHILL. Perhaps that is true, but, nevertheless, we are here in a legislative capacity, and when I get a letter, whether it is an inspired letter or not, I try to give not only an intelligent answer, but an answer that gives the facts.

The difficulty of this is to keep up with the mail in a campaign like that, as the lady well knows.

I know on pay TV I got 6,000 letters in about 10 days, or something like that, and I had to put on an extra girl for 2 months, but everybody that wrote me got a letter. I think that it is going to be up to us now to tell the people the purpose of the legislation, and that was the purpose of the discussion with the distinguished lady from St. Louis, and that is the reason I asked the question.

Mrs. SULLIVAN. May I say to my colleague that I believe the reason I did not get protesting letters on this is because I have been talking about it back home and explaining to them that this will insure them of safer products, not hurt them in any way.

They know I would not want to try to put the beauty business out of business or stop the use of cosmetics, or anything like that at all. Women are going to use cosmetics—that's all there is to it. It is like smoking. With all of the scares that have been reported, and all the things which have been written about the danger, people are smoking more and more. They are going to continue to smoke, I imagine. Similarly, women are going to use cosmetics. They are going to continue to have their hair dyed.

What this legislation would do is make sure that cosmetic products, including the hair dyes, are safe to use. That is all. But we also include all cosmetics, and not just the hair dyes—all of them—including the so-called magic potions which are marketed with a lot of drumbeating and hoopla, and which are supposed to take out wrinkles or something because they contain some mysterious ingredient that might turn out to be turtle oil.

Did you ever see a turtle's skin, and how turtle oil will take wrinkles out——

Mr. HEMPHILL. Will it do it?

Mrs. SULLIVAN. Well, if I thought it would, I would use it. [Laughter.]

Mr. HEMPHILL. Thank you very much.

Mr. ROBERTS. Mr. Sibal?

Mr. SIBAL. Thank you very much.

I, too, want to thank our colleague for a very helpful statement.

I have a question from a slightly different angle. What concerns me about this legislation, and I am very sympathetic with its purpose, obviously, we have a responsibility to protect consumers against possible injury, but I have in my district one of the major, perhaps the major research producer of hair dyes in the area, and a concern which has a very fine reputation.

I am concerned that they would go completely out of business, at least for a period of time. You shake your head no. None of their products have been approved. They are in production. They have done extensive research. The estimate is that it would take years for the FDA to test and process and approve each of their products.

Now, what would happen in the interim, even assuming that they are all safe and proper products for the market? What would happen to that concern and the employees and the economy of the area during the interim period between the time this legislation is passed and all these products could be tested properly?

Mrs. SULLIVAN. Mr. Sibal, were you here in the committee when the food additives bill was passed in 1958?

Mr. SIBAL. I was not.

Mrs. SULLIVAN. Well, the same thing was brought up. We gave them, if I recall right, some 2 years or more in order to meet these requirements, and this time was extended when it was found that some industries needed more time.

They would do the same thing in this kind of legislation.

The reason I shook my head when you were speaking was, that I have never seen so many dyed heads in all my life as the girls have today. Even girls in high school. That was unheard of a few years ago. They are not going to change their minds about dyeing their hair, but if the firm will stand behind its product, they should not be afraid to have it tested for safety.

Mr. SIBAL. It is not a question of being afraid to have it tested. I am sure the firm would be happy to have it tested.

The point is that until such time as the products have been tested, they are unmarketable.

Mrs. SULLIVAN. There would be reasonable time given to them.

Mr. SIBAL. Does this legislation so provide?

Mrs. SULLIVAN. I am certain it does; yes. I cannot tell you how much time it is. It is in the bill.

Mr. SIBAL. You would favor such a provision?

Mrs. SULLIVAN. There would have to be such a program. It is only natural. There would have to be. H.R. 1235, I see now, allows at least a year. The thing that I have been fighting for all these years is that since most people take it for granted that a product has been proven safe, before it is placed on the market, we should make sure it is safe. It is only after some one is injured or hurt that it is discovered, that a particular product often is not safe. So let us make it safe before they are put up for sale on the market.

Mr. SIBAL. Would you consider that a product which has been on the market for many, many years, with extensive use, with no history of injury, should be in the same category as a new product?

Mrs. SULLIVAN. I think in all of these bills there is what amounts to a grandfather clause in that a product which has been on the market for some length of time, with the proper credentials and a reliable company behind it, and with a long history of proven safety, would not have to go through the same process of tests. But any doubtful ingredient would have to be cleared in a reasonable period of time. There would be time allowed for that, just as was provided in the Food Additives Act. Products already on the market had an adequate period of time in which to be cleared. They were sold as usual in the meantime.

They would be required also to identify the ingredients and contents on the label. We had an episode a few years ago regarding hair sprays. There is still a very intensive research going on in St. Louis at the Jewish Hospital on hair sprays. Personally, I wish with all my heart that hair sprays would be taken off the market, or at least proved to be safe, because I still think there is a reasonable doubt as to whether or not those hair sprays are really safe.

Now, to the person who might use it once a week, I would say that there would probably be very little harm in it. To the beauty operator who uses it constantly on every client she has, and who is constantly breathing the fumes of this spray as it is sprayed on the hair, I think there is some danger. And then with the new hair styles today, the

girls have to use it every day when they rough up their hair and comb it into these new styles. It requires daily use of the spray to keep the hair in place, and if the sprays are not safe, this could be dangerous.

I still think there is a shadow of a doubt whether or not it is safe to breathe in these sprays.

Mr. SIBAL. I would certainly say to you that I, for one, and I am sure all the members of this committee, recognize that if the public is endangered by any product, then we must act to eliminate that danger.

And I think any responsible businessman or manufacturer would agree with this. I have never heard anybody argue with this.

I do feel, however, that we should be careful as we draft legislation that we do not, in attempting to cure one ill, create another ill.

Mrs. SULLIVAN. I thoroughly agree with you.

Mr. SIBAL. Thank you very much.

Mr. ROBERTS. The gentleman from North Carolina?

Mr. KORNEGAY. Mr. Chairman, I see the hour approaches 11, and I will simply say that we are delighted to have you with us this morning, Mrs. Sullivan, and appreciate so much your very fine statement.

Mrs. SULLIVAN. Thank you.

Mr. ROBERTS. The gentleman from Wisconsin?

Mr. THOMSON. No questions.

Mr. ROBERTS. Again, I would like to thank the young lady for her appearance.

Mrs. SULLIVAN. I thank you, Mr. Chairman.

Mr. ROBERTS. We have another Member of Congress here, the gentleman from North Carolina, who has a short statement.

STATEMENT OF HON. L. H. FOUNTAIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. FOUNTAIN. Mr. Chairman and members of the committee, I want to thank you for giving me this opportunity to appear before you this morning. My purpose here today is not to take a position on the general merits of H.R. 11581, but to express my objection to a particular section thereof which would, in my opinion, seriously hamper the work of the congressional committees which have responsibilities with regard to food, drug, and cosmetic legislation or the operations of the Food and Drug Administration. I refer to section 202 of H.R. 11581, amending section 301(j) of the Federal Food, Drug, and Cosmetic Act.

As section 301(j) is presently written, it prohibits—

> the using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

The effect of the amendments proposed in section 202 of H.R. 11581 would be to extend this confidentiality beyond "trade secrets" to include any information acquired by the Food and Drug Administration under the stated sections of the Food, Drug, and Cosmetic Act.

Since only the officers and employees of the Department and the courts are given access to confidential information under section 301(j), passage of section 202 in its present form would, in my opinion,

make it virtually impossible for the congressional committeees which have responsibilities in connection with food, drug, and cosmetic legislation or the operations of the Food and Drug Administration to obtain the information necessary for the effective discharge of those responsibilities.

Under the rules of the House, the Committee on Government Operations has the duty of "studying the operation of Government activities at all levels with a view to determining its economy and efficiency."

The responsibility for studying the operations of the Food and Drug Administration, as well as those of a number of other Federal agencies, has been delegated by the Committee on Government Operations to its Intergovernmental Relations Subcommittee, of which I am chairman. Our past experience in trying to fulfill this responsibility has shown that on occasion the Food and Drug Administration has used section 301(j) as a basis for withholding access to information which the subcommittee deemed necessary for the proper discharge of its responsibilities to the full committee and to the House. I have copies of two letters of recent date which will, I believe, demonstrate this problem. I would like to read them at this time.

They relate to a situation which arose in late April of this year when two prescription drugs were withdrawn from the market due to the discovery of dangerous side effects. Both drugs had previously been approved by the Food and Drug Administration under its new drug procedure and had been on the market for some time. In an effort to determine whether the Food and Drug Administration had fully and effectively met its responsibilities in the clearing of these two drugs for the market, the subcommittee sent the following letter to Commissioner Larrick:

MAY 2, 1962.

Hon. GEORGE P. LARRICK,
Commissioner, Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR MR. LARRICK: In connection with its responsibility for studying the activities of the Food and Drug Administration with respect to efficiency and economy of operation, the Intergovernmental Relations Subcommittee wishes to obtain information concerning two drugs which were recently withdrawn from the market due to the discovery of dangerous side effects. They are MER/29, manufactured by Richardson-Merrill Co., and Flexin, manufactured by McNeill Laboratories.

Will you please arrange for Mr. Donald Gray of the subcommittee's staff to examine your files containing the new drug applications for these two drugs and any other information you may have concerning them.

Your cooperation in this matter will be greatly appreciated.

Sincerely yours,

(Signed) L. H. FOUNTAIN,
Chairman, Intergovernmental Relations Subcommittee.

I received the following letter from Mr. Larrick in reply:

MAY 10, 1962.

Hon. L. H. FOUNTAIN,
Chairman, Intergovernmental Relations Subcommittee,
Committee on Government Operations,
House of Representatives, Washington, D.C.

DEAR MR. FOUNTAIN: We have your letter of May 2, 1962, requesting us to arrange for Mr. Donald Gray of the subcommittee staff to examine our files covering the new drug applications for MER/29 and Flexin.

We want to be as helpful as possible to your committee. However, the Federal Food, Drug, and Cosmetic Act imposes certain restrictions on us which we must respect. Under the law, we are forbidden to disclose any information submitted in connection with a new drug application that is entitled to protection as a trade secret. Our regulations further emphasize the fact that all information submitted in connection with new drug applications will be treated as confidential. The reason for these restrictions is to encourage manufacturers to make as full a disclosure as possible when they submit their new drug application, including information involving doctor-patient relationships.

We have uniformly declined to make the files on new drugs available to anyone except employees of the Food and Drug Administration. We are confident, however, that we can prepare a summary of these new drug applications that will contain all pertinent information. We will undertake the preparation of these summaries promptly and they will be sent to you as soon as they are completed.

After you have had an opportunity to review them, we will be glad to arrange for a meeting between Mr. Gray and our personnel who are familiar with these files to clarify any questions you may have. We should point out that even though these drugs have been removed from the market, we are actively investigating both of these cases to determine whether false statements were made in connection with the new drug applications or whether there was a failure to disclose material facts.

We hope that our suggested handling of your request will be satisfactory. Again let me say that we want to furnish you with all information that we possibly can within the limitations imposed on us by the statutes.

Sincerely yours,

(Signed) GEORGE P. LARRICK,
Commissioner of Food and Drugs.

Following receipt of this letter, members of the subcommittee staff talked with Assistant Commissioner Rankin and Mr. William W. Goodrich, the Department's Assistant General Counsel, Food and Drug Division. The staff assured Mr. Rankin and Mr. Goodrich that neither they nor the subcommittee were interested in seeing any information entitled to protection by law as a trade secret. I might point out that Mr. Larrick incorrectly states in his letter that his agency has uniformly declined to make the files on new drugs available to anyone except employees of the Food and Drug Administration. The fact is that our subcommittee staff has examined such files in the past, and FDA had not previously in our experience claimed confidentiality for these records.

The subcommittee staff was then assured by Mr. Rankin that, in view of these facts, our request would be reconsidered by the Food and Drug Administration. However, despite numerous telephone inquiries from the staff, no further action has yet been taken on the request; nor have the summaries which Mr. Larrick promised in his letter of May 10 been received.

I have gone into those details merely to demonstrate the difficulty which our subcommittee has encountered in obtaining certain information from the Food and Drug Administration under the existing section 301(j). I believe that the amendments proposed in section 202 of H.R. 11581 translate into law the interpretation which the Food and Drug Administration has already placed upon section 301(j), as outlined in Mr. Larrick's letter of May 10, and which I believe to be incorrect.

In view of the experience which our subcommittee has had under the existing section 301(j), I believe that enactment of section 202 of H.R. 11581 in its present form would be most undesirable and would make it virtually impossible for the subcommittee to perform its duties in connection with the operations of the Food and Drug Ad-

ministration. For this reason, Mr. Chairman, I would like to propose for the Committee's consideration an amendment to section 202 of H.R. 11581 to read as follows:

On page 32, line 25, immediately before the period, insert the following: "and inserting in lieu thereof the following: '*Provided*, That nothing in this Act shall authorize the withholding of information from the duly authorized committees of the Congress.' "

This language has been successfully used, I understand, in the organic act setting up the National Aeronautics and Space Administration and in the legislation setting up an Advisory Committee on Weather Control, and, doubtless, in other legislation.

I believe that the adoption of this or a similar amendment would enable our subcommittee and the other committees and subcommittees of the Congress having responsibilities with regard to food, drug, and cosmetic legislation or the operations of the Food and Drug Administration to meet their responsibilities more effectively and with greater dispatch. To me it is unthinkable that information, other than trade secrets, which is available to officers and employees of the Department of Health, Education, and Welfare, as big as it is, as well as to the courts, should not also be available to the Congress, which passes the legislation and appropriates the funds necessary for the Department's operations.

I thank you for the opportunity to be heard on this point which I believe to be of the utmost importance to the Congress.

Mr. ROBERTS. I think there may be some questions, and the gentleman may like to leave this point open and come back at our next meeting.

I am sure there will be some questions of the committee, but, in view of the fact that we have a quorum call, I think we had better recess the committee at this time.

Mr. MOSS. If we could at this point, Mr. Chairman, we have the second bell, and I think it may be difficult for the gentleman who is chairing a very important investigation to be available to us, I would just like to proceed.

Mr. FOUNTAIN. Sometimes, Mr. Chairman, I meet myself coming around the corner.

I am supposed to be some place else right now, but I thought this was so important to the Congress that it ought to be brought to the attention of the commitee.

Mr. ROBERTS. The Chair will be glad to yield to the gentleman from California.

Mr. MOSS. I would like to compliment the gentleman for bringing this to the attention of the committee. As chairman of the Information Subcommittee of Government Operations, the question which underlies the refusal here of the Food and Drug Commissioner to supply the information is one which was exhaustively heard by the subcommittee, I believe, in 1956.

It is an interesting fact that when Congress has intended to limit its own access to information, that it has been eminently successful in stating that in the statue.

There is nothing in the statute upon which the Commissioner relies or in the history of the discussions, either in committee or on the floor, indicating that Congress ever intended that this act as a barrier to the Congress or its committee for this information.

I would point out that we had such an intent when we passed the Internal Revenue Act, and we very clearly spelled out a limitation on the right of the Congress.

I certainly intend supporting the gentleman's amendment, but I want the record to reflect very clearly that I feel that the action of Food and Drug in this instnace is, as in many cases in other agencies, an act of Executive arrogance in claiming the right to withhold from the Congress that which it needs for a legislative purpose.

I feel that they have no case, based on law or appropriate precedent, to support the position they have taken.

Mr. ROBERTS. I thank the gentleman.

The subcommittee will stand in recess, and if the chairman of the Intergovernmental Relations Subcommittee can be available for our next meeting, I am sure the other members would like to pursue this question further.

The committee will resume its hearings in the same room tomorrow morning at 10 a.m.

(Whereupon, at 11:15 a.m., the hearing was adjourned, to reconvene at 10 a.m., Thursday, June 21, 1962.)

DRUG INDUSTRY ACT OF 1962

THURSDAY, JUNE 21, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

Mr. ROBERTS (presiding). The committee will please be in order.

Our first witness today is Mr. Edward J. Breck, of the John H. Breck, Inc., 115 Dwight Street, Springfield, Mass.

He is accompanied by our distinguished colleague, Mr. Boland of Massachusetts.

STATEMENT OF HON. EDWARD P. BOLAND, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. BOLAND. Mr. Chairman and gentlemen of the committee, first of all, I want to express my very deep appreciation at the courtesy you have extended to me in permitting me to introduce a very distinguished citizen from my area.

It is regrettable I cannot stay for the hearing. I have an Independent Offices Subcommittee Appropriations meeting immediately following this, and, consequently, I must leave. But I am happy to introduce one of the outstanding citizens of my area, one who contributes much to the community life of the city of Springfield and the State of Massachusetts.

He is the president of the John H. Breck Co., one of the leading cosmetic manufacturers in the United States, and a very interesting company indeed.

It was started by his father as an individual many, many years ago, and finally in 1929 it was incorporated. It has grown from a single member to over 800 employees.

I am sure that I need not tell you anything about the Breck products. They speak for themselves very eloquently and have through the years.

He is very interested in the legislation which you have currently under advisement and under consideration.

I know that it has a serious impact upon his company as it does upon the cosmetic industry throughout the United States. I am delighted to present Mr. Edward J. Breck to you to give his views, and I am sure you will listen to them with interest. I trust the advice he can give to this committee will be helpful to it in reaching its conclusions on the proposals before this committee.

Mr. Chairman and gentlemen of this great committee, I present Mr. Breck.

STATEMENT OF EDWARD J. BRECK, PRESIDENT OF JOHN H. BRECK, INC., SPRINGFIELD, MASS.

Mr. BRECK. My name is Edward J. Breck, and I am the president of John H. Breck, Inc., which has its principal place of business in Springfield, Mass.

The Breck Co. was incorporated in Massachusetts in 1929; and prior to that date had been conducted as an individual proprietorship by my father, John H. Breck, Sr., who is presently chairman of the board of directors.

This corporation, from its founding, has grown from 3 employees to a present working force of about 800 people, many of whom work, not only in all parts of the United States, but in many areas of the free world.

The Breck Co. is one of the largest manufacturers of shampoos in the world and is the largest manufacturer of liquid shampoo in this country.

The business of the Breck Co. is not confined to its shampoo product, as it is a manufacturer and marketer of many other cosmetic preparations, some of which are hair sprays, hair coloring formulas, permanent wave solutions, powders, soaps, and similar items.

We of the Breck Co., from its very inception, have dedicated ourselves to the achievement of consumer acceptance of each and every product bearing our name. It was and is our firm belief that consumer acceptance of products is only merited by marketing the very highest quality product that is capable of being produced and, with reference to such products, by exercising absolute honesty in any claims with respect to them.

The Breck Co., to realize its ambition, has always followed a careful and complete program with respect to the testing of each and every product produced by it. Our experiments, findings, and premarketing tests have insured the safety of our products, and this fact has been confirmed by excellent consumer acceptance.

Realizing that this committee has listened and is going to listen to several representatives of the cosmetic industry concerning the legislation proposed by H.R. 11581 and H.R. 11582, I will confine my comments to those sections of the legislation dealing with the requirements and procedures relative to new cosmetics and those referable to the repeal of the special exemptions in connection with hair dyes.

I fully appreciate that with the added activity, growth, and expansion of all phases of business, laws without administrations to enforce them are in vain. I fully appreciate that legislation must contend with and provide for a constantly moving set of facts. As you know, our industry has been and is presently subject to both legislative and regulatory controls. I do not think that one can rightfully expect that legislation or regulations concerning our industry should cease here and now. As a matter of fact, I think it can continue with advantage to both the Government and business, provided, however, that the proper necessity or urgency demands such governmental legislation. Without a clear and obvious necessity or obvious urgency, a mood of distrust is engendered between the Government and busi-

ness; and business may rightfully wonder whether it is faced with an increasing number of duties and a decreasing number of rights.

I respectfully suggest to this committee that the proposed amendments referable to new cosmetics contained in this legislation are clearly and totally unnecessary, and if enacted will prove disadvantageous to both the Government and the cosmetic industry.

Under the provisions of this bill, H.R. 11582, a manufacturer would be required to furnish the Food and Drug Administration with certain information concerning a new product. Upon the receipt of this information, the Secretary shall make the determination as to whether the application shall be approved or denied. The Secretary has the full authority to claim that the application is insufficient in any particular and to order further and subsequent reports by the manufacturer. An unfettered exercise of power is certainly beneficial to no one, and governmental departments are no exception to this rule. Present legislation fully and adequately protects any interest which is sought to be protetced further by this legislation.

A manufacturer, in formulating a product for the market, expends a vast amount of time, effort, and expense. From the laboratory to the retail shelf is an expensive, long, and tedious road. A manufacturer would indeed be foolhardy from the standpoint of his own reputation, not to carefully formulate and test the product to all practicable lengths before asking for consumer acceptance. In addition to this, from the very first hour of laboratory work, he must, at all times, consider the product in the light of all regulations applicable thereto, whether they stem from the Food and Drug Administration, the Federal Trade Commission, or any other governmental agency that may directly or indirectly control the item.

This legislation, as I see it, is basically aimed at insuring a safe cosmetic product, and when we examine this purpose in the light of necessity or urgency, I respectfully submit that neither necessity nor urgency require such legislation. If a cosmetic product is not safe, this and other governmental agencies presently have the power to act with deliberate speed concerning any such product. The Government presently possesses the tools to insure the consumer a safe cosmetic product. Some of these tools are seizure of the product itself and action on the part of the Government for multiple reasons, some of which are adulteration, misbranding, and deceptive packaging.

To enact this legislation would result in a vast expenditure of money on the part of cosmetic manufacturers, totally over and above that being expended to place new products on the market. Even after such an expenditure, detrimental to both the industry and, in fact, the Government, the inevitable delay and the further time and expense involved in securing an approval from the Secretary most certainly would seriously stem the growth of this industry which, like many others, looks to new products for its growth. Without such growth the industry loses, the Government loses, and the employee loses. If this additional expense is laid on top of the considerable amount expended to initiate and promote a new product, the consumer, too, loses because this cost must, at least in part, be reflected in the retail price of the product.

We in the cosmetic industry have a firm belief that in certain areas we should be permitted to judge for ourselves; and most certainly

what we make, how we make it, and when we can market it should be our decision, subject, of course, to all that legislation presently on the books. I do not think this an unfitting attitude on our part, and I think the record of this industry is, in truth, one of which it can be proud rather than one that needs this vast extension of power which would make the Secretary the sole judge and jury of its activity.

It is important to note that this proposed legislation covers products which have been successfully marketed for many years. To accomplish successful marketing of a product over a period of years means only one thing; namely, that the consumer has accepted the product. If your product is not safe, you cannot and will not achieve consumer acceptance. Bear in mind that those cosmetic products, thousands in number, which have for years had consumer acceptance, are not exempt from the provisions of this legislation. It is indeed difficult to find a logical reason why they are not.

The Breck Co. has expended considerable time, effort, and expense in developing hair coloring products. Faced with this legislation, as are other manufacturers of this product in the cosmetic industry, we find ourselves not figuratively but very literally out of the color business if the special exemptions for hair dyes are repealed as requested by this bill, H.R. 11582.

The history of the development of hair colors by the cosmetic industry is a relatively long one. The progress was slow and expensive. As a matter of fact, it was only because of the Food and Drug Administration's expressed feelings that this segment of the business grew rapidly. As late as 1955, the Food and Drug Commissioner, George P. Larrick, voiced the opinion of the Food and Drug Administration based upon extensive reevaluation studies and experiments available to it, when he stated that no major changes relating to the use of these materials was indicated. While the continued use of patch testing was advised, no reason was found to question the exemption now sought to be repealed.

It is extremely important to bear in mind that because of the very acquiescence on the part of the Food and Drug Administration, manufacturers in this industry saw fit to explore the potential in this field. It cost huge sums of money to do so. If this exemption is repealed by this legislation, manufacturers in the color field will find themselves in a helpless position. This is so because the colors found in practically all hair colors presently on the market are not provisionally listed under the color additive amendments, and their use will be prohibited. An effective permanent hair color cannot be manufactured from those few colors which are now provisionally listed and permitted to be used in hair coloring.

It is common knowledge in the industry that the investigation and chemical research necessary to obtain certification for many of these dyestuffs would take a long period of time, running to 2½ years or more. During this period of investigation and research, the sale and distribution of hair colors as we presently know them would be prohibited. Congress as late as July of 1960, in adopting the color additive amendments, most certainly did not intend any such unfair disadvantage to be inflicted upon manufacturers of hair colors because they expressly provided for their exemption. It is this very exemption provided for by Congress in 1960 that this legislation attempts to repeal.

The hair-color manufacturers' reliance on the Food and Drug Administration's statements and policies was strengthened by this action on the part of Congress in 1960; and in rightful reliance on the exemption, the manufacturers have expended very large sums of money to enhance the growth of this segment of the industry. This investment on the part of the cosmetic industry should not be forfeited, as it most certainly will be, by the repeal of these exemptions. There is neither necessity nor urgency for the repeal of these exemptions, and this severe blow should not be dealt by this legislation. In addition to its vitally affecting color manufacturers, remember that the beauty shop operators from coast to coast will be irreparably harmed in that almost 30 to 40 percent of their present business is derived from hair coloring. I am sure I do not have to impress upon you the further effect of this repeal as far as the female segment of our population is concerned. Denying them this luxury might well cause them literally to change color.

Because the Breck Co. has not experienced a large active participation as yet in the marketing of its hair-color products, I feel that the statistics and facts and figures of other companies whose representatives will address you will give you a clearer picture of the safety factor of these products. These facts and figures, I am sure, are the most conclusive evidence that there is no necessity for the repeal of the hair-color exemption.

I have dealt rather briefly, but, I hope, with a degree of clarity, with the facts relative to new cosmetics and hair-color preparations. I confined myself to these points, knowing that there are many other manufacturers from whom you will hear and that, of necessity, much of what you will hear will be repetitious.

My feelings with respect to the cautionary labeling requirements and to the factory inspection provisions are much the same as those expressed relative to new cosmetics and hair colors. I think both to be totally unnecessary, particularly in view of the powers of the various agencies conferred by legislation already enacted. I am sure these points will be adequately dealt with by the subsequent speakers.

At the present time, much is being said about the cooperation of the Government with business and business with the Government. Speaking for myself on behalf of the Breck Co., I most certainly subscribe to such mutual cooperation; and I think no honorable businessman should wish it to be otherwise nor, in truth, should any honorable legislator wish it to be otherwise.

It is, therefore, worthwhile to examine carefully this proposed legislation, especially with an eye to its necessity and urgency. In this consideration, it is important to appreciate the safeguards and controls already provided for by enacted legislation. It is respectfully submitted that here and now cooperation on the part of the Government, through this committee and its legislators, is in order; and this can be ably demonstrated by refusing to enact this proposed legislation. Failing this cooperation will result in more burdens of an unnecessary character being heaped upon the businessman in diminution of valuable and, indeed, sacred rights.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Mr. Breck.

You are presenting this on behalf of your own company, I believe?

Mr. BRECK. Yes, I am, Mr. Chairman.

The CHAIRMAN. Mr. Roberts, any questions?

Mr. ROBERTS. Mr. Breck, I appreciate your concern about this legislation.

What will be so expensive about pretesting these dyes that would lead to the calamity that you foresee in this statement?

Mr. BRECK. The knowledge of the dyes is somewhat limited. I believe the food and drug requirements under the color additive bill require 2.5 years of testing, and I believe that the past history of these dyes has indicated by usage that they are safe.

The expense involved in studies in terms of colors are beyond the dollars of the smaller manufacturer.

Mr. ROBERTS. Do you provide in the preparation of these dyes any direction to the cosmeticians for patch tests being made?

Mr. BRECK. Yes, sir; we do.

Mr. ROBERTS. How many tests do you think are actually made before these dyes are applied?

Mr. BRECK. I believe——

Mr. ROBERTS. As a rule, no patch test is used with these dyes, is that not true?

Mr. BRECK. I think a very sizable number of beauty shops do patch tests.

Mr. ROBERTS. Have you ever heard of anyone becoming infected because of the use of one of these dyes?

Mr. BRECK. Mr. Roberts, I would like to point out my limitations in commenting about the hair colors. Up to the present time we are manufacturers of temporary hair colors, and I would not propose to be an expert at this time in the area of permanent hair colors of the paraphyenylenediamine type.

Mr. ROBERTS. I am just talking about from your knowledge of the industry and the practices followed by the operators, if you ever heard of anyone becoming infected by the use of one of the dyes, either temporary or permanent?

Mr. BRECK. I am sure that there have been some allergic reactions.

Mr. ROBERTS. Sometimes those reactions can be very serious in nature, is that not true?

Mr. BRECK. I am not familiar with the exact consequences of the allergic reactions from permanent hair dyes.

Mr. ROBERTS. I might say the gentleman from Alabama is quite familiar with the fact that these can cause very severe infections, can be very serious in nature. They can endanger people's hearing. They can cause the loss of hair and do a good many things that are very costly and very painful and very dangerous.

I am sorry that I cannot agree with the gentleman that this type of dye should not have some type of pretest such as proposed by the bills introduced by the distinguished chairman.

That is all I have.

The CHAIRMAN. Mr. Collier?

Mr. COLLIER. Yes, I would like to ask just a couple of questions, if I may, as to the subject matter of title II on factory inspection and the authorities that go with it under this legislation.

Mr. Breck, does the State of Massachusetts have a department of public health with the authority to make health inspections, sanita-

tion inspections in food processing plants and, in fact, in any plant that produces products used for public consumption?

Mr. BRECK. Yes; they do.

Mr. COLLIER. To your knowledge, does this department have inspectors or sanitary engineers who have a responsibility of making these inspections and setting up reports of the results of these inspections?

Mr. BRECK. Yes, but we have never been subject to such inspection in our plant in Springfield.

Mr. COLLIER. To your knowledge, is such authority granted to the State department of public health in the State of Massachusetts?

Mr. BRECK. Yes; it is very similar.

Mr. COLLIER. Are you aware by any chance of any criticism in the past in your particular State of the performance of these responsibilities by the State health authorities?

Mr. BRECK. You mean lack of their activity?

Mr. COLLIER. Are you aware of any criticism or any incident that ever developed where they inadequately performed these responsibilities?

Mr. BRECK. I am not really aware of any.

Mr. COLLIER. So that you have no knowledge?

Mr. BRECK. No.

Mr. COLLIER. Does the city of Springfield have a municipal health department?

Mr. BRECK. Oh, yes.

Mr. COLLIER. Do the inspectors in the municipal health department have authority to make inspections with regard to conditions of sanitation in various plants in the city of Springfield?

Mr. BRECK. Yes, but to my knowledge, Mr. Collier, I do not think that they have ever visited our plant.

Mr. COLLIER. I believe that is all for the moment.

The CHAIRMAN. Mr. Moss?

Mr. MOSS. Mr. Breck, your company is a very reputable company, is it not?

Mr. BRECK. I hope so.

Mr. MOSS. Are all manufacturers in the field of cosmetics equally reputable?

Mr. BRECK. That question is very similar to the old one—When are you going to stop beating your wife?

Mr. MOSS. Oh, I think the witness, Mr. Chairman, has a pretty good idea of competition around the country. He competes in almost every market in the Nation. I know when I was in business, I had a pretty good idea what my competition did.

Some of them I regarded as honorable and some of them I would hesitate to vouch for, for 1 minute.

The CHAIRMAN. Well, if the witness wants to indicate the character and reputation of individual companies in the country——

Mr. MOSS. I asked the witness as to his knowledge, Mr. Chairman. I think the witness can respond for himself.

Mr. BRECK. I assume that there are degrees of perfection and degrees of——

Mr. MOSS. I am not asking for perfection, Mr. Breck. You do not legislate normally to prevent abuses for the great majority who do not attempt to abuse any right or privilege.

Mr. BRECK. Mr. Moss, I think what I am attempting to say is that I had the good fortune of having my business life operate under our free economic democracy and system.

At one time I was the only employee, and I feel that additional legislation, in its final analysis, is only helpful to large industry and has a tendency to throttle small industry in growing, and I think that I am speaking for the future of any small manufacturers who in this country in our democracy should have the same right to attempt to grow. I feel that there is sufficient legislation available——

Mr. Moss. Sir, that is very noble, but it is not responsive, and I would point out that this committee, during this session of the Congress, had to enact legislation giving to the Secretary of Commerce the authority to prescribe standards for brake fluids because we found that there were some very unethical manufacturers who were producing brake fluids that, when they were placed in your automobiles, did not give you brakes, and, therefore, we had to weigh a public need for protection against an individual right to deceive or to take advantage of an unwary buying public.

Now, the argument that you have made, in my judgment, would be applicable to the first enactment of the first food and drug statute.

If, in fact, everyone was reputable, if, in fact, everyone adhered to standards, then there would be no need to protect anyone, because the industry, itself, would be doing the job.

But, obviously, we have experience that shows that that is not the case, and that we do on occasion have to act in order to prevent the abuse of a right or a privilege in dealing with the public.

Mr. BRECK. Mr. Moss, the only additional thought I have with respect to protective enforcement is that I firmly believe that the appropriation of the Food and Drug Administration could be increased.

I think there are some very able and competent people in that department, who have the legislation necessary to do the job that you are interested in, and that perhaps only additional appropriation is needed for their department.

Mr. Moss. I am interested on page 7 of your statement because, after you have expressed your views as to the need for complete freedom in all other areas, you say:

> My feelings with respect to the labeling requirements are much the same as those expressed relative to new cosmetics and hair dyes.

In other words, you want exemption from the labeling requirements, is that correct, that you feel that the labeling requirements proposed here would be onerous?

Mr. BRECK. The cautionary labeling requirements should be sufficient under the present exemption.

Mr. Moss. Under the present labeling requirement you are required to place "Caution" on it.

> This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows. To do so may cause blindness.

Mr. BRECK. I am not suggesting the elimination of that.

Mr. Moss. But you are opposing the clarification on labels as to the content of the product and necessary advice as to what to do in the event a person experiences difficulty, are you not?

Mr. BRECK. No.

Mr. MOSS. What do you mean, then, by the term that your feelings about the labeling requirements are the same?

Mr. BRECK. Well, the labeling requirements should be kept with the exemptions for hair coloring as it now stands.

Mr. MOSS. You feel that no further clarification is desirable or necessary?

Mr. BRECK. That is right.

Mr. MOSS. That is all the questions I have, Mr. Chairman.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. I have only one question, Mr. Breck. I am somewhat familiar with your products because I have used your shampoos.

Mr. BRECK. Thank you.

Mr. YOUNGER. If we were to enact legislation that would cause harassment with a lot of inspectors running over your plant, would not that cause additional expense?

Mr. BRECK. We had a visit from a Food and Drug inspector, I think within the last 60 days, and it requires X amount of hours of X number of various departments to spend time with him.

Mr. YOUNGER. Your margin of profit is not too high on each bottle anyway, is it?

Mr. BRECK. Well, we wish it were more.

Mr. YOUNGER. If you were put to all this extra expense, it might be necessary for you to raise the price of your products?

Mr. BRECK. Well, I could not say to what extent that would be necessary.

Mr. YOUNGER. Then you think it would be all right to have more inspections of your formulas, your shipping, all of your clients and everything open for public inspection?

Mr. BRECK. No.

I think there is a limit to the frequency of inspections. The fact that an inspector can appear at your front door and just hand you a card at any hour, any time, this is the way it is right now, but I think there is a limit.

Mr. YOUNGER. They do inspect your plant now?

Mr. BRECK. Oh, yes.

Mr. YOUNGER. Have they ever filed any complaint against you?

Mr. BRECK. Not to my knowledge.

Mr. YOUNGER. That is all.

The CHAIRMAN. Mr. Dingell.

Mr. DINGELL. Mr. Breck, I have not had a chance to read your statement as carefully as I would like, but I was interested in this.

You oppose the factory inspection section of the bill, is that correct?

Mr. BRECK. Yes.

Mr. DINGELL. Do you oppose any other sections of the bill?

Mr. BRECK. I oppose the bill itself.

Mr. DINGELL. But specifically your opposition is directed to the factory inspection, or is it the entire piece of legislation?

The CHAIRMAN. Specifically his opposition has been to practically every section of the bill.

Mr. DINGELL. Let me pursue this a little bit here. You have never had any trouble with the Food and Drub Administration, have you?

Mr. BRECK. No; we have not.

Mr. DINGELL. Has your relationship with them been satisfactory in the past?

Mr. BRECK. Very satisfactory.

Mr. DINGELL. You have never been cited for violation of the food, drug, and cosmetic laws of any kind?

Mr. BRECK. Not up until 5 o'clock last night.

Mr. DINGELL. I happen to be aware that you manufacture an excellent product, a very highly regarded product. Do you have any reason to think that if this bill becomes law, your relationship with Food and Drug will be any different than it has been in the past?

Mr. BRECK. Mr. Dingell, I am just saying that I think there is sufficient law available and sufficient regulations by the Food and Drug and the Federal Trade Commission that if it is necessary for them to further enforce, then I think that they should be given larger appropriations, and in the past I have so urged the Senators and Congressmen from Massachusetts to do so on more than one occasion.

Mr. DINGELL. I thoroughly agree with you with regard to the fact that Food and Drug needs more appropriations, but that, I am sure you are aware, is the domain of another committee.

Mr. BRECK. Yes.

Mr. DINGELL. You have indicated you have never had any difficulty with Food and Drug so far as your relationships with them. I assume you have been able to work out whatever is necessary amicably on a formal basis, have you?

Mr. BRECK. That is correct.

Mr. DINGELL. You have had small differences with them and you have had opportunities to be in communication with them; have you not?

Mr. BRECK. Yes.

Mr. DINGELL. And you have always found them to be wholly cooperative in working these differences out on an informal basis rather than proceeding under the strict letter of the law; have you not?

Mr. BRECK. They are very competent people.

Mr. DINGELL. Coming, then, to this point, you run a thoroughly reputable concern.

You manufacture an excellent product and under, I am sure, very fine, wholesome conditions, adequate safety, pretesting, but you are aware that there are rascals in your trade, I am sure, who do proceed with less than due care for the public interest, insofar as the safety in the commodities they manufacture and also insofar as the manner in which they proceed to manufacture.

Am I correct?

Mr. BRECK. I would assume one would have to admit there were degrees of competence and ethics by various segments of all industry, yes.

Mr. DINGELL. And you are aware of the fact that over the history of the industry there have been unsafe commodities of the type that you merchandise by manufacturers other than yourself; and I say you manufacture a very safe and very fine line of commodities, but you are aware of this fact; are you not?

Mr. BRECK. Oh, yes.

Mr. DINGELL. And, of course, the danger from manufacturing and marketing of a dangerous commodity of this type to the consuming public is substantial; is it not?

Mr. BRECK. It could be on some few individuals that possibly might be allergic.

Mr. DINGELL. As a matter of fact, conceivably, an unsafe hair preparation could cause considerable difficulty and suffering to a person who used it as an innocent consumer; am I correct?

You do agree?

Mr. BRECK. Yes.

Mr. DINGELL. So the problem we have here is not one of protecting you from unwise and harsh intrusions into your business by the Food and Drug because you have already conceded that you have had an excellent relationship with them over the years.

By the way, you concede that you have no reason to assume that your relationship with Food and Drug would change if H.R. 11582 were to become law, do you?

Mr. BRECK. This places in the hands of the Secretary the power to grant approval of a new cosmetic, a new product. The question is: Does this place in his hands too much authority?

Mr. DINGELL. The real question, though, is this: You have no reason to assume that, if H.R. 11582 is passed, that a reputable concern like yours is going to face any different relationship with the Food and Drug Administration than you have faced in the past, do you?

Mr. BRECK. I do not know the unknown. I do not know what——

Mr. DINGELL. On the basis of your previous relationship with Food and Drug you have no reason to feel that in the future you will face any different relationship with Food and Drug if H.R. 11582 is passed than if it is not passed, do you?

Mr. BRECK. No, I suppose not.

Mr. DINGELL. And Food and Drug is not a malignant genie——

Mr. BRECK. No.

Mr. DINGELL (continuing). Which deliberately intrudes itself into the affairs of the industry in a hostile fashion, I am sure.

So, actually, the real problem here is one of giving an agency charged with protecting the consumers the maximum of protection from the dangers it might face from unsafe commodities; is that not it?

Mr. BRECK. That is it.

Mr. DINGELL. And this, of course, you do not oppose?

Mr. BRECK. I say that they have that authority, and they can do the job under the present laws and regulations that are now in effect.

Mr. DINGELL. But, assuming that more authority was needed, you would not object to them having more authority?

Mr. BRECK. I would rather have them have more appropriation to operate under the authority they now have.

Mr. DINGELL. But I am sure you understand this is the province, again, of another committee?

Mr. BRECK. Yes.

Mr. DINGELL. And we are considering the maximum protection for the American consumer, and your experience with the Food and Drug has been over the years that you have had an excellent relationship and have found no instance where they have behaved unwisely or unfavorably; am I correct?

I mean if they have behaved unfairly, tell us, and there may be justification for killing the bill.

Mr. BRECK. According to our technical director the answer would be no, but qualifying it, to us.

Mr. DINGELL. With regard to your particular operation, you have had no trouble?

Mr. BRECK. Yes.

Mr. DINGELL. Thank you very much, sir.

The CHAIRMAN. Mr. Dominick?

Mr. DOMINICK. Mr. Breck, do you carry product liability insurance?

Mr. BRECK. Yes, we do.

Mr. DOMINICK. Do you happen to know what the ratio of loss is on that?

Mr. BRECK. Ratio of loss?

Mr. DOMINICK. Yes, claims.

Mr. BRECK. No, I do not know specifically.

Mr. DOMINICK. The thing I was trying to find out is whether or not your experience has indicated that there is a real necessity to retest all the hair dyes which you have on the market.

Mr. BRECK. Mr. Dominick, I would prefer not to pretend to be an expert in the hair-color field. We are just entering the hair-color field.

We do know something about temporary hair dyes, but not about permanent hair coloring. The job of attempting to test the colors is an enormous one, as the whole industry is now faced with, under the color additive bill.

As the Secretary proposed the bill, it practically eliminates the use of anything but the certified colors, and we, to date, have not been able to make any permanent hair color of the right color under certified dyes or those already provisionally listed.

Mr. DOMINICK. Would this bill cover temporary as well as permanent dyes?

Mr. BRECK. Yes, it would.

Actually, we have a temporary hair coloring that includes dyes that we have done animal studies on for over a year. They are covered by patents.

Were we to list them as being certified, which we are positive they would be, they would be available to any other manufacturer to use, and, as the Secretary indicated by employing the word "all" in his statement, our temporary hair colors would actually have to stop being sold the day this bill went into effect.

Yet, we believe that the dyes we have are certainly able to be certified, but if we certify them, then they are available for every competitive manufacturer to use.

Mr. DOMINICK. Do you feel that shampoos are also covered under this bill?

Mr. BRECK. They certainly—not under the hair color section, but under H.R. 11582, they certainly are included.

Mr. DOMINICK. Is it your opinion that if this bill should pass, that all of the products which you have on the market would have to be retested?

Mr. BRECK. Yes.

Mr. DOMINICK. And, again, I come back to the question of the number of claims that you have for one sort or another either on efficacy or on some damaging effect which may have been created by the use of these.

Have you had many claims?

Mr. BRECK. Very limited.

Mr. DOMINICK. Is there a percentage figure that you can give on this?

Mr. BRECK. Our total complaint in 1961 was 12 per million units.

Mr. DOMINICK. Thank you, Mr. Breck. That is what I wanted to find out.

Mr. BRECK. This includes package broken or bottle frozen or "I dropped it," all kinds. This is not allergy.

Mr. DOMINICK. Let me go a little further, then. Were these claims made by your distributors as opposed to consumers?

Mr. BRECK. These were written complaints by consumers.

Mr. DOMINICK. By consumers?

Mr. BRECK. Yes, aerosol package did not work, no gas in it, just a wide variety in the total.

Mr. DOMINICK. And only a small percentage of that would be people who had had or who had claimed to have had some adverse effect?

Mr. BRECK. Yes; "dried my hair," and the like.

Mr. DOMINICK. From your experience, then, there would not seem to be any necessity of retesting your products, I would gather?

Mr. BRECK. We do not feel it would be necessary, but under the bill we would be required to do so or to have expert witnesses testify to the Food and Drug Administration that, in their opinion, these are safe products.

Mr. DOMINICK. If all these dyes were to be retested that are now out, and if all the drugs were to be retested that are now out, for efficacy as well as for safety, how long, in your estimation, would it take to do this?

Mr. BRECK. It would take certainly from the date of the passage of the bill probably about 3 to 4 years.

Mr. DOMINICK. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Rogers, do you have any questions?

Mr. ROGERS of Florida. No questions.

The CHAIRMAN. Mr. Breck, the committee is glad to have the benefit of your views here.

I assume you do not indicate to this committee that there should be any loopholes insofar as safety requirements in cosmetics are concerned?

Mr. BRECK. That is correct.

The CHAIRMAN. The Secretary of Health, Education, and Welfare testified the day before yesterday, mentioning the hairdye situation. I am well aware of the fact that some Washington representatives sent out a bulletin to the beauticians throughout the country and really got them all excited and concerned about it, maybe appropriately, I do not know. From my mail, I think they are convinced that by the introduction of these bills, an effort is being made to put them out of business, and to prevent the charming ladies of this country from becoming more charming.

But when you get right down to it, the Secretary testified that because of the use of certain coal-tar dyes as a base for hair dyes, that people can become permanently injured.

Mr. BRECK. I read his statement.

The CHAIRMAN. Stating that in many instances people had gone blind because of the use of it.

Mr. BRECK. No, I was not familiar with that.

The CHAIRMAN. You read the statement, though, you said?

Mr. BRECK. Yes.

I did not recall that he said that.

The CHAIRMAN. He certainly did say that.

Mr. BRECK. He did?

The CHAIRMAN. That is what he testified here before the committee the day before yesterday.

Now, do you know whether or not hair dyes that are being used today all have a coal-tar base?

Mr. BRECK. I am not as familiar as I hope to be sometime in the future with permanent hair coloring.

The CHAIRMAN. Do you produce hair dye?

Mr. BRECK. Not up to this moment. We produce a temporary hair color, which does not have the same base as permanent hair dyes.

The CHAIRMAN. "Temporary hair color," now what does that mean? Does that mean it will color it temporarily?

Mr. BRECK. That is right, Mr. Chairman. It just externally coats the hair, and it does not change the molecular structure of the hair, such as the permanent coal-tar dyes.

I prefer not to be involved in being an expert on permanent coal-tar hair color.

The CHAIRMAN. Then you have not had enough experience to know just how extensive?

Mr. BRECK. No.

The CHAIRMAN. How extensive is this statement with reference to permanent injury of people as a result of its use?

Mr. BRECK. No, I do not.

The CHAIRMAN. I hope somebody who is familiar with this long history will give the committee the benefit of the information on that before these hearings are concluded.

On behalf of the committee, I wish to thank you for your appearance here and for your testimony.

It had been my hope that we could have made greater progress here this morning.

We have innumerable witnesses to be heard.

It will certainly be difficult to start with another witness at this time, particularly witnesses representing the national associations, who, I judge, have rather lengthy statements.

If there is anybody here that was scheduled to appear today who would like to take about a minute to get into the record, I would be glad to have him take that opportunity. I see there are no takers of the suggestion.

The committee will not sit this afternoon. The House is in session under rules that will not permit us to sit. That is why I was trying to hear anyone who wanted to put his statement in the record. The House is going into session in about 2 or 3 minutes, so we cannot start with another witness at this time.

Mr. LONG. Mr. Plaut has a very short statement.

The CHAIRMAN. I notice Dr. Emil G. Klarmann is with you. You might identify yourself for the record.

STATEMENT OF WALTER N. PLAUT, PRESIDENT OF LEHN & FINK PRODUCTS CORP.; ACCOMPANIED BY DR. EMIL G. KLARMANN, TECHNICAL DIRECTOR

Mr. PLAUT. My name is Walter N. Plaut, president of Lehn & Fink Products Corp., and with me today is Dr. Emil G. Klarmann, who is manager of technical services of Lehn & Fink Products Corp.

He has been active for many years in the scientific work of the Chemical Specialties Manufacturing Association, in the Toilet Goods Association, the Society of Cosmetic Chemists.

In his capacity as chairman of the Precautionary Labeling Committee of the CMSA, he had the honor of presenting the industry's position before both the Senate and House committees of Congress in the matter of the then pending Federal hazardous substance labeling legislation.

Just for further identification, Lehn & Fink is a corporation whose stock is listed on the New York Stock Exchange and whose sales for the fiscal year will be in excess of $50 million.

We have plants in Bloomfield, N.J., Toledo, Ohio, Lincoln, Ill., Europe, South America, Central America, and Africa. The corporation has approximately 2,200 employees and in excess of 5,000 stockholders.

Lehn & Fink manufactures and markets cosmetics and toilet goods, proprietary products, and cleaning and disinfecting compounds under such familiar names as Tussy, Dorothy Gray, and Lysol. Lehn & Fink and its predecessor businesses have been engaged in making and selling cosmetics for more than 85 years.

It is my considered judgment that the present provisions of the Federal Food, Drug, and Cosmetic Act are entirely adequate for the protection of the consuming public. On the basis of our long experience in this field, I am convinced there is no actual or threatened hazard to users of cosmetics sold by Lehn & Fink or by our industry in general.

Our manufacturing and marketing techniques, which are commonly shared by the industry, conform to the rigid standards of premarketing testing, quality control, sanitation, and honesty which are imposed not only by the Federal law, but also by the laws of many of the States in which we operate.

I am aware that with certain cosmetics, as with almost every commonly used food product or clothing fabric, there may be a problem presented by the relatively very small number of users who unfortunately have an allergic reaction. However, there is nothing in the proposed bill which would add one measure of protection against this problem. Under the bill, reliance would still be necessary on the kind of careful premarketing testing which we always do to assure ourselves that the group of potential allergic users is no greater than is common in the case of the hundreds of other items of everyday use which share this kind of problem. It is also pertinent to point out that in almost every case of allergic reaction which has come to our attention, the reaction involved low-grade symptoms, such as rashes, and not major systemic injury. Certainly, our experience has indicated no threat to the public health which would justify subjecting our entire industry to an unnecessary system of premarketing clearance as proposed in this bill.

Furthermore, we feel most strongly that this bill would subject us to restrictions which are in certain ways more severe than those imposed on the food and drug industries. Nothing in the history of our industry would justify any such unreasonable increase in the severity of regulatory control by comparison with the control of food and drugs which present, from any commonsense viewpoint, so many more obvious and substantial potential hazards to the public health.

In particular, we think that the following changes in the present form of H.R. 11582 represent a minimum program for assuring fair and reasonable treatment of our industry:

1. We believe that the bill should be revised (sec. 101—605(a)(1)) to insure that cosmetics being marketed at the time the new law becomes effective shall be exempted from the law if they are generally recognized as safe by qualified experts on the basis of proven past performance over the years. For instance, at least 90 percent of the ingredients used in the cosmetics our company produces have been used safely in cosmetic applications for more than 10 years. We see no need at all, then, for having to embark upon an expensive and time-consuming testing program to prove what has already been proven under actual-use conditions. Having to institute such a testing procedure is obviously unreasonable and would be unfair to our industry. In fact, this revision we request would place us in the same position as the food industry under the food additive amendments, by making clear that where experience based on common use in cosmetics has proven the safety of the ingredient, it shall be exempt from the requirement of a new administrative determination of safety.

2. We feel the bill should clearly state (sec. 101—605(a)) that approval by the Secretary would not be required whenever a cosmetic is offered for a new use that is substantially like an established use, or where the formula for a cosmetic has undergone only minor revisions.

3. It is our opinion that the provisions (sec. 101—605(d)(1)(a)) of the bill which permit the Secretary to require test data to support applications for findings of safety are unreasonably broad. In particular we object to a requirement that safety be demonstrated by all applicable methods where the scientific community is satisfied that one or two test methods provide absolutely conclusive data. It is entirely possible where such discretion exists that we would be subject to administrative harassment even though we had made available perfectly satisfactory scientific data.

4. We are opposed to the mandatory requirement that the Secretary prevent the marketing of a cosmetic such as lipstick, which might be inadvertently ingested, merely because limited animal test data indicated theoretically possible carcinogenic effects. As the bill now reads (sec. 101—605(d)(2)), he would have to act even though he was personally totally satisfied that a cosmetic presented no carcinogenic danger at all to humans, on the basis of this kind of selected data and despite general support in the scientific community for his conviction that there was no actual danger at all.

5. We think the Secretary should not be vested (sec. 101—605(j)(1)) with such absolute power whereby he might require our industry to make burdensome changes in recordkeeping practices, especially since

we think our current practices have proven to be entirely consistent with the protection of the public health.

6. Lastly, as a prominent manufacturer and distributor of hair coloring products, I join with the other companies in this branch of our industry in deploring the removal of the so-called hair-dye exemption by H.R. 11582 (sec. 103). There is no evidence that the consuming public is not adequately protected by the present requirement for warning labels on each item sold. If manufacturers had to use only certified colors, the whole industry would be substantially destroyed, at least until such time as the complicated and time-consuming process of color certification could be completed on the dyes we use. Furthermore, it is doubtful that a large number of effective hair-coloring dyes would be certified as a result of this process, unless it is clearly recognized that the present pattern of use accompanied by warning notices is reasonable and effective. I would strongly urge, at a minimum, that this provision, if included at all, be deferred until its real significance can be further evaluated and until such time as industry and the Food and Drug Administration can cooperatively agree upon and secure a reasonable supply of hair-coloring dyes.

Thank you for your kind attention to this statement.

The CHAIRMAN. Mr. Plaut, thank you for your statement, which I think is a very good one.

The committee will give consideration to your request. Your final statement is rather interesting to me. I gather from that that the industry and the Food and Drug Administration cannot agree on what would be reasonable in this field?

Mr. PLAUT. I believe that we can agree.

The CHAIRMAN. You have not?

Mr. PLAUT. We have not under this new 11582.

The CHAIRMAN. Has there been any attempt to bring about such agreement?

Mr. PLAUT. There has been no discussion, to my knowledge.

The CHAIRMAN. But do I understand that you indicate by this that there is something that needs to be done to improve the present procedures?

Mr. PLAUT. Not necessarily. We feel that the present labeling requirements are sufficient.

The CHAIRMAN. You said postpone it until you can agree on what is needed.

Which do you mean?

Mr. PLAUT. That is just exactly what I mean.

The CHAIRMAN. That everything is all right?

Mr. PLAUT. We feel that the present labeling requirements are adequate. If there is an area for compromise, I think that this should be discussed by the two groups.

The CHAIRMAN. Thank you very much.

Mr. PLAUT. Yes, sir.

The CHAIRMAN. That concludes the hearings this morning.

The committee will adjourn until 10 o'clock tomorrow morning.

(Whereupon, at 11:05 a.m., the hearing was adjourned, to reconvene at 10 a.m., Friday, June 22, 1962.)

KANSAS STATE UNIVERSITY
OCT 1 1962
MANHATTAN, KANSAS

DRUG INDUSTRY ACT OF 1962

FRIDAY, JUNE 22, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

As the first witness this morning, we will have Mr. H. T. Austern, of the National Canners Association.

Mr. Austern?

STATEMENT OF H. THOMAS AUSTERN, COUNSEL FOR THE NATIONAL CANNERS ASSOCIATION

Mr. AUSTERN. Mr. Chairman and members of the committee, my name is H. Thomas Austern. I am counsel for the National Canners Association.

That association's formal statement identifying the activities of its 600 members located in 44 States is filed with the committee.

The CHAIRMAN. Do you care to have your entire statement placed in the record as you have presented it and proceed to give an analysis and résumé of it?

Mr. AUSTERN. We respectfully ask that it be included at this point.

The CHAIRMAN. Very well, let it be included in the record.

(The statement of the National Canners Association is as follows:)

STATEMENT OF THE NATIONAL CANNERS ASSOCIATION

The National Canners Association is a nonprofit trade association of more than 600 member canners with plants located in 44 of the 50 States. These canners pack approximately 80 percent of the Nation's production of canned fruits, vegetables, meats, specialties, and seafoods.

The association opposes the enactment of title II of H.R. 11581.

That title would amend section 704 of the Federal Food, Drug, and Cosmetic Act, to authorize any designated employee of the Federal Food and Drug Administration to enter any cannery and to inspect not only the factory premises and all "pertinent equipment, finished and unfinished materials, containers, and labeling therein"—as the present law permits—but in addition to inspect "all things therein (including records, files, papers, processes, controls, and facilities) bearing on * * * violations or potential violations of this act."

By sections 301(f) and 303 of the existing act, the refusal to permit such unlimited ransacking of the files of a private business is made a crime punishable by both fine and imprisonment.

The National Canners Association on behalf of the canning industry vigorously opposes the enactment of title II, as it applies to foods, because there is no demonstrated need for this endless expansion of inspection, because it will frustrate rather than foster the purposes of the act, and because in converting an "inspection" into an unlimited "search and seizure," to produce evidence on

which men and companies may be criminally prosecuted, it plainly violates the fourth amendment to the Constitution.

PAST ASSOCIATION SUPPORT OF PURE FOOD LEGISLATION

At the outset the committee will note that the National Canners Association's opposition to title II of this bill represents the first instance in the association's 55-year history that it has taken a position in direct opposition to legislation proposed and supported by the Federal Food and Drug Administration.

In order that the committee may fully appreciate our reasons for opposing this legislation, we would like initially and briefly to review for the committee the canning industry's cooperation in the enactment and administration of Federal pure food regulation in this century.

The National Canners Association was founded in 1907 shortly after the enactment of the Food and Drug Act of 1906, which had been vigorously supported by a great majority of canners in this country. From the very beginning these two organizations—the National Canners Association and the Food and Drug Administration—established a spirit and practice of cooperation that has continued to the present day.

The canning industry's support of the 1906 Food and Drug Act was followed in subsequent years by the active efforts of this association and its members to support additional legislation proposed by the FDA that would affect food manufacturers. The most significant legislative proposals that have been actively supported by NCA included—

The McNary-Mapes amendment to the 1906 act, providing for standards of quality and fill of container for canned foods—which legislation was proposed and sponsored by the canning industry;

The Federal Food, Drug, and Cosmetic Act of 1938, which was enacted by Congress to replace the original 1906 act;

The 1953 Factory Inspection Amendment, which provided for compulsory inspection of food and drug establishments, of their equipment, raw materials, and finished goods, containers, and labeling;

The Hale amendment, designed to speed up and simplify FDA rulemaking procedures;

Legislation requiring pretesting and the establishment of tolerances for pesticides, food additives, and color additives.

In no instance has this association opposed fundamental legislative proposals of the FDA, even though on occasion, when the association has supported the basic objectives of FDA proposed legislation, we have proposed some detailed changes in the procedural and administrative provisions ofthe various bills.

This mutual respect and cooperation between NCA and the FDA has been referred to with gratification on many occasions by both organizations. In 1956, upon the occasion of the 50th anniversary of the enactment of the Federal pure food law, we reaffirmed our support of that legislation and pledged our "continued cooperation in the development of further regulations for consumer protection." In that resolution the association membership urged upon Congress that "increased appropriations for enforcement of the Federal Food, Drug, and Cosmetic Act be accorded the highest priority to the end that this vital work in consumer and canner protection may be effectively continued."

In 1960, when the association deemed it appropriate to reaffirm its support of the FDA, the membership again adopted a resolution referring to the "established policies of mutual trust, confidence, and full coopration", between the two organizations. That resolution called attention to the fact that "the consumer, the Food and Drug Administration, and the canning industry have benefited from what Commissioner George P. Larrick has termed 'the habit of close cooperation' between the National Canners Association and that Administration."

On both sides, this has been more than formal oratory. Instead, it has reflected five decades of mutual respect—on the part of the industry for dedicated public servants performing an important public service; and on the part of the agency for constant research efforts and effective programs that have contributed to accomplishing the purposes of the act. This atmosphere of full and forthright cooperation has permeated the ranks of the administrative agency, the association staff, and the canning industry.

We have referred to this history so as to afford to this committee a reference point against which to appreciate the significance of the association's firm opposition to title II of H.R. 11581. An industry that has cooperated on a day-to-day basis with the FDA for more than 50 years in the enactment, administra-

tion and enforcement of food regulation legislation does not lightly take a position of direct opposition to the FDA on what the latter considers to be an important legislative proposal.

But the canning industry firmly believes that overriding principles make it necessary for us to take this position, and vigorously to oppose the creation in a Government agency of inquisitorial powers which we are convinced will provide no significant public benefit, and which is an unconstitutional invasion of the Bill of Rights of the Federal Constitution.

THE PRESENT LAW

In the spring of 1953, this committee was confronted with the problem created by the *Cardiff* case (*United States* v. *Cardiff*, 344 U.S. 174) in which the U.S. Supreme Court held that entry to inspect a food factory, even within the limits carefully prescribed, required permission of the owner.

This association, along with most other food trade associations, urged that entry and inspection, within the scope provided in the Act, should be made compulsory.

Both the majority and minority of this committee were aware that the Food, Drug, and Cosmetic Act of 1938 presented sensitive and difficult constitutional questions. What the act prohibited in terms of adulteration encompassing aesthetic and not health questions, what it banned as misbranding including elusive questions of economic deception, were stated in general and not specific terms. Informal, changing, and often unstated administrative interpretations operated, and unrevealed working tolerances were prevalent.

Nevertheless, the act was a criminal statute. In addition to seizure and injunction, penal prosecution with fines up to $10,000 and imprisonment up to 10 years could be, and had been, imposed for violations. More important, the penal responsibility was what is known as strict criminal liability. Neither motive nor intent to violate—or even knowledge of the facts—is required. Nor is it even open to show that the highest standards of care are exercised. If adulteration or misbranding occurs, that alone permits conviction. Indeed, individual men can be held criminally liable under circumstances where the employing company is acquitted. See *Dotterweich* v. *United States*, 320 U.S. 277 (1943).

That rule of strict criminal liability—under which a man or a company can be convicted in the absence of any intent to violate the law, even without any knowledge or awareness of the facts, and without any possibility of defending on the ground that all due care was exercised in his operations—has been severely criticized by many scholars. See Mueller, "On Common Law Mens Rea," 42 Minnesota Law Review 1043 (1958); Hart, "The Aims of the Criminal Law," Law and Contemporary Problems (1958) 401, 423. See, also, *Morissette* v. *United States*, 342 U.S. 246 (1952).

Neither in 1953 was the food industry asking, nor is it today, that this fundamental of the act as a criminal statute be changed, harsh as its application has been demonstrated to be in many cases. But this committee must be aware of the nature of the criminal statute to which it is now asked to add these unlimited inquisitorial powers to examine every paper, file, and document in a food factory—any or all of which may then be made the basis for a criminal prosecution under this rule of strict liability.

In 1953 the committee was clearly aware of this aspect of the basic act which made the problem of compulsory factory inspection—if it could be sustained in the face of the fourth amendment prohibition of unlawful searches and seizures—incredibly difficult.

The majority of this committee surmounted the constitutional difficulty by making it plain that the scope of inspection after entry was to be limited to the factory premises, and to all pertinent equipment, finished and unfinished materials, containers, and labeling therein—in short, to what the inspector could observe and sample.

The committee went further and, as to these specifics on what could be inspected, added that the inspection must be "within reasonable limits and in a reasonable manner"; that written notice must be given; and that an immediate report be given the owner as to any objectionable materials or unsanitary conditions. (See H. Rept. 708, 83d Cong., 1st sess. (1953)).[1]

[1] In 1953 this committee also left untouched the provisions of section 703 requiring that where shipping records, showing the receipt of articles in interstate commerce, were to be examined, there had to be a specific request in writing, and further specifying that evidence so obtained could not be used in a criminal prosecution of the person giving it.

Yet even with these limitations in section 704 as to the scope of what could be inspected, a minority of this committee could not surmount the constitutional difficulties on factory inspection. They insisted that since compulsory inspection could yield evidence on which criminal prosecutions could be based, the traditional requirement of a search warrant, grounded on probable cause, was appropriate. In their view, backed by judicial citation, there was no distinction between an "inspection" and a "search" where what was seen and found could lead to criminal prosecution.[2]

What is now proposed discards all of this committee's careful work in 1953. Compulsory inspection of a food plant will under title II of H.R. 11581 cover "all things therein (including records, files, papers, processes, controls, and facilities)."

Every record, file, letter, paper, bill, invoice, formula, and personnel data sheet can be demanded; every file rummaged; if the inspector concludes it "bears" not only on actual violation but also on potential violation. The penalty for refusal is criminal conviction.

No wider, more sweeping, and startling inquisitorial power has ever been proposed. Standing alone, it does violence to the fourth amendment. Coupled with a criminal statute—imposing strict penal liability without reference to actual knowledge, intent, or motive, or care taken—under general prohibitions whose content and administrative interpretation are often unknown, and can change from time to time—it is an even more startling invasion of the Bill of Rights.

Hence this committee must carefully examine where this proposal came from, its purpose and desirability, what compelling and vital need has been shown for it, and whether anyone could with good conscience square it with the Constitution each of us as citizen and Government officer must uphold.

PRESENT PROPOSAL ORIGINATED IN DRUG INDUSTRY ANTITRUST INVESTIGATION

The present proposal appears to have originated during the course of the extensive investigations of the pharmaceutical drug industry conducted by the Antitrust Subcommittee of the Senate Judiciary Committee, beginning in June 1960. In these hearings it had been suggested that the failure of some drugs to conform to the standards of the United States Pharmacopoeia derived from inadequate manufacturing controls. The legislative proposals introduced by Senator Kefauver, covering wide areas of additional control for drug manufacturers, included provisions granting the authority to examine the files and records of drug manufacturers. (See S. 1552, 87th Cong., 1st sess., Apr. 12, 1961, sec. 508.)

Needless to say, the problems inherent in the manufacture and control of therapeutic drugs are wholly and vastly different from those presented by the manufacture of foods. Drugs are therapeutic agents and the possible hazards of their use must always be balanced agains the necessity for curative effect. Active drug ingredients are often extremely potent, and perhaps in some instances require close governmental supervision, and even batch certification, in their manufacture. With these problems concerning the drug industry, food manufacturers have no familiarity and take no position.

Wholesome foods are not drugs. In their manufacture the chief concern is soundness of raw material and sanitation in the factory kitchen. In their sale, the elements of flavor, contributed by recipes and manufacturing skill, attractiveness, and convenience and low cost are the important factors.

These distinctions are recognized throughout the substantive sections of the Federal Food, Drug and Cosmetic Act. Foods, drugs and cosmetics are dealt with in separate titles. Title IV sets forth the provisions controling food; title V the necessarily different provisions for drugs and devices; and title VI the requirements with respect to cosmetics.

Because of the historical format that originated in 1906, however, the enforcement sections of the Federal Food, Drug and Cosmetic Act are identically

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[2] As Mr. Justice Douglas pointed out in *Eaton* v. *Price*, 364 U.S. 263, 272 (1960), this is the English rule. The Justice added that under this requirement of an antecedent warrant, "no complaint is heard that this stultifies enforcement there [in England] of the regulation of public health and safety. Certainly with this procedure available—the procedure of antecedent justification before a magistrate that is central to the fourth amendment * * * there is no need to be satisfied with lesser standards in this area." 263 U.S. at 272. A warrant to enter based on reasonable grounds is required under the English Foods and Drugs Act. Food and Drugs Act, 1955, 4 and 5 Eliz. 2, C. 16, sec. 100(2). See Waters, "Rights of Entry in Administrative Officers," 27 University of Chicago Law Review 79 (1959).

applicable to all three substantive title. The controlling concept is not simply a food, a drug or device or a cosmetic. Instead, it is an "article".

For this historical reason alone the factory inspection provisions, applicable alike to food, drugs, devices, and cosmetics, are presently found in only a single section, section 704.

But the drafting conveniences which may have been appropriate more than five decades ago are not necessarily rigidly applicable today. In a statutory edifice now covering 92 columns of text, the primitive concept of treating alike for every regulatory purpose products as disparate as drugs and devices, foods, and cosmetics, is hardly necessary.

Even more, it offers no basis for a bland assumption that any degree of factory inspection possibly required by one type of product must automatically be applied to all others.

NO SHOWING OF NEED

Apart from all problems of constitutionality, it is assumed that Congress does not enact sweeping controls, comprehensively invading every private enterprise, without a complete demonstration of need.

In the present instance, the first suggestion that factory inspection of food plants needed to be extended to a sweeping search and seizure of all records and papers was contained in a communication to the Speaker of the House by Secretary Arthur S. Flemming dated January 17, 1961. This proposed a more limited form of expansion of factory inspection than is contained in title II of H.R. 11581. In support of this proposal, Secretary Flemming stated:

"Amendments (a) to extend the factory inspection provision of the act (sec. 704) to all records, files, papers, processes, controls, facilities, and things bearing on violations, or potential violations of the act and (b) to clarify the factory inspection provisions by expressly including consulting laboratories. (The first of these is *not limited* to inspection relating to *drugs*, although the immediate occasion for it arises in connection with drug manufacture, because for *obvious reasons* the same authority is needed for other articles subject to the act.)" (Italics supplied.)

After more than 18 months of study, it is difficult to determine what reason exists for the present proposal, let alone reasons which are obvious for the wide ambit of authority asked to rummage in all of the files. Instead, the requested inquisitorial power over every food factory appears to be both unwarranted and unnecessary.

Clearly, the request cannot rest upon any need for greater control of plant sanitation.

The outstanding record of American food processors and manufacturers is widely acknowledged by all responsible authorities, including the Food and Drug Administration itself. In a recent speech delivered by Kenneth L. Milstead, Deputy Director of the FDA's Bureau of Enforcement, it was said:

"There is no question that the American people have the purest, safest, most nutritious food of any people on earth. Members of the food industry can be proud of the contribution they have made to the health and well-being of our people."

Examination of raw material receipts and scrutiny of plant operations were the controlling bases for the 1953 amendment, and the authority then given has been admitted by the FDA itself to have been adequate.

It has been suggested that bacteriological contamination has now assumed greater importance with the development of convenience foods. But this again is related to sanitation and the adequacy of processing equipment, both of which are discernible under the present factory inspection authority.

It has also been urged that the food and drug inspector must be able to determine the qualification of food plant employees. Presumably this underlies the requested authorization to rummage through all personnel records. One hardly needs to be a Jacksonian to wonder why it is necesary for a food and drug inspector to determine the educational qualifications of workers employed in canneries, dairies, or other food factories. The competency of food plant employees can hardly be determined from their paper records.

Beyond this, for what purpose should a food and drug inspector be given access to the employment history—education, salary, previous employment—of every plant employee? The manufacturer remains absolutely responsible—both criminally and civilly—for what is produced.

Is FDA authority to extend to telling the manufacturer, through search of personnel files, who is or is not to be employed?

This leads to an essential examination of three other questions on this bill.

In the first place, the committee must insistently ask what is to be done with the information obtained by a fishing expedition through the files of every food manufacturer.

Subsection (b) of section 704, as proposed to be amended, requires that the inspector make a report in writing to the owner. In the case of the food plant, that report need cover only improper raw materials or insanitary conditions. In the case of drugs, there are additional items for the report, but for foods only data that can be visually observed, and not information dredged from the files and private papers, are to be covered in the required report.

What, then, is to be done with what information may be turned up in the files? The information taken from the files and private papers—on the theory that it might relate to an actual or potential violation—can of course be used for criminal prosecution. The fishing expedition purpose of this phase of the requested authority thus becomes obvious.

Nor can any real need for the unprecedeneted and unlimited paper search, here asked to be authorized, be found in the constantly reiterated suggestion that only the "shady operator" or the "corner cutter" or the food plant operator who has something to hide can possibly object to this proposal. That argument is usually buttressed by reference to the recognized fact that in the happy cooperative atmosphere that has prevailed in the food industry, many companies voluntarily supply information to the FDA far beyond the scope of the authorized factory inspection.

But the committee must understand that it is not those who have something to hide who are here objecting to this unnecessary and unlimited intrusion into their private affairs. And the distinction between cooperation and unlimited compulsory search of all of one's papers is a difference fundamental to the American constitutional system.

Indeed, from this point of view the present proposal would frustrate rather than advance the purposes of the act. This unlimited search proposal would provide no significant additional safeguards against the operations of questionable or marginal manufacturers, but would intsead seriously interfere with the operations of reputable manufacturers. In all likelihood, it is the marginal operators who maintain a minimum number of processing, testing, and control records. If it is their purpose to skirt the requirements of the act, it cannot be expected that they would keep in their files documents that would establish proof of their violation.

On the other hand, the proposal before this committee would fairly seriously affect the operations of most food processors who do their best to produce wholesome, high quality products; for it is these manufacturers who maintain the most comprehensive and accurate files and records.

Most food products necessarily derive from natural commodities raised in an external environment. The processor must subject these natural commodities to high-speed, efficient processing techniques that will provide consumers with a high quality, wholesome finished product. A necessary adjunct to this increasingly complex processing operation is the maintenance of careful quality control procedures, testing techniques, and statistical methods, all designed to assure the wholesomeness and quality of the finished product.

As this committee well knows, the act, with respect to food, relates not only to questions of safety, but it is also concerned with what are commonly referred to as economic and aesthetic violations. In fact, safety is seldom a factor in the enforcement actions brought by the FDA against food products. Food adulteration cases with few exceptions involve questions of aesthetics or deception rather than safety.

But even though questions of safety are seldom present, any violation of the act, no matter how technical or unintentional, exposes the responsible party to criminal prosecution, heavy fines, and even jail sentences. Past FDA enforcement practices make it clear that these criminal sanctions are not reserved solely for adulteration cases involving a question of safety.

The controls and records of food manufacturers that are designed to assure a high level of uniformity and quality and to guarantee the safety of the products produced, also are effective in reducing to an absolute minimum the opportunity for a technical, unintentional violation of the aesthetic and economic provisions of the act. These controls and records have proved highly successful. It is now proposed that FDA inspectors should be granted access to the wide variety of records and files maintained by food processors. It

is out firm conviction that the only result of this grant of unprecedented authority would be to interfere with the maintenance of these records and the operation of carefully designed quality control techniques.

Processors' records also deal in many instances with the raw product as it is received in the plant. These are working papers. Because these commodities are natural commodities raised in an external environment, close questions are often presented as to whether their use will result in an aesthetic adulteration of the finished product. On many occasions, it is determined on the sorting table that the particular raw product will not be used, but the records will not reflect that action. One does not count every imperfect pea, bean, or tomato removed on the sorting table. Inspectors' access to these records on raw material receipts will do no more than raise unfounded suspicions on the part of inspectors, and expose processors who have taken the greatest pains to the risk of criminal prosecution for violations that may have no real basis in fact.

We cannot too strongly emphasize our concern that this unlimited search authority, if granted to FDA inspectors, will have principal impact upon reputable manufacturers. In 1953 the FDA asserted that its primary concern was careless and unscrupulous manufacturers, and this claim has now been repeated as the basic reason for this legislation. It seems clear, however, that no amount of FDA access to processors' files will improve upon the efforts already being taken by the great bulk of this country's food processors. Instead, the effect will be to discourage some manufacturers from keeping records, and the bill will have virtually no impact upon careless or unscrupulous operators. If this legislation is in fact aimed at marginal manufacturers, it plainly will not achieve its intended purpose.

THREAT TO TRADE SECRETS

Unrestricted access to FDA inspectors to files and records of food manufacturers will unnecessarily expose vital trade secrets and will seriously threaten the very existence of those companies hat depend upon carefully developed recipes and processing techniques. Recipes and other trade secrets involved in the manufacture of food products are with few exceptions entrusted only to a relatively small number of personnel in each company. It cannot be questioned that trade secrets such as these are valuable property rights that benefit not only the company involved but also the consuming public.

The taste and flavor of a food may be dependent upon the quantity of spices which are included, or, as every housewife knows, its consistency and color, upon the order and manner in which the ingredients are mixed, or the manner of preparation. Under the present factory inspection authority, all of the raw materials can be checked for wholesomeness and method of storage and handling; all of the equipment can be examined and its adequacy and conditions of use determined; and all of the packaging and labeling verified.

Why the public health or safety warrants the further examination of recipes, manufacturing procedures specified, or other trade secrets is difficult to discover. As to the dangers of this power, it must be remembered that today's inspector may tomorrow be the employee of a competitor. If he is, he can hardly be expected to brainwash himself of every recipe, formula, personnel record, or trade secret that he has encountered.

It is no answer to refer to section 301(j) of the Food, Drug, and Cosmetic Act or to section 1905 of title 18 of the United States Code, both of which provide criminal sanctions against the exposure of trade secrets obtained in the course of carrying out official responsibilities under the act. Research has uncovered no instance in which these sanctions have been invoked. The proponents of this legislation cite the absence of prosecutions as a basis for concluding that no such disclosures have ever occurred, but it is more likely that no cases have been brought because it is impossible to know whether a technical advance or use of an ingredient has resulted from a competitor's research or from information improperly or illegally obtained.

At any rate, the question is not necessarily one of outright exposure of trade secrets by Federal inspectors. We do not see how criminal prohibitions can force an inspector to erase from his mind trade secrets he has picked up in the course of his examination of confidential company records. If he is subsequently employed by a competitor of that company, we do not believe that the inspector's disclosure of this information to his new employer could ever be unearthed.

CONSTITUTIONAL OBJECTIONS

We do not question the sincerity of those proposing title II or their belief that in some cases their enforcement job would be facilitated by its enactment. But as has been observed, "The official's measure of his own need often does not square with the Bill of Rights" (359 U.S. at 382).

As we have already noted, the unprecedented search authority sought in this bill raises the gravest constitutional doubts—doubts which were uppermost in the mind of this committee when it formulated the present inspection provisions in 1953.

Indeed, it was to avoid these constitutional difficulties that the specific requirement was imposed that the physical inspection be made "within reasonable limits and in a reasonable manner" (See H. Rept. No. 708, 83d Cong., 1st sess. (1953), page 7)). As repeatedly stated in the debates, inspection of documents and records was not regarded as "reasonable" and was therefore foreclosed (see 99 Congressional Record 8991, 8999, 9007 (1953)). Thus Congressman Priest was able to say that because the bill did not provide for the inspection of documents and records, it was "an inspection bill and not a search and seizure bill" (99 Congressional Record 9000 (1953)).

Even with these important limitations on administrative power, we have also noted that there were many legislators who had substantial apprehensions as to the constitutionality of the provision enacted in 1953.

Now, however, a bill is proposed which would sweep aside every one of those limitations and, along with them, would attempt to sweep aside the constitutional rights which are protected under the present statute.

An analysis of the constitutional issues centers in the fourth amendment which prohibits unreasonable searches and seizures. That amendment, which lies at the heart of the basic constitutional protection granted by this part of the Bill of Rights, has consistently been held to apply not only to natural persons, but also to organizations of natural persons, that is, companies, whether incorporated or not (see e.g., *Hale* v. *Henkel*, 201 U.S. 43 (1906); *Silverthorne Lumber Co.* v. *United States*, 251 U.S. 385 (1920)).

It is, of course, true that the protection of the fourth amendment is not identical for individuals and business organizations where there is a court subpena or a specific administrative order to produce documents issued by a duly authorized agency of the Government. Compare *Boyd* v. *United States*, 116 U.S. 616 (1886) (involving a natural person) with the following cases involving business organizations: *Wilson* v. *United States*, 221 U.S. 361 (1911); *Oklahoma Press publishing Co.* v. *Walling*, 327 U.S. 186 (1946); *United States* v. *Morton Salt Co.*, 338 U.S. 632 (1950).

These specific administrative orders to produce designated documents are sometimes called constructive searches.

As stated in the *Oklahoma Press* case, such constructive searches, where there is no actual physical entry and search but only a judicially enforcible order to produce, do not necessarily pose the basic threat to liberty which the fourth amendment was designed to prevent. They usually require an application to court for their enforcement, and it is possible to review judicially their scope and relevance.

As the cases show, even a specific order to produce records of a business organization is subject to constitutional limitations. The documents ordered to be produced must be reasonably relevant to the matter under investigation and the order must not be unduly burdensome. The significance of these requirements is highlighted by recent decisions striking down orders to produce where the purpose of the investigation was not adequately stated in the orders. *Montship Lines, Ltd.* v. *Federal Maritime Board*, 295 F. 2d 147 (D.C. Cir. 1961); *Hellenic Lines, Ltd.* v. *Federal Maritime Board*, 295 F. 2d 138 (D.C. Cir. 1961).

Neither court subpenas nor other orders to produce papers are wide open.

No subpena from a court or administrative order, phrased in the language in title II of this bill, could constitutionally surmount the fourth amendment.

But, far more important, what is here involved is not an order to produce specific documents, but an actual search, involving physical entry and demand of unlimited access to records and files. Here the courts have been especially vigilant in their protection of the citizen and in their careful scrutiny of governmental action. In this area, the courts have refused to sanction administrative excesses committed against both individuals and groups of individuals banded together in a business organization. See, e.g., *Silverthorn Lumber Co.* v. *United States, supra; Go-Bart Importing Co.* v. *United States*, 282 U.S. 344

(1931); *Hearst* v. *Black*, 87 F. 2d 68 (D.C. Cir. 1936). In no instance have unlimited fishing expeditions been permitted.

One of the most important decisions is the landmark case of *FTC* v. *American Tobacco Co.*, 264 U.S. 298 (1924), in which Justice Holmes, speaking for the Court, laid down some basic principles which are particularly relevant here. Although the specific facts of the case involved only a court order to produce certain records before the FTC, the Commission argued before the Court that it had "an unlimited right of access" to all corporate records and documents which related in any way to any possible violation of the governing law. It was largely to this extravagant claim that the Court addressed itself in holding that no such authority was granted by law. As stated by the Court (264 U.S. at 305–06):

"Anyone who respects the spirit as well as the letter of the fourth amendment would be loath to believe that Congress intended to authorize one of its subordinate agencies to sweep all our traditions into the fire * * * and to direct fishing expeditions into private papers on the possibility that they may disclose evidence of crime * * *. It is contrary to the first principles of justice to allow a search through all the respondents' records, relevant or irrelevant, in the hope that something will turn up."

That these principles have a continuing vitality, and that courts are still vigilant in protecting private individuals and business organzations against unlimited Government access to files and records, is demonstrated by such recent decisions as *Hunt Foods & Industries, Inc.* v. *FTC*, 286 F. 2d 803 (9th Cir. 1960), cert. denied, 365 U.S. 877 (1961); *United States* v. *International Nickel Co.*, CCH Trade Reg. Rep. par. 70,279 (S.D. N.Y. 1962).

But the present bill seeks to give to the Food and Drug Administration precisely the clearly unconstitutional kind of authority physically to ransack records and files. As the courts have so frequently made plain, these provisions raise basic questions under the fourth amendment.

No discernible limits have been set on the scope of this authority. It is difficult to conceive, in the case of such an all-embracing statute, that there would be any document which would not "bear" on a violation or "potential" violation of the act, or any file which would be immune from Government search. The criterion in the bill is "bearing" on a "potential" violation of a sweeping statute—with criminal prosecution based on strict liability. Such arbitrary and unlimited power is not consistent with the fourth amendment—which was designed to prohibit this very type of sweeping executive warrant to enter and to search for evidence under a criminal statute.

No relevant analogy can be drawn between the authority this bill would grant, and the authority to require inspection of products and physical conditions. That limited authority was granted to FDA by this committee in the 1953 amendment. The National Canners Association fully supported it as necessary and proper when carefully limited in scope. The validity of such specific authority to inspect commodities and to establish appropriate standards through inspection was confirmed by the Supreme Court in *Currin* v. *Wallace*, 306 U.S. 1 (1939).

But the present bill, which would extend this authority to all "things," including documents and records of every conceivable kind, goes far beyond any constitutionally recognized governmental power. These documents and records have traditionally stood on a different footing from inspection of physical conditions involving sanitation and from the actual products to be shipped in commerce.

Similarly, no analogy can be drawn between the unlimited searching of files authority sought here and the authority physically to inspect premises that was upheld in the recent case of *Frank* v. *Maryland*, 359 U.S. 360 (1959). That case, which has been characterized as "the dubious pronouncement of a gravely divided Court" (364 U.S. 269), involved the inspection of a home for rodent infestation. A divided Court upheld the power to demand a physical and limited inspection of premises, even in the absence of a search warrant, when there was a specific complaint, external evidence of rats, and hence reasonable grounds to believe that rodent infestation existed inside the premises.

One of the factors relied upon by the Court was that the purpose of the inspection was not in any sense to search for or seize evidence that could be used in a criminal prosecution. The only possible result of the rodent inspection was an official warning to clean up, which if unheeded could lead to criminal action. The criminal action would not follow on evidence derived from the inspection itself.

The differences between this bill and the authority upheld in the *Frank* decision emphasize the constitutional difficulties in the present proposal. First, the *Frank* case did not involve unlimited access to documents and records, but only the historically accepted power to enter and physically to inspect sanitary conditions on the premises. This is the same limited power to inspect that is granted by the present section 704 of the Food, Drug, and Cosmetic Act. It is not the wide-open search authority asked in this bill.

Second, the authority exercised in the *Frank* case was premised on the existence of probable cause, whereas the authority sought here would require no cause of any kind. Finally, one avowed purpose of the authority which this bill would grant, unlike the authority exercised in *Frank*, is to obtain evidence for purposes of criminal prosecution. It was the absence of that purpose that was crucial in the *Frank* case. It is the presence of this purpose here that gives rise to serious and grave constitutional difficulties.

These constitutional questions which caused such concern to this committee and to the Congress in 1953, and which resulted in a carefully worded and precisely limited inspection power, still exist today. There has been no change in the controlling constitutional principles—principles which were recognized then and should be recognized now.

In view of the compelling reasons outlined above for rejection of the proposal that food plant records and files be thrown wide open to FDA inspectors, we strongly urge that present food factory inspection authority as contained in section 702 of the act remain unchanged.

Mr. AUSTERN. With your permission, I shall briefly summarize and underscore the canning industry's objection to title II of H.R. 11581.

That title begins on page 30 of the bill at line 6. The focus of our objection is to the amendments made to section 704 of the existing law by the language on page 31, lines 1 through 9.

Mr. Chairman, for the first time in 55 years the National Canners Association finds itself in direct, fundamental, and complete opposition to a proposal by the Food and Drug Administration.

That opposition is even more striking when this committee remembers that in 1953 we were before you sponsoring, side by side with the FDA, the amendment to this same section 704, which gave the FDA the right to enter and to inspect a food factory and made it a criminal offense to refuse entry.

We are talking today about food, not drugs or cosmetics.

The CHAIRMAN. Let me get this correct, so we can follow you.

Did you say that you came to the Congress in 1953 with an amendment to the Food and Drug Act?

Mr. AUSTERN. Yes, sir.

And we sponsored the change in section 704, which made the refusal to permit inspection a crime.

We were here side by side with the FDA to support that. Today we are here in complete, fundamental, and thorough opposition to the changes now proposed to be made in section 704.

The CHAIRMAN. That was adopted in 1953?

Mr. AUSTERN. Yes, sir.

The CHAIRMAN. All right.

Mr. AUSTERN. Now, to point up the key issues, may I pose two questions for each member of this committee:

If the Fire Marshal of the District of Columbia came to your office here on the Hill and wanted to come in to make a physical inspection as to whether there were any fire hazards, would you let him in?

We think you would.

But if some branch of the executive department asked for statutory authority to enter your office regularly and to go through every one of your files—every letter, paper, memorandum, or record—to de-

termine whether you and your office staff were complying with, or might be violating, any of the laws bearing on the conduct of Congressmen, would you question whether that was desirable legislation?

Would you concern yourself whether the sweeping authority sought was a prohibited search and seizure under the fourth amendment?

Would you not take a hard look as to the asserted necessity for that type of recurrent and regular fishing expedition through all of your office files?

And if the laws, under which you and your office staff might be criminally prosecuted on the basis of what an inspector could find by rummaging through your files, if those laws were not specific, but only general and vague, would you not worry even more about this invasion of the traditional American right to be free from unreasonable searches and seizures?

As James Otis put it on this very point 185 years ago, would you want to grant authority to any agency which would "place the liberty of every man in the hands of every petty officer"?

Even more striking, Mr. Chairman, suppose those statutes, controlling what a Congressman and his staff might do, were enforced under a rule of law which meant that the violator can be convicted without any evidence of intent, or motive, or knowledge of the facts, and even where the most abundant care to avoid wrongdoing has been exercised?

That rule would mean that the periodic search through all of your office files might produce evidence that would permit a criminal prosecution merely on what turned up in the files without any opportunity for justification.

Would you not take a hard look at what is being proposed?

Those inquiries, Mr. Chairman, may be helpful in focusing on why the food industry objects to these proposed title II amendments.

This new authority asked, regularly to go through every record, file, and paper, is an enforcement authority applicable to every section of this food and drug law. It is not limited to drugs.

To appreciate the meaning of the proposed amendment, two salient and, I believe, uncontradicted features about the whole act must be recalled by this committee.

First, as applied to food, most of its prohibitions are stated only in general terms.

What are called adulterations are controlled by general phrases, such as "may have become contaminated," or "make it appear better or of a greater value than it is."

Let me make it clear that nothing in this discussion about the authority to rummage through files has anything to do with the wholesomeness of any food or the sanitation in any food factory.

There is abundant authority to cover that area in the present factory inspection authority given in 1953 to the FDA.

Moreover, the controlling rules on food production under this law usually fall in the area of esthetics, not gross contamination as you would ordinarily think about it.

These rules impose, and, we believe, properly impose, manufacturing standards of cleanliness far and above what any housewife demands in her kitchen.

But the point must be emphasized that this law, whose violation is a crime, is not specific.

Many of its requirements are in the most general terms. Their interpretation is constantly changing; their meaning is always being expanded.

On what is called misbranding, the controlling statutory provisions are even more general.

"Prominence," "purports to be or is represented as," and other inherently vague phrases are legally controlling.

In short, in this complicated and comprehensive law, occupying this entire printed pamphlet, the do's and don'ts are not specific.

But the second basic point to remember is that this statute is a criminal law. It imposes what is called strict and absolute criminal liability.

Intent to violate need not be proved. Motive is immaterial. Knowledge of the facts constituting the crime need not be established.

Nor is it even open for the one being criminally prosecuted to show that the highest standards of care were exercised.

If an adulteration or misbranding under any one of these sections occurs, that alone makes the conviction.

That kind of absolute criminal liability, gentlemen, is the same as is imposed on a man who sells liquor to a minor. He is guilty no matter how old the customer looked, whether he had a beard, and even where he presented a forged identity card.

Under this entire Food and Drug Act, the same strict and absolute criminal liability applies.

Individuals and companies can, and have been convicted in the absence of knowledge or any intent to violate and despite the highest standards of care.

Indeed, you may be surprised to know that individuals have been held criminally liable under that strict rule where their companies were acquitted on the same charges.

As Mr. Justice Frankfurter said in that case:

> This law dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing.

That need not be shown.

As the committee may know, that kind of absolute criminal responsibility has worried Congress since 1906. It rests upon the paramount necessity of "protecting the public health and safety." It has been severely criticized by many legal scholars, particularly where embodied in this very general statute that deals with esthetic and economic requirements even more than it does with public health and safety.

No one in the food industry is arguing here today that this rule of strict criminal liability should be changed—harsh as its results often are.

We are insisting that when you come to look at the proposal now being advanced to permit a virtually unlimited fishing expedition into all of a company's files and records, you keep in perspective the unique kind of criminal law with which you are dealing.

In that connection, Mr. Chairman, we were struck by the fact that throughout his entire testimony on Tuesday, the Secretary never once referred to the fact that this was a criminal statute.

He did not deal with the use that could be made in criminal prosecutions what was turned up in regular fishing expeditions through a man's files.

Turning directly to title II, the vital question is the difference between an "inspection" and an unconstitutional search and seizure.

That question is also not new to this committee. In 1953, I am confident the chairman will recall, when the authority to enter to make a physical inspection was made compulsory and refusal made a crime, the same question was heatedly debated.

The committee will remember that the majority were willing to go along only because the compulsory inspection was limited to a physical inspection of the factory, and what was in it.

This committee and Congress not only made it perfectly clear that the inspection was limited in scope, but it also went further and insisted that even this limited physical inspection be made at "reasonable times and within reasonable limits and in a reasonable manner."

You will find what you enacted in 1953 set forth on page 30 of the bill at lines 14 through 25.

You will notice on lines 24–25 that the entry and inspection you provided was limited to inspecting the factory premises and "all pertinent equipment, finished and unfinished material, containers, and labeling therein."

Even so, the chairman I am sure will recall, in 1953 a minority of this very committee was sorely troubled about the Bill of Rights.

They insisted that because compulsory entry and inspection could yield evidence for a criminal prosecution, the traditional requirement of a search warrant was appropriate.

By the way, gentlemen, that search warrant is required in England where there is no fourth amendment.

But now you are asked to overthrow all of your careful work and consideration in 1953.

You are asked to include under compulsory entry and inspection:

all things, including records, files, papers processes, controls and facilities.

An inspector can come in and regularly rummage through every record, file, letter, paper, bill, invoice, formula, and even personal employment records. He can come back time and again.

The only limitation on what he can demand to see is that the records, papers, and files "bear" on a violation or a potential violation of the act.

That is no limitation at all.

As the FDA interprets the many provisions of this comprehensive statute, there is no paper or any file that it would not assert bears on a potential violation of the act.

The penalty for refusing to let the FDA inspector rummage through the files is a criminal prosecution under section 301(f) and fine or imprisonment, or both.

The information obtained by rummaging through all the files can be used to prosecute both the company and employees under that rule of absolute criminal liability embodied in the whole law.

No wider, more sweeping, and startlingly inquisitory power has ever been asked.

We object to that proposal on the ground that it plainly violates the fourth amendment in the Bill of Rights.

We believe that there is no demonstrated need for that expansion of inspection so as to convert it into an unlimited search and seizure of all records and papers on a regular and recurring basis.

We believe for the reason spelled out in our statement that it will frustrate rather than foster the purposes of the act.

As to any need, we have heard nothing that supports this request, even if it were constitutional.

This proposal is not necessary for the protection of the public against unwholesome foods or insanitary conditions. Not only can, and does, the present authority to inspect bring those to light, but the FDA has also repeatedly made it clear that the American food supply is wholesome and clean.

The canning industry and National Canners Association, I might add, have been repeatedly commended by the FDA for their work in that area.

Now, on Tuesday, the Secretary, in response to the chairman's question, talked about the asserted need to get shipping records.

He read from some report about a cannery where a factory inspection had indicated some insect damage in the canned product.

The Secretary said that the canner had refused to furnish his shipping records and that refusal had impeded enforcement because the particular packer was using his own trucks.

The committee should be interested in at least five things about that report.

In the first place, the insect damage talked about, despite the colorful adjectives employed, probably involved levels of insect damage that no housewife would concern herself about in her own kitchen.

As I noted, the canning industry operates under far higher standards than any housewife employs in a kitchen.

The CHAIRMAN. The terms the Secretary used the other day, I think, was that any housewife would be concerned about it.

Mr. AUSTERN. It was pretty plain.

The CHAIRMAN. Are you saying that it contained something that no housewife would be concerned about?

Mr. AUSTERN. If you will give me 5 minutes, I will come to that point, too, sir.

But, Mr. Chairman, the point that the Secretary made was that because that canner was using his own trucks and had refused to give his shipping records, that impeded enforcement.

Now, sir, you heard that complaint made. I would like to give you four reasons why that complaint is unfounded.

First of all, under section 404 of this law the FDA is authorized to put under immediate emergency permit control any food factory in which the food might be contaminated with micro-organisms. That would immediately require a permit from the FDA to ship anything further in interstate commerce.

Next, under section 302 of the present law, the FDA could get and in some cases has gotten an injunction completely prohibiting the further interstate shipment of any products until the conditions were changed. It could, in effect, have closed the plant.

Next, under section 402(a)(4), that processor could have been criminally prosecuted on what they say the physical inspection is said

to have revealed. The FDA could readily have gotten a warrant for the specific shipping records. Why did it not do so?

Even more striking, and possibly a clue, perhaps the Secretary forgot that under section 703 of the existing law the FDA can get shipping records from any carrier. To do so, it must make a written request and those records then cannot be used in a criminal prosecution.

Even if that packer was in part using his own trucks, section 703 now contains the authority to demand the shipping records of any carrier, public or private.

But, again, please note that if those shipping records were gotten under section 703, they could not be used to prosecute criminally. Maybe that affords a clue as to why the shipping record authority, which is now in the law, was not used. The committee may remember that the Secretary never mentioned those abundant powers in this statute.

As a practical matter, Mr. Chairman, as Commissioner Larrick told you on Tuesday, canners usually supply their shipping records.

The FDA inspector can always go down to the railroad station or the trucking office and get them anyway under section 703. He has got complete and abundant authority.

It is somewhat difficult, sir, to understand why that single, isolated and odd instance discloses any real need for a sweeping and recurrent fishing expedition into every record, file, and paper in every food plant.

I will not rehearse the fact that that dragnet appears to have emerged out of the extensive Senate hearings and the controversy about the registration of manufacturers of prescription drugs.

As Commissioner Larrick so aptly said:

> There are no drugs that are 100 percent safe. It is always a relative proposition.

Well, foods, sir, are not drugs, and if the committee wishes to pursue the obvious differences between foods and prescription drugs, we have dealt with that beginning on page 6 of our statement.

There are, however, some points about food that warrant brief and specific comment in connection with this amendment.

It has been said that only the shady operator, only the food manufacturer who has something to hide, can possibly object to this proposal.

It is not the shady operator who is here objecting. Instead, it is the entire canning industry whose performance has been constantly commended by the FDA itself.

Next, I invite you to examine our statement where we demonstrate, we believe, that a recurrent and roving expedition through the private papers of every company will not foster enforcement against the few shady operators who may want to cut corners. Shady operators notoriously do not maintain files and records showing their own misconduct.

But, more fundamentally, that argument that only the criminal fears an unlimited and repeated rummaging through all of his files cannot serve, we submit, to justify an invasion of the basic rights protected by the Federal Constitution.

If the physical inspection of a food factory, or the analyses of samples produced, yields reasonable grounds to suspect a violation, the FDA can readily get a warrant from either a Federal or a State court to examine any specific records that might disclose the violation. But fishing expeditions through everybody's files, on a regular and continuing basis, cannot be justified either, by characterizing the need as convenient.

As Mr. Justice Douglas once observed:

> The official's measure of his own need often does not square with the Bill of Rights.

Finally, to go back to my opening illustration, I doubt that many Members of this Congress would accept the argument that some executive department should be authorized to roam through the files of every Congressman because only those who were violating some law would have any real objection to doing so.

As to the argument that it is necessary for the FDA to examine employee records, we also deal with that one in our statement. Suffice it to say that the qualifications of anyone to work in a cannery, or any food factory, or, indeed, to inspect it, can hardly be discerned from reading his paper employment record. It is the owner of the factory who is made absolutely criminally and civilly responsible for what is produced.

The FDA does not, and should not, have authority to decide who is or is not to be permitted to work in a food factory.

Next, Mr. Chairman, I invite you to look on page 31 at lines 14 through 23. That is the language which the committee insisted be put into this factory inspection section in 1953. It requires that the FDA inspector give the plant owner a report in writing about what his inspection turned up on bad materials or insanitation in order that the conditions might be noted and remedied.

But there is nothing included in this bill that requires the inspector telling anyone what that tour through the files and papers has brought to light.

But that information, so obtained, can be made the basis for a criminal prosecution.

Last Tuesday, Mr. Springer asked the Secretary some questions about what might be done with the information obtained by rummaging through the files.

There was, of course, no mention that it could be used in a criminal prosecution.

But the Secretary went on to urge that the FDA inspector had no right to reveal to the public the information that might be obtained in rummaging through the files, and he went on to say that the provisions of section 301(j) of this law would protect against that happening.

I hope this committee will examine section 301(j) both as it now is, and as you propose to amend it in this bill in the section, at the end there, section 202. That section, Mr. Chairman, you will discover, provides that the inspector is prohibited only from using the information "to his own advantage."

He is specifically authorized to turn all of it over to the Secretary or to the FDA for criminal prosecution or for any other purpose.

And, sir, under section 705 of this law, the Secretary and the FDA

are entitled to publish anything where they conclude that "gross deception to the consumer" might exist. No one can review the Secretary's or the FDA's judgment on what is to be published.

I suggest with all respect that if, for example, consumer complaints were rummaged, there is nothing in the law to protect or to control that information, or any other, from being made the subject of an FDA press release.

I doubt that any responsible FDA Commissioner would do so, but we are talking about authority and a constitutionally guaranteed protection, not administrative discretion.

Now, sir, even casual publicity can be damaging, and this may interest you, Mr. Chairman, in the light of your earlier question.

On Tuesday the committee heard a canner who was mentioned by name, talked about, and you also heard that man's pack talked about in most derogatory terms.

If you recall what was read by the Secretary, the clear meaning was that everything that named canner packed was unfit.

He is not a member of NCA. I know nothing about him or his plants. But out of curiosity I had the official FDA notices looked at. Now, there was a third seizure of 600 cases in June 1961. That is FDA Notice 27–381. That seizure was not contested.

What do you suppose the FDA did with those 600 cases, Mr. Chairman?

The notice recites "delivered to charitable institutions." That means for consumption by hospitals and other institutions. Well, so much for that.

I would like, finally, if I may, briefly to summarize the core of this constitutional argument which we seriously urge.

The fourth amendment prohibition against unlawful searches and seizures protects both individuals and companies.

Even under a court subpena, when the court issues the subpena for documents, or an administrative agency orders someone to produce specific papers, it is well established that the constitutional protection applies.

A written demand for documents must be specific. It cannot be too broad. It cannot be a fish net that covers everything.

The specific documents ordered to be produced must be relevant to what is being investigated. The demand cannot be unduly burdensome.

More than 20 years ago, the Supreme Court made it clear that "an unlimited right of access to every piece of paper in order to see if there is any possible violation of law" would trench on the fourth amendment.

As Mr. Justice Holmes so aptly put it, there can be no—

> fishing expedition into private papers on the possibility that it may disclose evidence of crime * * * and in the hope that something will turn up.

Mr. Chairman, no court subpena, no written administrative order to produce phrased in the language of what you are here asked to authorize would survive a constitutional challenge.

But the constitutional vice here goes much deeper.

Here you are asked under the guise of an "inspection" to authorize the recurrent physical ransacking of all records and files by an FDA inspector.

There are no real limits, as I pointed out, on what can be included.

What is really being sought here is not the right to make a legitimate inspection, but authority to engage in plainly unconstitutional search and seizures, and, even worse, that authority is backed by a criminal sanction.

If a canner, big or small, refuses to permit the inspector to roam through the files and papers whenever he comes in, that is a crime. In our statement, sir, we give you the judicial authorities, and there is no need for me to elaborate them here.

I will also pass, because we have covered it in our statement, that you may be told that there are other inspection statutes.

Well, of course, that is not the same as a periodic and unlimited search through files.

You may also be told that there are some Federal statutes that permit access to records. Please examine them carefully. You will find that the authority they grant is wholly different than this title II.

Most of them relate to regulated industries where a license or a franchise is necessary in the first place to go into business, but, more important, the access order requires an application to a court for its enforcement.

It is, therefore, possible judicially to review the scope, the reasonableness, and the relevance of what is asked.

One does not, under any existing law, act to the peril of a criminal prosecution if he disagrees with an inspector. We know of no case, Mr. Chairman, where the Supreme Court has upheld as constitutional, under any statute, the administrative power to enter physically and regularly to demand virtually unlimited access to search through all records, papers, and files, and all things therein.

Consequently, sir, with all respect, the canning industry, and, as far as I know, the entire food industry, vigorously opposes title II of this bill.

There is no need for it, and while we do respect the sincerity, the high purpose, and the zeal of those who are asking for it, we are equally convinced that the proposal would frustrate rather than foster the purposes they want to achieve.

We are even more confident that this committee will not extend compulsory entry and inspection, now authorized to the fullest constitutional extent, and convert it into a sweeping and constant and recurrent search and seizure that is plainly contrary to the Federal Constitution.

We are confident, sir, that the committee would not do that even if this was the ordinary criminal statute. We hope that no one will even consider doing it on this comprehensive enactment, which bases criminal prosecution on absolute criminal liability without reference to motive, intent, knowledge of the facts, or any standard of reasonable conduct.

Thank you, sir.

The CHAIRMAN. Does that conclude your statement, Mr. Austern?

Mr. AUSTERN. Yes, Mr. Chairman.

The CHAIRMAN. Mr. Rogers, any questions?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mr. Austern, I appreciate your statement. I think you have brought out some very good points for the committee to consider.

I wondered how you interpreted the language on line 3 of page 31 of the proposed bill?

Mr. AUSTERN. Bearing on whether articles which are adulterated or misbranded, sir?

Mr. ROGERS of Florida. The language that I am concerned with are those words "which are adulterated or misbranded." In other words, do you feel that there must be a finding that articles are adulterated or misbranded before this, as you call it, fishing expedition into records and papers would be made?

Mr. AUSTERN. May I, without being captious, sir, suggest that you take a bearing on the word "bearing" on line 2, because that participle, as I interpret this proposal, modifies everything that follows it.

Now, bearing on whether articles are adulterated or are——

Mr. ROGERS of Florida. It does not say bearing on whether articles are adulterated. It says "bearing on whether articles which are adulterated."

Mr. AUSTERN. May I endeavor, sir, to answer your question without our getting into a discussion here of these semantics.

I have studied that language now for about 18 months. I have been privileged, sir, to talk with experts about it, including, I might add, some of those who will be responsible for enforcing it, and I am firmly convinced that in their view this provision—there would be no file one can find—this provision would cover anything.

I have asked about raw material prices, and they gave me a theory why that might "bear," in the words of this provision as to "prices at which goods are sold." They had a theory on that, also. Research, papers, all research work, might also bear on potential violations of the act.

Now, without going through what might appear to be somewhat tortuous language here, that seems to be the intent, and that, we are convinced, would be the interpretation.

Mr. ROGERS of Florida. Because I would be concerned, if there is a determination and they find goods that are adulterated or misbranded and then want to go in, to me, that would be a great difference from going in and searching to see if they can find something.

Mr. AUSTERN. Well, they have that authority, sir.

Can I refer you to section——

Mr. ROGERS of Florida. I am talking about this new authority, not what they have now, but the new authority that you are objecting to, namely that of letting them go in to look at records.

Mr. AUSTERN. They go in and get samples. If they look at those samples and there is an adulteration, why, they can seize everything of the same lot in that plant now.

They can get a marshal's monition and go in there and do it.

Now, you will hear——

Mr. ROGERS of Florida. Then you do object, as I understand it, if adulterated goods are found, even though they might now have the authority to go in and get records, if they find the adulterated goods, you still would object to giving them this authority, if they have found adulterated goods?

Mr. AUSTERN. Seizures, sir, I do not object to that. The canning industry has never objected to the seizure powers. We are as interested as anybody else in removing anything from the market that is unlawful.

What we are talking about here is to search, inspect "all things there including records, files, papers, processes, controls, and facilities."

I am not talking about a physical inspection of goods. If I can refer you back to page 30, line 25, I submit, sir, we have in the authority authorized by this committee in 1953, which we sponsored, the right to inspect finished and unfinished materials.

Mr. ROGERS of Florida. Yes.

But I am talking about where there is a determination that there are adulterated goods, sir.

Mr. AUSTERN. What determination, sir? Perhaps I do not understand the question.

Mr. ROGERS of Florida. Suppose they find on the shelves of a store adulterated goods.

Mr. AUSTERN. They now have the power.

Mr. ROGERS of Florida. All right, now let me finish, sir.

Mr. AUSTERN. I am sorry.

Mr. ROGERS of Florida. They find the goods.

Now, they want to go back and trace it and see how it has come about, and they come into the plant and say, "We would like to see the records that pertain to this," and this seems to relate to bearing on whether articles which are adulterated, not any other articles that may be produced, but the articles which are adulterated.

You seem to feel that you do not want them to have those records to see what has happened in that condition.

Now, if the articles are not adulterated, I certainly can see your position.

But where they have found adulterated goods on the shelves of a store being presented to the public, you still would not want them to come in and be able to trace those particular articles?

Mr. AUSTERN. I am embarrassed, sir, because if this section to which I have addressed myself for 35 minutes somewhat vigorosuly, is as narrow as you suggest it is, then apparently all of us, both in and out of the administration, have been misreading it, because if I understand the question, you are talking about the situation where the Food and Drug makes a seizure.

I call tell you from some 30 years' experience that if they make a seizure, they can file interrogatories and ask questions and get all of that information in the seizure proceeding.

Mr. ROGERS of Florida. Then why do you object to this?

Mr. AUSTERN. Because this is a fishing——

Mr. ROGERS of Florida. If they can do the same thing?

Mr. AUSTERN. As far as that is concerned, I am not even arguing that point on seizures.

They have got all the power in the world to go in and check the code numbers. If they find a parcel of goods with a code number in a distributor's warehouse and they want to go back to the plant to see how many of that code they have got, they are free to do it.

They have been free to do it since 1953, and we never opposed that authority.

Now, if that is all this means, I have been wasting my time.

Mr. ROGERS of Florida. Then you have no objection?

Mr. AUSTERN. No, sir.

Mr. ROGERS of Florida. You would have no objection, then, if this is restricted to goods that they have found that are adulterated?

Mr. AUSTERN. What is the "this," sir?

Mr. ROGERS of Florida. Whatever the goods may be, if they are adulterated.

Mr. AUSTERN. If they want to go look for goods with the same code numbers which are comparable to what they found in the trade, they have had the power.

I did not object in 1953. I do not object today.

But if the "this," if the antecedent to that pronoun "this," means that if they find something in the field and then want to come back to the factory at any time and rummage through every paper in the place, we object vigorously.

Mr. ROGERS of Florida. I do not think it implies that:

To inspect at reasonable times within reasonable limits and in a reasonable manner the factory—

and so forth,

bearing on whether articles are adulterated or misbranded.

Mr. AUSTERN. What, sir, do you do with the next "or," "or which may be manufactured or sold"?

Mr. ROGERS of Florida. "Introduced in interstate commerce," the misbranded article.

Mr. AUSTERN. And do you believe that the language beginning on line 4, "or which," that phrase, and the second phrase on line 6, "or are being manufactured," and particularly that wide-open phrase in line 9, "or otherwise bearing on violations or potential violations," that that must relate to some kind of a determination that there are adulterated goods?

Mr. ROGERS of Florida. Well, suppose this committee writes it that way.

Mr. AUSTERN. If you wrote it that way, I do not think we would talk too much.

Mr. ROGERS of Florida. You would not have any objection?

Mr. AUSTERN. I would not have any objection.

Mr. ROGERS of Florida. Thank you, Mr. Austern. Thank you, Mr. Chairman.

The CHAIRMAN. Do you think that they should have the authority to inspect such records and so forth, facilities and all, bearing on whether articles may or may not be manufactured?

Mr. AUSTERN. I am not sure, sir, that I apprehend what would be encompassed within such authority.

The CHAIRMAN. Apparently this would be intended for them to determine whether or not the given article may or may not be manufactured on the basis that it is not safe or should not be made available for human consumption.

I assume that is it.

Mr. AUSTERN. It does not say that. This statute is very complex. It deals with a great many more things besides what is fit or unfit for human consumption.

Under that authority they could come in and say: "We would like to see all your research because maybe you are about to make something. We would like to look at all your label drawings. Maybe

you are about to have a label which will not be sufficiently prominent."

The CHAIRMAN. I do not believe you comprehend what I have in mind, Mr. Austern.

Mr. AUSTERN. May I leave it this way, sir——

The CHAIRMAN. Should an agency have the authority to make a determination whether or not a particular article or product should be manufactured, absent any information that such article is contrary to the best interests of the public?

Mr. AUSTERN. What are they going to use that information for, a criminal prosecution?

The CHAIRMAN. No; that is not what I am talking about. If you would follow me, "and (2), to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, consulting laboratory, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein," and now this new language, "and all things therein (including records, files, papers, processes, controls and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale," would that not give the agency the authority to make a determination as to whether or not a particular article could be manufactured?

Mr. AUSTERN. If I have followed that——

The CHAIRMAN. Or am I reading the language wrong?

Mr. AUSTERN. Well, if I have followed that language, sir, I am constrained to say that in view of this absolute criminal liability, and since that information may be used for a criminal prosecuton, that that kind of "come any time you want, go through the files, if you say you want to look for something to determine whether it may be lawful," that violates the fourth amendment, and I cannot escape that conclusion on what I have read.

The CHAIRMAN. Thank you very much for your testimony, Mr. Austern.

Mr. AUSTERN. Thank you, sir.

The CHAIRMAN. Mr. Edward Brown Williams, general counsel to the National Association of Frozen Food Packers, Washington, D.C.

Let me say I personally am glad to have you before this committee to present testimony on this important subject. I know that you have given many years of very close study to these problems.

STATEMENT OF EDWARD BROWN WILLIAMS, GENERAL COUNSEL, NATIONAL ASSOCIATION OF FROZEN FOOD PACKERS

Mr. WILLIAMS. Thank you very kindly, Mr. Chairman.

I feel reasonably sure that this encounter will be pleasant.

I am appearing on behalf of the National Association of Frozen Food Packers, as you have stated, with respect to the same provisions of H.R. 11581 which Mr. Austern has discussed.

This association is a broadly based national association of the frozen food industry.

This is an industry, as you may know, with a very large production, which is now in excess of 7 billion pounds annually, with a total retail value of nearly $5 billion.

The CHAIRMAN. Talk a little louder, so we can hear you a little better.

Mr. WILLIAMS. I merely stated, sir, by way of introduction, that the association in question is a national association of the frozen food industry; that the industry has now reached a production yearly in excess of 7 billion pounds; that it has a retail value, this production, of nearly $5 billion.

Mr. Austern has, I think, very persuasively discussed such vital constitutional aspects of the proposed expanded inspection authority which would be granted under H.R. 11581. My statement will deal primarily with the practical results of the type of inspection which is now sought, certain other legal aspects of the matter, and the question of the need for the additional authority which the bill would provide.

The association supported the factory inspection amendment to the Food, Drug, and Cosmetic Act which was adopted by this committee and the Congress in 1953, after the original inspection provisions of the 1938 act had been declared invalid by the Supreme Court. This support was evidenced by a resolution of the board of directors of the association, which was communicated to the chairman of this committee by letter of April 21, 1953.

The association and its membership are opposed, however, to the extension of the authority of FDA to inspect food establishments, which is contained in section 201(a) of H.R. 11581.

The purport of that section has been stated by Mr. Austern, and I must say, with respect to the questions which Mr. Rogers raised with Mr. Austern, that I am somewhat bewildered about the point which Mr. Rogers was attempting to make.

If the purpose of this inspection is to determine whether or not there are goods in the factory or establishment which are adulterated or misbranded, and, therefore, violative of the statute, then all of the objections which Mr. Austern has made are fully pertinent, and I think it should be emphasized, as Mr. Austern mentioned, that there is an alternative authority in this provision.

The language which was read,

> authorizing inspection of all things in the factory bearing on whether articles which are adulterated or misbranded,

and so forth, is an alternative to

> otherwise bearing on violations or potential violations of the act.

As we understand this bill, its purpose is to permit inspection of all records and all papers in the establishment which bear on potential violations of this act in order to determine whether any potential violation of the act is inherent in the business operations of the firm.

The CHAIRMAN. Mr. Williams, I don't think that there has been a meeting of the minds as to just what Mr. Rogers had in mind.

As I understood him, I think what Mr. Rogers had in mind was this: Should adulterated products be discovered on the shelves, would there be anything wrong with requesting and obtaining the records from a particular company that manufactured that particular product?

Mr. WILLIAMS. I must wonder, when you ask that question, Mr. Chairman, what the purpose of obtaining those records is, if they know that the product is adulterated?

The CHAIRMAN. As the Secretary said the other day, and I am merely repeating the question that he raised, which has some merit; namely, the need to find out where the adulterated product went.

I cannot imagine any reputable company wanting to withhold such information.

Not that this is necessarily comparable in any way, but we remember the episode in regard to the cranberries which, in a way, was really a serious problem but in another way I think we will all admit that it was rather unusual.

But it seems to me if an adulterated product was found on the shelf somewhere, would there be anything wrong in tracing that back to the manufacturer and obtaining such records with respect to that particular product to find out where it is?

Under present law, can the agency follow that particular product and deal with a situation of this sort?

Mr. WILLIAMS. There are two points involved there, I think.

In the first place, many establishments readily hand over those records to the Food and Drug Administration today.

The CHAIRMAN. I should think they would want to, but some might not.

Mr. WILLIAMS. Secondly, section 703, to which Mr. Austern refers, 703 of the act, authorizes the Food and Drug Administration to obtain such information from carriers.

But the principal point, to my mind, involved in this aspect of the matter is that it is not just shipping records that Food and Drug would be authorized to examine under this statute.

If this were limited to shipping records, we would have an entirely different problem from the problem we have under the statute, under the bill as it is now written.

It is an unlimited authority.

The CHAIRMAN. I know your concern, and I know the concern of manufacturers. That has been presented here.

Since you mentioned Mr. Rogers, and, unfortunately, he had to leave, I do not think he should be misunderstood as to what he said in dealing with this particular problem.

Can it be adequately dealt with under present law?

Mr. WILLIAMS. I believe it can.

The CHAIRMAN. All right.

Mr. WILLIAMS. We have discussed the scope of the section, and I think that the food industry generally is in full agreement with Mr. Austern that it is difficult to think of anything which FDA would be interested in inspecting which would not have a bearing on violations or potential violations of the act. As we read the language of the bill, FDA could inspect virtually anything it wanted to, if the amendment to section 704 should be adopted.

When section 704 was amended in 1953, this committee, in its report, and Members speaking on the floor of the House, emphasized that the amended section would not authorize FDA to inspect formula files, complaint files, personnel records, or financial statements; and that inspection was to be limited to the specific subject matters listed in the amended provision.

Clearly, however, the files and records denied FDA in 1953, as well as others, could be reached under the language of H.R. 11581. Under

the broad language of the bill, personnel files, quality control records, financial records, such as those relating to the cost of raw materials and selling prices of the finished product, research and development and laboratory testing records, and processing records, would all be subject to inspection since they might have a bearing on a violation or potential violation of the act. It is a measure of the scope of the bill that not even confidential communications between establishments and their attorneys would be excluded by its language, and that the records of local retail grocery stores would be subject to the inspection for which it would provide authority. Data obtained from such an inspection could, as has been pointed out vigorously, be used in both criminal and civil proceedings brought at the instance of FDA against the food products, the company, and individual officials of the company. We know of no good reason why this almost unlimited authority, denied FDA in 1953, should be granted now, in 1962.

We do not believe that it is demonstrable that FDA needs the broad inspection authority which it seeks in order to protect the public from adulterated or misbranded foods. FDA has repeatedly recognized the excellence of the American food supply and the great contributions toward its improvement which processors have made. The matter of the safety of processed foods is not truly an issue before the public, this committee, or the Congress. The principal control on the sanitation of processed foods is the desire of the processor to market a high quality, wholesome product. Government regulation of commerce in foods, because of the inherent limitation on its effectiveness arising out of the sheer magnitude of the regulated industry, will always be of supplementary and secondary importance to the care and controls used in the manufacturing process. To assist the packer in the development and use of effective controls, the National Association of Frozen Food Packers is engaged in a continuing program of furnishing information and advice to its membership on sanitary controls and facilities, which has included a series of widely attended seminars on plant sanitation held at various key points in the United States.

I would like to refer, Mr. Chairman, if I may, to a statement which was made by Secretary Ribicoff in his testimony the day before yesterday.

The Secretary stated that it was a deeply disturbing fact that all too often our inspectors are met with refusals to permit comprehensive and effective inspection in food, drug, and cosmetic manufacturing establishment; that they are refused access to certain files which are named in the Secretary's statement.

We are at a loss, frankly, to comprehend why it is regarded as a deeply disturbing fact that establishments sometimes refuse FDA inspectors access to information which Congress in 1953 refused to authorize FDA to obtain.

Where, however, new usages in food production and processing have indicated the desirability of new legislation to protect the public, this committee has sponsored, and the Congress has adopted, the necessary laws. The food additives amendment and the color additive amendments have vastly increased FDA's powers to protect the consuming public, and they were broadly supported by industry. These amendments, together with the basic act, are in their essentials just

what FDA asked of the Congress. Let me state in more detail why we think this existing FDA authority is adequate and the requested authority is not needed.

SCOPE AND EFFECTIVENESS OF INSPECTION UNDER PRESENT LAW

In the area of food regulation we are dealing primarily with adulteration on account of insanitary condition of plant or of product; with product identity; and with misbranding.

Adulteration of foods by reason of insanitary conditions or raw materials can readily be ascertained under the authority of the present law. Furthermore, analysis of the finished food will readily reveal the presence of filth. The ability of FDA under its present authority to protect the public in this area has been well known for many years.

Similar considerations are applicable to the matter of FDA's ability to protect the public from false or misleading labeling of food, including the misrepresentation of the nature of particular products, in the sense of their identity. This, of course, is known as misbranding under the statute. Unfinished materials, containers, and labeling are specifically made subject to inspection under present law. Inspection of materials, containers, and labeling has been shown by experience to be an effective means of detection and apprehension of misbranded articles, when coupled with the analyses of the finished foods which FDA is fully competent to make. This has been and continues to be done by the agency on a regular and routine basis.

To the extent that questions of safety are involved, they concern largely specific ingredients in the nature of additives, a matter which will be briefly considered hereinafter. First, however, I would like to note the serious problems inherent in unrestricted inspection.

PROBLEMS INHERENT IN UNRESTRICTED INSPECTION

It may be granted that the practically unlimited inspection authority now proposed would make for convenience of administration in some respects. The increased ease of administration which might result from broader inspection authority must, however, be weighed against the discouragement of continued maintenance by industry of proper records, and against industry apprehension of divulgence of trade secrets, which the exhaustive type of inspection advocated by FDA would engender. The expanded authority requested must also be evaluated from the standpoint of its infringement upon basic constitutional concepts of privacy and the privilege against self-incrimination which is inherent in the inspection scheme under consideration.

It would certainly not be conducive to the continued maintenance of proper records of research and development projects, laboratory product tests, and quality control experience if establishments subject to inspection were given notice by the kind of legislation under consideration, that these records—which are not now within the inspection authority—could be obtained by FDA and used as a basis for a criminal or civil action against the company involved and its officers. Such records may be entirely irrelevant to the legal status under the act, of food which is actually produced and sold to the public. They may have served only as a guide to the processor in producing

the article finally marked or as an indication that adjustments or changes should be made in processes or materials, before the food is placed on the market. Yet, the processor would be faced with the necessity of proving irrelevance of such records from his own files if they were brought forward in a legal proceeding by FDA. Moreover, substantial, conscientious processors who conduct research, testing, and control operations would alone be affected, since only these processors keep such records.

Like considerations are involved in the opening of complaint files to inspection. We can discern no substantial usefulness to FDA of such files relating to foods, which would justify the disadvantages to industry involved in a requirement that they be made available to the agency. The use of complaints by a regulatory agency in aid of its enforcement of the statute is patently subject to abuse. Complaints are frequently totally unfounded. The matter complained of may bear no relation to the use of the food involved, or the cause of dissatisfaction or alleged injury may be gross misuse or improper handling of the food by the complainant, who often is either ignorant or irrational or may be seeking to make a case of damages to himself without just cause. Uninformed or irrational complaints, or even those containing justifiable or helpful criticisms, are easily subject to being reported by the inspector in such manner as to give rise to unwarranted inferences of violations of law by the inspected establishment. They may be made the basis for enforcement action and even publicized without proper regard for all pertinent circumstances.

Inspection by FDA of formulas, recipe files and processing records has, we submit, little or no substantial justification as a device for protection of the public. Here, as in the matter of inspection of the other records which has been discussed, FDA can readily ascertain, under its present inspection authority and by analysis of the finished food, whether it is adulterated or misbranded under the statute.

This is an area of vital trade secrets which are of the essence of the competition upon which our economic system is grounded. The food industries have, in the public interest, supported the increased appropriations to FDA which permit the agency to enlarge its staff, including its corps of inspectors.

We believe, however, that in the field of foods, the increased force of inspectors should be employed primarily to expand the frequency of inspection visits to the many thousands of processing plants under FDA jurisdiction. The time and energies of this force should not be devoted to the ferreting out of trade secrets and other confidential matters which will not be of material assistance in the enforcement duties of the agency but which can constitute a significant detriment to the competitive efforts of inspected firms.

If this question is to be approached realistically we must take account of the risk that inspectors will disclose trade secrets (such as formulas, recipes, or processing procedures) to competitors, either inadvertently in the course of their Government employment or after entering industry employment; and that the risk of such disclosure mounts as the number of inspectors is enlarged. The fact cannot be overlooked, moreover, that under certain circumstances agency officials are authorized by the statute to make public trade secrets in the possession of the agency.

These dangers of disclosure of confidential information and trade secrets must be balanced against any advantages to the public interest in requiring food processors to divulge such data. It seems evident that where foods are concerned, the scales are tipped heavily in favor of nondisclosure, for the reasons which I have stated.

We believe that FDA has no legitimate claim to a power to examine the personnel files of food processors and to pass upon the qualifications of such personnel. There is no substantial connection between FDA's enforcement duties and the qualifications of officials and employees who exercise no functions directly involving food processing. Yet even the files of top managerial personnel might have some bearing upon potential violations of the act and apparently would therefore be subject to examination under H.R. 11581.

It is obvious that the qualifications of technical personnel will in large measure contribute to the quality level of the product of the establishment. We cannot, however, concede to FDA the power to determine the adequacy of such qualifications—a power which FDA was denied by the Congress in 1953. This would be a direct participation in the business of the processor, by an agency which has no responsibility for the success of the business, and without resultant benefits to the public. Personnel qualifications are frequently matters of opinion. They do no more than furnish general background information to the inspector. They do not determine identify of the food or wholesomeness of ingredients—the principal factors involved in food processing regulation. These factors cannot be established one way or the other by examination of such files. They can only be established by examination of plant sanitation and an analysis of the food itself.

We can see no justification for authorizing a Government agency to delve into matters so personal to the employee and which have such an indefinite relationship to the enforcement aim of the agency—the apprehension and exclusion from commerce of adulterated and misbranded foods. The indeterminate connection of this kind of inspection with the statutory mission of the agency emphasizes the infringement upon constitutional rights of privacy inherent in the type of legislation proposed in H.R. 11581.

RELATIONSHIP OF SUBJECTS OF EXPANDED INSPECTION AUTHORITY TO STATUTORY ENFORCEMENT STRUCTURE

Permit me, for a moment, to consider more specifically the propriety of the proposed increased inspection authority in its relation to the enforcement structure of the statute.

It ought to be regarded as axiomatic that data obtainable by mandatory factory inspection should be demonstrably material and relevant to the enforcement powers granted under the statute, as distinguished from general information relating to the business of the inspected establishment. A regulatory agency should not be endowed with powers to require the production of private, confidential data concerning conditions or activities which are not violative of the statute itself and do not constitute an effective basis for a conclusion that the statute has been violated.

To the extent at least that such a grant of power is legislated, we would seriously question the validity of the legislation as being without reasonable relation to the purposes of the statute.

Basically, the offense under the Federal Food, Drug, and Cosmetic Act, where foods are concerned, is the adulteration or misbranding of the food. Thus, for example, the failure of the president of a company, or its general manager, or even some of its technical personnel to possess, on paper, qualification which the enforcement agency deems adequate, is not an offense under the basic act, nor would such failure in the case of food processing personnel, be made an offense under H.R. 11581. Nor would the lack of qualifications of personnel constitute a showing that the food prepared by them was either adulterated or misbranded under the statute. Proof of violation depends essentially upon a factual showing of the condition of the food itself, or of its labeling, or at least that it was prepared under unsanitary conditions. It is clear then that FDA must deal with the subject matter of the enforcement provisions of the act, i.e., the food, or the physical conditions of the processing plant in order to invoke available legal sanctions.

Consider financial records, cost data, and price data. Regardless of what the agency found upon inspection of such information, it would not have established a violation and it is difficult to see how such records and data could be an effective aid in establishing a violation although they might, in the broad language of H.R. 11581, have a "bearing on * * * potential violations of the act."

Complaint files fall into the same category. The situation is rare indeed, in the case of foods, where the complaint presents a situation which could give rise to legal action by FDA against the processor or the food itself. Even in such a case, evidence of the actual condition of the food or its labeling must be obtained.

Similar comments are applicable to the matter of inspection of research and development, laboratory testing, and quality control records.

These subjects of the proposed extension of inspection authority plainly do not bear intimately upon matters of adulteration and misbranding of food as do the subjects of inspection under present law, namely, the physical facilities of the establishment itself, finished and unfinished materials, containers, and labeling. The latter are directly related to misbranding and adulteration. The newly proposed subjects of inspection are not. We believe that this committee will reject such an expansion of authority as unneeded and as of dubious constitutionality.

FOOD AND COLOR ADDITIVES

The food additives amendment to the Federal Food, Drug, and Cosmetic Act was adopted by Congress in 1958, and the color additive amendments were adopted in 1960, both with wide industry support, in order to require adequate pretesting of substances used in food which are not known to be safe at use levels, and to provide for the establishment by FDA of tolerances or limitations upon the use of such substances so that excessive or unsafe amounts would not be incorporated in food.

The enactment of the food additives amendment was widely hailed as a benchmark of a new era in the protection of consumers from hazards which might result from the developing use in foods of new substances or of substances whose safety might be questionable. It is perhaps the most powerful weapon on the FDA arsenal. Yet now, we are told, it is not enough.

Hazards to health which may arise from the use of color or food additives should be discussed against the background of the significance and scope of the concepts of safety and toxicity of such substances. The following points are important points of this background:

(*a*) The safety of a substance is not the test of whether it may be added to food without clearance under the food additives amendment. The point has been widely misunderstood. The test is, regardless of the demonstrability of safety, whether such safety is generally recognized by qualified experts. This means, in practice, that it is subject to regulation unless FDA considers that it is generally recognized as safe. Since new substances must await general recognition of safety, under the FDA view, they are treated as food additives, whether or not FDA knows that they are safe under proposed conditions of use.

(*b*) It is likewise essential in considering the role of additives in food processing to understand that primary factors involved in determining the harmfulness of additives generally are the amounts and conditions in which they are used. Thus, a substance may be toxic when ingested in large quantities, but harmless when consumed in lesser amounts.

(*c*) Under the statute FDA is directed, where it finds a tolerance is required, not to fix the tolerance at a level higher than is required to accomplish the intended effect of the additive.[1]

Moreover, under FDA rgeulations an additive for use by man will ordinarily not be allowed a tolerance that will exceed one one-hundredth of the maximum amount demonstrated to be without harm to experimental animals.[2]

It is evident, therefore, that there are few absolutes involved in the concepts of safety and toxicity of food additives; that not all of the uses of additives present hazards even though they are subject to regulation; and that the statute and FDA regulations contain built-in safeguards against excessive use of additives, entirely apart from the civil and criminal sanctions which constitute a continuing warning to processors against unauthorized use of such substances and entirely apart from the scope of FDA's inspection authority.

There is no question that under present law FDA has the means to determine whether unauthorized additives are being used in food or whether those which have been cleared are used in the amounts permitted by FDA regulations.

The existing power to inspect establishments, including warehouses, finished and unfinished materials, and containers (packaging materials) permits FDA to determine whether an additive is used in the plant. To obtain such information it is not necessary to inspect personnel records, quality control, research and development or laboratory testing records, or formula files. If an additive has been brought into the plant for direct addition to the food, or for use as a machinery lubricant, an inspection of the processing operation will disclose in which foods and in what amounts the additive is employed. In any event, an analysis of the finished food will provide

[1] Secs. 409(c)(4) and 706(b)(7) of the act.
[2] 21 C.F.R. 121.5 and tentative color additives regulations.

evidence of the presence and amount of the additive in the food. If the additive is a component of a packaging material which may migrate to the food, the primary sources of information for FDA are the manufacturer of the material and an analysis of its components.

It is recognized that in the past FDA occasionally has been faced with difficulties in detecting the presence of particular components of food or of packaging materials because of the lack of adequate analytical methods. This is not, however, a matter which is relevant to the question of whether there is a need to inspect records and files to determine the presence and amount of additives in food. This is clear from the law and FDA regulations.

The Food and Color Additives Amendments [3] and FDA regulations [4] provide for submission to FDA of a description of practicable methods for determining the quantity of the additive in the raw, processed, or finished food and of any substance formed in or on food because of its use, or where applicable, methods for determining the quantity of an additive that will migrate to food. The test proposed must be one that can be used for food control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel.

If necessary methods of analysis are not submitted by the applicant for a food additive regulation, his petition under the law is not approved. It cannot persuasively be maintained, therefore, that FDA needs to look at records and files of formulas or anything else other than those things it is now empowered to inspect, in order to protect the public against unsafe use of food or color additives.

Let us add this further point: Even if FDA should find an indication of the excessive use of an additive from looking at a file, such as a formula or recipe card, this knowledge alone would not enable the agency to act against the processor or the food. The food itself, or the packaging material, would have to be analyzed in any situation which is readily conceivable, in order to provide an adequate evidentiary basis for legal action.

CONCLUSION AND SUGGESTED AMENDMENT

There are substantial differences between problems of food regulation and those of the regulation of drugs, devices, and cosmetics which are inherent in the nature and use of those articles.

We are convinced, for the reasons which you have heard, that there is no need or justification for increasing the authority of FDA to inspect food processing establishments. We respectfully suggest that, because of this circumstance and the basically different considerations which separate problems of drug control from those of food control, the provisions of section 704(a) relating to inspection of foods should be removed to a new subsection of section 704, without any change in the scope of inspection presently provided.

This course would be entirely consistent with the basic scheme of the statute, which has from the beginning contained separate adulteration and misbranding provisions for foods, drugs, and cosmetics. If, for whatever reason, a case is made for inspection provisions for drugs, devices, or cosmetics differing from the provisions now in effect, which

[3] Secs. 409(b)(1)(D) and 706(b)(5)(A) of the act.
[4] 21 C.F.R. 121.51 and tentative color additive regulations.

are adequate for food establishments, it is entirely logical that there be a separate subsection relating to foods.

That concludes my statement, Mr. Chairman.

The CHAIRMAN. Thank you, Mr. Williams.

Mr. Roberts, any questions?

Mr. ROBERTS. Mr. Williams, I am sorry, I was not here for all of your statement. I had to leave. But, as I get it, you interpret this section 201(a) would give the FDA authority to inspect personnel records of all employees connected with the operation?

Mr. WILLIAMS. Yes, sir; that is correct.

Mr. ROBERTS. Has there been any claim made by the FDA, to your knowledge, that this might be necessary in connection with sanitary conditions under which the employees work, I mean as to proper uniforms, proper gloves and so forth, in certain types of canning?

Mr. WILLIAMS. I should be inclined to doubt that that is the basis for it.

So far as I can gather from reading statements emanating from the agency, one of the principal reasons for wanting to look at the qualifications of personnel has to do with their ability to handle food additives.

Mr. ROBERTS. You mean as to their technical experience?

Mr. WILLIAMS. Yes, sir.

At least I have heard that given as a reason.

Mr. ROBERTS. You mean as to amounts of preservatives or additives that are to be contained in a certain batch of food?

Mr. WILLIAMS. Yes, sir.

Mr. ROBERTS. As to whether or not they are competent to judge whether they are putting in proper amounts and putting in proper ingredients?

Mr. WILLIAMS. I am not sure of the rationale behind the feeling that there should be such authority, because it seems to me that FDA and the public are fully protected for the reasons which I have stated. The regulation authorizing the use of the food additive establishes a tolerance.

Some of them go into great detail about how the food additive is to be used and in what amounts. I cannot personally conceive of a situation where there would be any need to inspect the personnel file when the inspector can be right there in the factory and see how it is being done, sir.

Mr. ROBERTS. In other words, you contend that under present authority they would be able to watch an operation where the employees were engaged in measuring or using measuring devices to place the additives in the containers from which the cans are filled or bottles are filled or whatever containers may be used?

Mr. WILLIAMS. Yes, sir.

Mr. ROBERTS. They can do that at the present time?

Mr. WILLIAMS. Yes, sir.

And they can by inspection of the factory find what additives or substances which they might consider additives have been brought into the factory, and by the inspection of which you just spoke they can see how it is used, and by an analysis of the food they can determine how much is in it.

Their regulations, basically, although they have not been followed completely, but, basically, the law and regulations require that methods

of analysis of the food be provided by the petitioner for a food additive regulation, so that they have the thing pretty well hemmed it, as I see it, sir.

Mr. ROBERTS. That is all.

The CHAIRMAN. Mr. Springer?

Mr. SPRINGER. No questions.

The CHAIRMAN. Mr. Kornegay, any questions?

Mr. KORNEGAY. Mr. Williams, I, too, am sorry I was not here for your entire statement.

I gather, though, from the portion of it which I heard, that you feel that this bill will authorize and permit the FDA to inspect the personnel files of any food processor; is that right?

Mr. WILLIAMS. Yes.

We know from the history of inspection legislation that that is what the Food and Drug Administration wants. They wanted it in 1953 and it was denied them.

Mr. KORNEGAY. Would that also include the authority to pass on pertinent qualifications of personnel?

Mr. WILLIAMS. I can conceive of no reason for inspecting personnel files except to determine whether the qualifications satisfied the Food and Drug Administration.

Mr. KORNEGAY. In your interpretation of this act, I think you mentioned you thought it was in reference to the people who were handling the food additives and things of that sort?

Mr. WILLIAMS. That was one reason that has been given.

Mr. KORNEGAY. Yes.

Would it go all the way down the line to the bean snappers and the potato peelers?

Mr. WILLIAMS. Under this bill, I am convinced that that is exactly what they could do.

Mr. KORNEGAY. Now, the health departments in the various counties, cities, and States in which the plants are located, they would have jurisdiction insofar as health qualifications are concerned over the personnel in food-processing plants, would they not?

Mr. WILLIAMS. Yes, sir, I believe they do. I am not sure of the extent to which they exercise their authority.

Mr. KORNEGAY. Do you know of any jurisdiction or any State which does not have health laws which pass upon the health qualifications of those working in the food-processing plants?

Mr. WILLIAMS. It is my understanding that that is a general condition that such laws do exist.

Mr. KORNEGAY. Under the existing law, is there not authority for inspecting the plants, products and the labeling on those products?

Mr. WILLIAMS. Yes, sir.

The physical facilities and other things in the plant, which, as I attempted to point out, are directly related to the purpose of the statute and to its enforcement structure. These other things are of an indeterminate relation to them, and sometimes, I am sure, of no relation whatsoever. We feel that Congress simply is not about to give them such an indeterminate and expansive authority.

Mr. KORNEGAY. Does the FDA now have the authority; that is what I want to find out?

Does not the FDA now have the authority to inspect the plants?

Mr. WILLIAMS. Yes, sir.

Mr. KORNEGAY. The preparations, the food or foodstuffs, both finished and unfinished?

Mr. WILLIAMS. Yes, sir.

Mr. KORNEGAY. Labeling?

Mr. WILLIAMS. That is correct.

And that authority was supported by the food industry in 1953, and specifically by the National Canners Association, whose representative has just testified, and by the National Association of Frozen Food Packers, which I represent.

Mr. KORNEGAY. And the food additive amendments provide for pretesting of all food additives?

Mr. WILLIAMS. Yes, sir.

Mr. KORNEGAY. That provision exists in the law now, is that right?

Mr. WILLIAMS. Yes, sir, and it might be commented that when these new amendments, one of which is the food additives amendment, were passed by Congress and when the Food and Drug Administration was up here asking for them, there was no suggestion that they would not be adequate for their purposes.

But now the suggestion is and the pressure is for additional authority, and one of the reasons given for asking for the additional authority is that they need it to enforce these new amendments such as the color additives amendment.

Mr. KORNEGAY. They were passed in 1958, I believe; is that correct?

Mr. WILLIAMS. Sir?

Mr. KORNEGAY. The food additive amendments were passed in 1958?

Mr. WILLIAMS. 1958, yes, sir; after the 1953 amendment to the inspection provision was passed.

Mr. KORNEGAY. I believe you are counsel for the National Association of Frozen Food Packers?

Mr. WILLIAMS. Yes.

Mr. KORNEGAY. Since the passage of the 1958 act, have any misfortunes or bad situations arisen among those members of your association that have come to your attention?

Mr. WILLIAMS. With respect to food additives?

Mr. KORNEGAY. With respect to food additives.

Mr. WILLIAMS. Not that I know of.

Mr. KORNEGAY. Mislabeling?

Mr. WILLIAMS. They have not come to my attention.

Mr. KORNEGAY. Have any lawsuits been filed over adulterated foods since that time?

Mr. WILLIAMS. I do not doubt that the Food and Drug Administration has picked up some foods since that time which are frozen foods, but, so far as I know, there has been no litigation with respect to the presence of additives in frozen foods; at least, to my knowledge, there has not been.

Mr. KORNEGAY. The FDA now has the authority, does it not, to confiscate contaminated or adulterated foods?

Mr. WILLIAMS. Yes, sir.

Mr. KORNEGAY. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Collier?

Mr. COLLIER. Thank you, Mr. Chairman.

Pursuing the question and using a hypothetical case that Mr. Rogers did previously, Mr. Williams, let us say, for example, that in retail store A someone gets a product which they assume has been adulterated

or has made someone ill. The normal thing for that person to do would be to call the local health department.

Let us say that it was discovered that not through faulty refrigeration, for example, but, rather, in the ingredient of the product, there was something that caused an adulterated condition. Subsequently, this case went to the Food and Drug Administration. Now is there or would there be any objection on the part of a processor to permit the Food and Drug Administration to secure from them the shipping records that were necessary to determine where else this product had been distributed for very obvious reasons of public interest? Would you say that this procedure was proper and in the best interests of the consuming public?

Mr. WILLIAMS. I would say that in 99 percent of the cases, whether there was authority of law or not, that if such a violation as you have described were established, that the records would be handed over to the Food and Drug Administration without question.

Mr. COLLIER. Now, under existing law and existing authority, would this be possible without this legislation?

Mr. WILLIAMS. Under existing law, the authority of the Food and Drug Administration, with respect to shipping records, is to obtain them from carriers.

Mr. COLLIER. Is it your understanding or interpretation of this legislation that it would provide this authority to the Food and Drug Administration regardless of whether a plant did business in interstate commerce or whether they were confined to intrastate commerce?

Mr. WILLIAMS. No, sir.

If the operations of the plant and its shipments are confined to intrastate commerce, the act would not reach it.

Mr. COLLIER. I may be wrong, but I find no restriction in this legislation that would restrict it to inspection of a plant, whether it did interstate commerce or intrastate commerce.

Mr. WILLIAMS. Yes, sir.

I think you will find, for example, that the section 301 entitled "Prohibited Acts," section 304 relating to seizure, the first being a criminal provision, the second a condemnation provision, both are limited to shipments of goods in interstate commerce or goods which have been shipped in interstate commerce, and are held for sale or for other use after shipment in interstate commerce.

Mr. COLLIER. Under those circumstances, then, I would assume until I had further edification that this would foreclose an inspection in any plant that did not do business outside of the State of processing?

Mr. WILLIAMS. That is basically the case, sir, yes.

Mr. COLLIER. However, in the face of this, are you aware of the fact that most departments of public health, and in my own State of Illinois we have a division of foods, dairies and standards which has the right at present to make inspections within our own State, equipped with laboratories necessary to analyze food products and so on.

Now, they also, of course, have the right to go into any plant and make these inspections if that particular company does business in interstate commerce, because the facility and packer is in the State of Illinois.

Would it be your opinion that if this bill were adopted, then there would be no further need for the State health inspectors, sanitarians,

to pursue their present functions as provided under the laws of the State of Illinois except in those plants which are strictly in intrastate commerce, or would there still be a need for these State——

Mr. WILLIAMS. I think there would still be a need. It might be somewhat reduced by the additional authority which the Food and Drug Administration would have, but I think there would still be the same need as there is now, bearing in mind the difference in the scope of authority under the bill and under the present act.

Mr. COLLIER. In other words, you feel that if there is a food processing plant in the State of Illinois doing business interstate commerce, and this bill is enacted providing all the authority granted to the Food and Drug Administration, there would still be a need for the State division of foods, dairies, and standards to continue to operate when, in fact, would they not be doing exactly the same thing?

Mr. WILLIAMS. I am not sure that I have grasped the point which you are making.

Are you by any chance thinking in terms of the possible preemption of inspection authority by the Federal Government?

Mr. COLLIER. Exactly.

I am just trying to determine at what point this legislation, if it is enacted, would, in fact, overlap the existing authorities in the various States as provided under the various State health codes, and in the operation of the various State health departments, which have been functioning in most States for a long, long time.

Mr. WILLIAMS. I think there is an overlapping now, sir.

I think, again, if I understand your question properly, that there might be a more serious question. I have not studied the matter from that standpoint, of whether the Federal Act, with its detailed inspection provisions, would be regarded by the courts as having preempted the field so that the State would have no longer any authority to do those same things.

I have not, as I say, considered that matter. It is conceivable that that probably might arise.

Mr. COLLIER. Just one further question.

Using the hypothetical case that we used at the beginning of my interrogation, and assuming that a situation exists with a retail store having an adulterated product, would it be your opinion that under this legislation, as a representative of the Food and Drug Administration began to pursue the other sources of delivery of this product, that divulging the purpose of their visit to the other retailers would be entirely discretionary, under the terms of this bill?

Mr. WILLIAMS. Let me see if I understand you.

Do you mean is there any prohibition in the bill against an inspector telling a competitor of the person——

Mr. COLLIER. A competitor or a customer.

Mr. WILLIAMS (continuing). Or a customer. He is inspecting because there is something wrong with the product?

Mr. COLLIER. That is right.

Do you find any restriction against this practice?

Mr. WILLIAMS. No, I do not find any restriction of that type.

The restriction is narrower than that.

Mr. COLLIER. Mr. Chairman, in view of the time, I believe that is all.

The CHAIRMAN. You do recognize that the Federal Government has a responsibility in connection with interstate problems of food and drugs and that the States also have their responsibility in this connection?

Mr. WILLIAMS. Yes, sir.

The CHAIRMAN. And that those responsibilities should be maintained and coordinated insofar as possible?

Mr. WILLIAMS. Yes, sir.

Mr. COLLIER. Mr. Chairman, excuse me if I might add this responsibility is also recognized by the Federal Government.

At the present time the various State health departments are, in fact, receiving subsidies from the Federal Government for the operation of their health departments.

The CHAIRMAN. If the States are going to get subsidies, it has been my experience and observation, that there may be other groups that are going to get subsidies out of the Federal Treasury, too.

After all, the States have people that operate the States just like the people that operate the Federal Government. They are human and good Americans, trying to get the best out of life they can.

I am not going to take any time because the hour, as Mr. Collier has said, has arrived when we have to go over to the House. But I am a little bit puzzled about your statement, Mr. Williams, and the statement of Mr. Austern, before you, with reference to the provision in the bill authorizing the Department to control personnel.

I am unable to locate anything in title II of the bill about personnel.

Would you point it out to me?

Mr. WILLIAMS. Yes, sir; I would be glad to.

I think that all things therein, including records, files, papers, processes, controls, and facilities bearing on those things mentioned, and bearing otherwise on violations or potential violations of this act, can only include personnel records.

It must.

And, furthermore, as a matter of history——

The CHAIRMAN. Personnel records is one thing, but the qualification of personnel is another.

Mr. WILLIAMS. That is why they would want to look at the record.

We know that from the history of this matter.

I have just been given by Mr. Austern a speech by Mr. Larrick, the Commissioner of Food and Drugs, at the convention of the National Canners Association in January in which he states:

> To make a complete inspection, the Food and Drug inspector must be able to determine that this employee is qualified to do his job.

We know that as of 1953, when the Food and Drug Administration was before this committee with respect to the amendment of section 704, the factory inspection provision, that they then urged that they should have this authority. In fact, they urged it before the Supreme Court.

The CHAIRMAN. The language about qualification of personnel is included in title I of the bill referring to drugs but I do not find where it is included in title II, unless you can read it into the bill, as you have indicated a moment ago.

Mr. WILLIAMS. I think that the scope is such that it must be read into it, and if it is not intended, then it should be made very clear that it is not.

The CHAIRMAN. I agree with that.

In the explanation or section-by-section analysis which was submitted to the committee by the Department, the following explanation is given for title II, "Strengthening of Factory Inspection Authority":

Section 201 of the bill would amend section 704 of the basic act to clarify and strengthen existing inspection authority by specifically requiring the owner or person in charge of the establishment (which is subject to inspection) to permit inspection of all things in the establishment (or vehicle) bearing on whether there is a violation or potential violation of the act, including records, files, papers, processes, controls, and facilities having such a bearing.

Now, that is the part that you object to strenuously?

Mr. WILLIAMS. Yes, sir.

The CHAIRMAN. Furthermore, they say:

This amendment is needed in order to overcome doubt as to the present scope of the inspector's authority, engendered by the legislative history of the reenactment of section 704 of the act in the 83d Congress.

You are familiar with that record.

Do you know of anything within the legislative history that impedes their efforts to carry out their responsibility?

Mr. WILLIAMS. It depends on your definition of what their responsibilities are or should be.

They feel that they should have the authority to inspect formulas, records, and files generally.

It was stated specifically——

The CHAIRMAN. The responsibility is for a specific purpose, and it is stated in the act.

Mr. WILLIAMS. That is correct.

The CHAIRMAN. They are asking for this authority in order that they may carry out that responsibility.

Mr. WILLIAMS. The point is that this committee was convinced in 1953 and the Congress was convinced that it was extending adequate authority to the Food and Drug Administration at that time, and statements were made by members of this committee on the floor and the committee report of this committee made it perfectly clear that the things which they are now asking by way of extension of 704 were not granted in the amendment of 1953.

The CHAIRMAN. Then you do not know of anything that was "engendered"—and I use that term—by the legislative history of the 83d Congress that prohibits them from doing what they should do in carrying out their responsibility?

Mr. WILLIAMS. No, sir.

We supported the amendment in 1953.

We agreed with the legislative history, and we believe that that is sufficient for them to carry out their responsibilities.

The CHAIRMAN. They say:

Further, the bill would amend section 704 the act to make clear that factories, warehouses, and establishments in which food, drugs, devices, or cosmetics are processed or packed (as well as in establishments in which they are merely held) after introduction into interstate commerce are subject to inspection authority.

Do you object to that?

Mr. WILLIAMS. Are you reading from the present provision?

The CHAIRMAN. No, I am reading from the statement which the Secretary sent up here explaining the bill. I judge from this that

they want authority to inspect this product after it is introduced into interstate commerce as well as authority for them to inspect it before it is introduced into interstate commerce.

Mr. WILLIAMS. They have that authority now.

The CHAIRMAN. They do have that authority?

Mr. WILLIAMS. With respect to goods which are held after shipment in interstate commerce; yes, sir.

No, we did not object to that, and we do not object to it.

The CHAIRMAN. Thank you very much.

We are glad to have your testimony.

Mr. WILLIAMS. Thank you, sir.

The CHAIRMAN. The committee will adjourn.

I cannot give an indication as to when these hearings will resume, unfortunately.

There are many witnesses we had hoped to get to this week. We have been slow. It is certainly not the fault of the chairman or any member of this committee. It is a situation over which we had no control whatsoever. If we have inconvenienced anybody, we regret it very much.

If it is going to be necessary for you to make another trip to Washington, I am sorry about that. We will give rather wide latitude for people to insert their statements in the record for the benefit of the committee if it would be otherwise inconvenient for them to come back.

The committee will adjourn until a date to be announced at a later time. There will be sufficient time for anyone to make his arrangement accordingly.

(Whereupon, at 12:10 p.m., the committee adjourned subject to the call of the Chair.)

88589—62——12

DRUG INDUSTRY ACT OF 1962

MONDAY, AUGUST 20, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:10 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

Today we resume the hearings on drug legislation and we expect to continue for the rest of this week until we have completed the hearings.

It will be our purpose to try to hear everyone who desires to appear and present information and testimony on this legislation.

I might remind everyone that the committee at this time will limit its consideration to the bill H.R. 11581.

It will be recalled that I introduced this proposal at the request of the administration and at the same time I introduced the companion bill, H.R. 11582, devoted primarily to cosmetic and therapeutic devices.

H.R. 11582 will not be pursued at this time because it is the desire of the committee to give full time and attention to the proposed drug bill. There has been some question as to the effect H.R. 11581 would have on the food industry. We have already held some hearings on that phase of the legislation.

The Chair does not feel it would be his responsibility to separate it at this stage of the hearings. It will be up to the committee to determine what it wishes to do in consideration of that phase of the proposal when the hearings are concluded.

These hearings were suspended some time ago in order that the committee could go into another important subject proposed by the administration, transportation legislation which required the attention of the committee.

At that time, I might say in all frankness, the long consideration that had been given by the other body of drug amendments seemed to have reached a point where it was doubtful that any formal action would be taken.

However, with recent events and reports that I have received, it is rather apparent that determined efforts should be made to get a bill.

In view of the changed events, I thought it was important for these hearings to be held this week.

I would also like to say to my colleagues I regret the fact that we seem to have been caught with the hearings this week, when the House is virtually in recess. Other Members of the House have been permitted to leave Washington and return to their districts.

However, since these hearings had been announced more than 2 weeks ago and so many people would again be inconvenienced if we did not go ahead, and since it would further delay the consideration of the bill after the brief recess, I decided that this was the most appropriate action that we should take.

I am sure my colleagues will understand the decision in this matter, and I think it is commendable that so many members decided to remain here this week and participate in these hearings. I personally want to think these members for it.

As I have stated publicly, it is my hope and desire that those who will participate in the hearings during the week will keep in mind not only the letter of the Legislative Reorganization Act of 1946, which is the procedure that guides hearings, and the rules of the House, but the spirit of that provision will be kept in mind.

I do not want to limit any witness. We have never pursued a course yet of limiting witnesses, but I might say I do not propose to sit during these hearings and listen to unusually long and repetitious statements.

I hope that will be kept in mind by everyone, with a full understanding of what we propose to do. We want to make a good record, a full and complete record, and the committee, I am sure, will help do that.

It will be recalled that we held 4 days of hearings in June. The committee received the cooperation from a number of witnesses, in addition to those representing the administration and the agencies involved. Since this matter has narrowed down to one bill, we should continue the hearings in an effort to develop the best possible record for the objectives sought.

Today we have the Pharmaceutical Manufacturers Association. There will be a number of witnesses representing that association, because that industry is primarily affected, along with the general public. There will be some others representing other phases of the industry.

The first witness this morning will be Mr. Eugene Beesley, who will present the general position of the Pharmaceutical Manufacturers Association on this legislation.

Mr. Beesley, we will be glad to have your testimony.

STATEMENT OF EUGENE N. BEESLEY, PRESIDENT OF ELI LILLY & CO., AND CHAIRMAN OF THE BOARD OF DIRECTORS OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY LLOYD CUTLER, ESQ., OF WILMER, CUTLER & PICKERING

Mr. BEESLEY. Thank you, Mr. Chairman.

I am Eugene N. Beesley, president of Eli Lilly & Co., of Indianapolis, a manufacturer of prescription medicines since 1876. I am testifying today as chairman of the board of the Pharmaceutical Manufacturers Association, whose 140 member companies produce more than 90 percent of the prescription drugs used in this country.

Recent tragic events involving a drug developed abroad have reminded all of us of the need for meticulous care in the introduction

and use of today's complex new medicines. It should reassure the American people that Congress, the executive branch of Government, and the pharmaceutical industry are constantly examining the many safeguards already in effect and searching for ways to strengthen them.

The fact is that safety checks on drugs have long been more effective in the United States than anywhere else in the world. But our job is to make certain that these safeguards are improved whenever possible and that we push on vigorously to fill present gaps in scientific knowledge, so that we can predict more accurately and completely the effects of new medical compounds on man.

Our association has already asked for stronger regulations governing our industry. It has supported measures to strengthen the food and drug laws in ways that will further the public health. We have opposed only those proposed measures which, in our judgment, would impair the ability of our industry to serve the public. We outlined our views to Congress in hearings before the Antitrust and Monopoly Subcommittee of the Senate Judiciary Committee in December 1961. The chairman of the subcommittee, Senator Kefauver, characterized our proposals at that time as "important steps forward," representing "industrial statesmanship of a high order."

We support a number of objectives which certain provisions of H.R. 11581 and the revised Senate bill S. 1552 are intended to achieve. We believe that these provisions modified to provide appropriate procedural safeguards and prevent unnecsssary overregulation would be in the public interest.

All of us should be aware of one danger. In the emotional atmosphere which surrounds drugs today, there will undoubtedly be presure from some for hastily conceived action which could produce more harm than good. The Congress and the administration must be careful not to let the pendulum swing too far. Unnecessary regulation can weaken and even destroy an industry which has been inventive and productive for the public good. We believe that this committee, with its long experience in complex health matters, will give new legislation the careful attention it deserves.

In these introductory remarks I shall briefly mention some basic principles which we hope will guide Congress as it considers new drug legislation. I shall also outline our recommendations in a very general way.

The other pharmaceutical industry witnesses who are here with me will discuss in detail the many complex provisions of proposed legislation. The committee has been supplied with a list of our witnesses and the sections of H.R. 1581 each will discuss.

HEALTH PROGRESS IN THE UNITED STATES

As we sit here today, we should not forget for one moment the tremendous advances that have been made in this country in the development of lifesaving medicines. Let us recall some startling facts:

About 4.5 million Americans are alive today who would be dead if the mortality rate of 25 years ago still prevailed.

Twenty-three years have been added to the lifespan of the average American since the turn of the century.

Since 1944 the death rate from influenza has dropped 90 percent; the rate from tuberculosis, 83 percent; acute rheumatic fever, 83 percent; syphilis, 79 percent.

The death rate among mothers in childbirth has declined by over 90 percent since 1940. The infant mortality rate has been cut almost in half.

The United States has made more important drug discoveries in the last two decades than all the rest of the world combined, and seven times as many as the next leading country.

Since 1949 the U.S. pharmaceutical industry has increased its own annual research and development expenditures for human medicines by more than 600 percent, from $34 million to almost $248 million. The percent of income invested in research and development by producers of medicines is almost three times the average for all industry.

The CHAIRMAN. Are you giving that on an annual basis?

Mr. BEESLEY. Yes, I am, Mr. Chairman.

The health professions as a whole are responsible for this heartening progress of man against disease, and prescription drugs have played a vital part.

GUIDELINES FOR NEW LEGISLATION

I hope we agree, therefore, that concern for the public health is to be the overriding element in considering new legislation. If a proposal serves to advance the health of the American people, it should be enacted; if not, it should be rejected.

In this respect, the Government has certain responsibilities. These are to approve the manufacturer's standards for production and quality of medicines; to conduct thorough inspections to insure adherence to these standards; and to punish those who ignore such standards. These are vital functions.

Industry, too, has vital responsibilities: To invest in a broad scientific search for new and improved medicines; to conduct thorough trials of new compounds to prove their safety and value before they are introduced; to establish and maintain proper quality controls at every step of manufacturing; to make medicines available wherever they are needed; and to maintain a constant flow of accurate and comprehensive scientific information about its products to the medical profession.

While Government regulation can prevent distribution of medicines which are below acceptable standards, no amount of regulation can, in itself, produce a safe and effective medicine. Safety and effectiveness must be built into a drug in the first place by the painstaking, step-by-step production and testing processes of the manufacturer. As members of this committee know, many producers of medicines strive for standards of excellence far higher than any which might be imposed by Government.

Moreover, Government regulation in itself can never create lifesaving drugs. This, too, depends in large measure upon the initiative and enterprise of industry.

It is important to public health, therefore, that Government regulations should not hamstring the medical advances produced by the industry. Disease and death can result from unnecessary delay in

permitting a lifesaving drug to reach the public, just as surely as they can result from inadequate Government regulation.

Let me illustrate. Penicillin has saved thousands of lives—perhaps hundreds of thousands—since it first became available. But penicillin can also cause loss of life or serious injury to a relatively few because of allergic reactions. However, if overcautious and restrictive Government regulation had blocked its testing and introduction 20 years ago, some lives would have been saved while a multitude of other lives would have been lost.

I am simply emphasizing, therefore, that the regulatory action of Government and the creativity, competitive initiative, and ultimate responsibility of industry both make very valuable contributions to public health. Public health will suffer if we concentrate on either factor alone and neglect or retard the other. Sound legislation in the public interest thus requires a wise and careful balancing of Government controls with private freedoms and responsibilities.

RECOMMENDATIONS OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

In arriving at our recommendations on new legislation, we have tried to reach a wise balancing of all such considerations. Our objective has been to make possible the maximum contribution by both Government and industry in carrying out their respective responsibilities to protect and advance the public health.

Let me point out—before outlining our position—that many of the provisions of H.R. 11581 do not vest new power in the Food and Drug Administration. Rather, they clarify and, in some instances, enlarge and strengthen existing powers.

For instance, the effectiveness of drugs is already assessed by the FDA in passing on new drug applications and labeling claims. Experience has shown that under existing law the FDA can and does take the time needed to carefully evaluate new drug applications. Drug producers today maintain records for FDA inspection. FDA can remove unsafe drugs from the market and, through labeling requirements, can protect the public from unjustified claims of effectiveness. The FDA already reviews and passes on manufacturing and control procedures for new drugs. Under present law, false drug advertising is illegal.

Although it seems evident that FDA already has substantial authority in the areas covered in H.R. 11581, we endorse the following basic concepts of the bill in the belief that public health protection will be strengthened:

1. Before introducing a new drug, the manufacturer should be required not only to show the Food and Drug Administration that the drug is safe but also to present substantial evidence that it is effective in producing the results claimed.

2. FDA must have ample time to consider the safety and effectiveness of new drugs before they are introduced—but unnecessary delays in permitting valuable new medicines to reach the public must be avoided.

3. Manufacturers should be required to maintain records of experience with new drugs and other information bearing materially on safety and effectiveness and to make such information available to the FDA.

4. The FDA should have authority, after a hearing, to withdraw a new drug from the market if in the light of new evidence it is not shown to be safe or if there is a lack of substantial evidence that it has the effects claimed for it.

5. The inspection powers of FDA should be broadened to cover all facilities, controls, and records materially bearing on violations of the law.

6. FDA should be authorized to remove any drug from the market if the facilities or controls used in its manufacture are inadequate to assure the claimed identity, strength, quality, and purity.

7. A special program of controls and recordkeeping should be enacted to prevent illicit distribution of barbiturates and amphetamines.

8. FDA should be given standby authority, after a hearing, to designate an official, or generic, name for a new drug if a suitable name does not result from the existing voluntary procedures.

Furthermore, we believe that the public interest will be served if Congress goes even further than the present bill stipulates. Specifically, we propose that:

All manufacturers of drugs be required to register with the Food and Drug Administration, identifying their plants and their products to the agency responsible for inspecting and regulating their operations.

All manufacturers of drugs be subjected to mandatory inspection by FDA at least once every 2 years—and more frequently if unsatisfactory conditions make this advisable.

FDA's ability to deal with the serious health hazard of drug counterfeiting—the production and sale of drugs by fly-by-night operators who pass off their merchandise as the products of reputable manufacturers—be strengthened by including provisions specifically penalizing drug counterfeiters.

Additional and adequate funds be allocated to FDA. While we recognize that appropriations are not in the special province of this committee, it seems to us extremely important that FDA should be provided the necessary substantial expansion of staff, facilities, and funds to enable it to carry out effectively these broadened responsiiblities.

There are certain provisions of H.R. 11581 which we oppose because, in our opinion, they would be detrimental to health progress. These include the unnecessary extension of cumbersome and expensive batch certification to all antibiotics; proposed regulations affecting biological drugs which would, without benefiting the public, add to the already complex and overlapping Government controls over biologicals; unrealistic requirements to present a complete drug treatise in each medical journal advertisement; and the provision authorizing the Secretary to withdraw a drug from the market before any hearing, without so much as prior notice to, and consultation with, the manufacturer. With respect to this last provision, we certainly agree that an unsafe drug should be promptly forced off the market if not removed voluntarily by the manufacturer—but the Secretary already has ample power for this purpose.

The program of legislation which we recommend will, we are confident, significantly strengthen public health protection. It will also preserve the opportunity for industry scientists to make their

own distinctive contributions to medical science. There are desirable changes in the legislative language of H.R. 11581 which need careful attention, and these will be discussed in detail by witnesses who follow me.

In concluding, Mr. Chairman, let us all be reminded that many of our health problems stem not from any inadequacy of law or law enforcement but from the limitations of present scientific knowledge of complex life processes and the ways in which drugs may affect them.

To add yet another scientific task force to help solve this basic problem, the Pharmaceutical Manufacturers Association has recently established a Commission on Drug Safety, composed of distinguished scientists. The commission will review the scientific information now available, and research being conducted, in an attempt to extend the frontiers of knowledge in the field of drug testing.

The chairman of the commission is Lowell T. Coggeshall, M.D., a former Assistant Secretary for Medical Affairs in the Department of Health, Education, and Welfare. For many years he has directed medical activities and biological sciences for the University of Chicago. A list of the commission's members is attached to my statement.

However broad our present knowledge, ahead of us lies always the great unknown. We must move constantly forward toward understanding of the mysteries of life and life processes.

Our industry will continue to discharge, to the very best of its abilities, its responsibilities in research and production and widespread distribution of medicines that can save human lives and relieve human suffering. With your help, regulatory functions of Government can be strengthened to the same ends—and in such a way, we hope, that this Nation's leadership in medical affairs throughout the world can be maintained. Through dedicated effort on the part of all of us this Nation certainly can move forward to standards of health as yet undreamed of.

The CHAIRMAN. Mr. Beesley, I notice you have attached to your statement a brief statement of your own educational training, background, and experience.

Mr. BEESLEY. Yes.

The CHAIRMAN. This will be included in the record, together with the names and brief statement of each of the members of the Commission on Drug Safety.

(The documents referred to are as follows:)

EUGENE N. BEESLEY

Eugene N. Beesley, who is serving a second term as chairman of the board of directors of the Pharmaceutical Manufacturers Association, is president of Eli Lilly & Co. Born January 29, 1909, in Thorntown, Ind., he was graduated from Thorntown High School in 1925 and received a bachelor of arts degree from Wabash College in 1929. Later he attended law school at night and in 1943 received a bachelor of laws degree from the Indiana University Law School.

Beesley joined Lilly in June 1929. After several assignments as a salesman and as a district manager, he returned to the home office in 1941. In the following years he held executive positions in the fields of personnel, sales, and administration and was elected president of Eli Lilly & Co. in April 1953. He is the fifth president of the 86-year-old firm and the first president from outside the Lilly family.

In addition to serving on Eli Lilly & Co.'s board of directors, Beesley is chairman of the board of Eli Lilly International Corp. and a member of the boards of eight other Lilly subsidiaries in foreign fields. He is vice president and a

director of Lilly Endowment, Inc. He is also director of the United Fund of Greater Indianapolis, Inc., and the American Fletcher National Bank & Trust Co., Indianapolis.

He is a board member of the National Industrial Conference Board; a trustee of the National Fund for Medical Education, and the National Fund for Graduate Nursing Education; a director of the Radio Free Europe Fund, the American Arbitration Association, and the United States Rubber Co.; and chairman of the executive committee of the board of trustees of Wabash College. He is also a member of the American Pharmaceutical Association, the Indiana Pharmaceutical Association, the United States Committee of the World Medical Association, the American Bar Association, and the Indiana Bar Association.

DePauw University has conferred upon him an honorary doctor of laws degree; the University of Toledo, an honorary doctor of science degree; and Wabash College, an honorary doctor of laws degree.

He is married to the former Marian Crehore, of Elyria, Ohio. They are parents of two children: Mary Louise, who is married to Needham S. Hurst; and Mark C. Beesley.

STATEMENT OF PROFESSIONAL RECORDS OF MEMBERS OF COMMISSION ON DRUG SAFETY

Dr. Paul R. Cannon, 69, pathologist, retired as chairman of the Department of Pathology at the University of Chicago in 1957. He had served as department head for 17 years and was professor of pathology at the university for 25 years. Dr. Cannon has been editor of the American Medical Association's Archives of Pathology since 1954, and he is a former president of the American Society of Pathologists & Bacteriologists, the Association of Immunologists, the Chicago Pathological Society, and the American Society of Exploratory Pathology. The latter organization conferred the Burdick Award on him in 1948. He received his Ph. D. from the University of Chicago in 1921. He also was professor of pathology at the University of Mississippi for 3 years. He was a recipient of the Groedel Medal of the American College of Cardiology in 1958.

Thomas Francis, Jr., M.D., 62, has been professor of epidemiology and chairman of the Department of Epidemiology, School of Public Health at the University of Michigan Medical School since 1941. He earned his M.D. from Yale University in 1925. Dr. Francis is a past president of the Society of American Bacteriologists, the American Society for Clinical Investigation, and the American Epidemiology Society. He served as director of the Influenza Commission from 1941 to 1945, as a consultant to the Secretary of Defense, and as director of the University of Michigan poliomyelitis vaccine evaluation program. He was also professor of bacteriology and director of the bacteriological labs for New York University. Among his awards are the Howard Taylor Rickets Medal, the Lasker Award of the American Public Health Association, and the American College of Physicians' James D. Bruce Memorial Medal.

Dr. Philip S. Hench, internationally known authority on arthritis and rheumatism, was awarded the Nobel Prize in physiology and medicine in 1950 for his work with hormonal drugs on arthritis and rheumatism. A native of Pittsburgh, Pa., Dr. Hench, 66, was also the recipient of the American Public Health Association's Lasker Award and the Page One Award of the Newspaper Guild of New York. He has been associated with the Mayo Foundation and Graduate School of the University of Minnesota since 1921 as professor of medicine there since 1947. Dr. Hench is a fellow of the American Medical Association and the American College of Physicians; a member of international, National, State, and local professional associations and societies; a foreign member or foreign correspondent for several professional associations; and chief editor of the American Rheumatism Reviews, published by the American Rheumatism Association. He has contributed about 200 articles to medical journals. A graduate of Lafayette College in 1916, Dr. Hench received an M.S. degree in internal medicine from the University of Minnesota, his medical degree from the University of Pittsburgh, and studied at the University of Freiburg and Ludwig-Maximilians-Universitat, in Munich. Honorary degrees have been awarded him by Lafayette, the University of Pittsburgh, Washington & Jefferson College, Western Reserve University, the National University of Ireland, and Middlebury College.

Chester S. Keefer, M.D., 65, was a special assistant to the Secretary of Health, Education, and Welfare in 1946 and has been director of Boston University-Massachusetts Memorial Hospitals Medical Center since 1959. He has also been

Wade professor of medicine, Boston University School of Medicine since 1940. From 1940 to 1959, he was director of the Robert Dawson Evans Memorial Hospital and physician-in-chief at Massachusetts Memorial Hospital. During World War II Dr. Keefer was with the Office of Scientific Research and Development, where he was responsible for allocation of penicillin, then in critically short supply. He received his M.D. from Johns Hopkins University in 1922. Dr. Keefer has been instructor in medicine at Johns Hopkins and associate professor in medicine at both Peiping Union Medical College in China and Harvard Medical School. He has served as resident, visiting, and consulting physician at numerous institutions and is a regent and past president of the American College of Physicians. His work with HEW brought him the Medal of Merit.

Theodore G. Klumpp, M.D., 59, is a former Chief of the Drug Division, Food and Drug Administration (1936–41) and is now president and director of Winthrop Laboratories of New York City. He was instructor in internal medicine and assistant clinical professor at Yale University Medical School in 1932–36 and adjunct clinical professor of medicine at George Washington University in 1940–41. He serves the U.S. Department of Health, Education, and Welfare as a member of its Panel on Aging, and is also a member of HEW's Medical Advisory Committee, Office of Vocational Rehabilitation. Dr. Klumpp is a vice president and member, board of trustees of the U.S. Pharmacopeia Convention. In 1961 he was chairman of the committee on rehabilitation of the American Heart Association. From 1955 to 1957 he was vice president of the National Health Council of New York City. He was chairman of the Medical Services Task Force of the Hoover Commission on Organization of the Executive Branch of the Government from 1953 to 1955. In 1951 he served as a director of the World Medical Association. During World War II Dr. Klumpp held membership on War Production Board committees concerned with the development of penicillin mass production and pharmaceutical manufacturing. His fellowships include the American Association for the Advancement of Science and the American Society of Clinical Investigation. A native of New York City, Dr. Klumpp is a graduate of Princeton University and the Harvard University School of Medicine.

John T. Litchfield, M.D., 49, is a specialist in pharmacology and drug safety evaluation. He is director of the experimental therapeutics research section of Lederle Laboratories, Pearl River, N.Y. Born in Minneapolis, he received his M.D. from the University of Minnesota in 1936 and was an assistant and later associate in pharmacology at Johns Hopkins University School of Medicine from 1937 to 1943. He studied under the famed physiologist-pharmacologist, Dr. E. K. Marshall, renowned for his work on the sulfa drugs and other agents. Dr. Litchfield returned to the University of Minnesota in 1943 as assistant professor, and did research there in various fields of chemotherapy. He joined American Cyanamid Co.'s Stamford, Conn., laboratory in 1945 as group leader in the chemotherapy department, leaving in 1954 for his present position. During 1944, he was with the Office of Scientific Research and Development, the Government agency that administered all scientific work associated with the war effort. Dr. Litchfield is a member of the Society of Pharmacologists, the Society of Experimental Biology, the American Chemical Society, and a fellow of the New York Academy of Chemotherapy.

Maurice R. Nance, M.D., 46, is an internist (specialist in diagnosis and nonsurgical treatment of disease) with special training in pathology, the science of the origin, nature, and course of diseases. He is medical director of Smith Kline & French Laboratories in Philadelphia. A native of Reidsville, N.C., Dr. Nance graduated from the Medical College of Virginia in Richmond in 1941 and did his residency at Bryn Mawr Hospital, Pennsylvania, specializing in pathology. He was an associate in pathology there in 1947 and 1948 and was in private practice limited to internal medicine from 1946 to 1955. Dr. Nance first became associated with the Philadelphia drug firm in 1948.

Leonard A. Scheele, M.D., 55, for 23 years was a career officer with the U.S. Public Health Service, serving from 1948 to 1956 as the Surgeon General. He is now senior vice president of Warner-Lambert Pharmaceutical Co. of Morris Plains, N.J. He received his medical degree from Wayne State University in Detroit in 1934. Dr. Scheele's 8 years as Surgeon General were highlighted by the establishment of the Salk polio vaccine distribution system and development of the construction aid program for non-Federal hospitals and universities. He was responsible also for administration of the many specialized research facilities and programs of the National Institutes of Health. Beginning in 1937, and again after World War II service, he was assigned to the National Cancer Institute, becoming its director in 1947.

Among Dr. Scheele's professional offices and memberships are: Fellow, American Public Health Association; diplomate, American Board of Preventive Medicine; member, National Citizens Committee for the World Health Organization; Chief Delegate of the United States to the World Health Assembly for 7 years between 1949 and 1956; member, advisory committee, CARE, Inc.; governing member, Arthritis and Rheumatism Foundation; committee of sponsors, National Society for Crippled Children; visiting lecturer in public health, Harvard University School of Public Health.

Dr. Leon H. Schmidt, 53, a pharmacologist, has been research professor in biological chemistry at the University of Cincinnati College of Medicine since 1950. He has also been director of the Christ Hospital Institute of Medical Research since 1936. He received his Ph. D. from the University of Cincinnati in 1932. Dr. Schmidt is a consultant to the National Institutes of Health and the National Research Council Advisory Medical Board. He is a member of the executive committee of the Veterans' Administration Committee on the Chemotherapy of Tuberculosis. He serves on the editorial boards of a number of medical and technical publications and is a member of many organizations, including the American Association for the Advancement of Science, the World Health Organization, the American Academy of Microbiology, and the American Association for Cancer Research.

Austin Smith, M.D., 49, for 10 years was editor of the most widely read medical journal in the world, the Journal of the American Medical Association. During the same period (1949–58) he was editor in chief of all AMA scientific publications. From 1953 to 1959 he was executive editor of the World Medical Journal. He became president of the Pharmaceutical Manufacturers Association, a professional and trade organization of prescription drug manufacturers, in 1958. He was director of the American Medical Association's Division of Therapy and Research from 1946 to 1950, and secretary of AMA's Council of Pharmacy and Chemistry in 1942–49. He is author of various books and articles related to drugs. Dr. Smith is chairman of the board of directors, U.S. Committee, World Medical Association, and council emissary of the United States to WMA. He holds memberships in many organizations, including the Society of Experimental Biology and Medicine, American Society of Pharmacology and Experimental Therapeutics, and the American Therapeutic Society. Dr. Smith was born in Canada and received his doctorate in medicine from Queens University, Kingston, Ontario.

Thomas B. Turner, M.D., is a microbiologist and has been dean of the medical faculty of Johns Hopkins School of Medicine since 1957. An authority on spirochetal diseases and poliomyelitis, Dr. Turner, 60, is a consultant to the Surgeon General of the U.S. Army. He is a member of the general advisory committee and vice chairman of the committee on virus research and epidemiology of the National Foundation, as well as a member of the advisory committee on personnel for research of the American Cancer Society and the national advisory council of the National Institutes of Health. Born in Prince Frederick, Md., Dr. Turner received his B.S. degree from St. John's College in Annapolis, of which he is now a member of the board of visitors and governors, and he earned his M.D. degree at the University of Maryland. He is a fellow of the American Public Health Association, has been awarded the Legion of Merit, and is a member of the Association of American Physicians and the American Society of Clinical Investigation.

Josef Warkany, M.D., is noted for his research in endocrinology and prenatal deformities. A fellow of the Children's Hospital Research Foundation in Cincinnati, Dr. Warkany, 60, has been attending pediatrician at Children's Hospital since 1935. He is also professor of pediatrics research at the University of Cincinnati and attending pediatrician, pediatric and contagious divisions, Cincinnati General Hospital. Dr. Warkany is a diplomate of the American Board of Pediatrics and a member of the American Pediatric Society, the Society of Pediatric Research, the Ohio Medical Association, the Society for Experimental Biology and Medicine, and the Cincinnati Academy of Medicine. He was awarded the Mead-Johnson award in 1944 and the Borden award in 1950. A native of Vienna, Austria, he come to the United States in 1932 and was naturalized in 1938. He studied at the Real-Gymnasium in Vienna and received his medical degree from the University of Vienna in 1926.

The CHAIRMAN. I assume that does conclude your statement?

Mr. BEESLEY. It does, yes.

The CHAIRMAN. I should like to compliment you on a very fine statement, brief and concise, stating emphatically the views of your organization.

Mr. BEESLEY. Thank you.

The CHAIRMAN. Are there any members who have any questions?

Mr. FRIEDEL. Mr. Chairman, I want to compliment Mr. Beesley for his very fine statement.

Mr. BEESLEY. Thank you.

Mr. FRIEDEL. I remember visiting your plant.

Mr. BEESLEY. I recall your visit with pleasure.

Mr. FRIEDEL. I remember the research you were doing there, but there are a few question I would like to ask.

Do you presently need to get the approval of the FDA before distributing a drug to so-called experts for investigational or experimental use on human beings?

Mr. BEESLEY. No, we do not.

They have the power to require information to be supplied, and within the last 2 weeks regulations have been proposed which would inform FDA about the clinical work that is being done.

Those regulations—I think we have 60 days in which to give our opinions about the regulations.

The general purpose of the regulations, as I understand them, is to give FDA information about the clinical investigations that are going on.

Mr. FRIEDEL. Do you think that you need to have their approval?

Mr. BEESLEY. I beg your pardon?

Mr. FRIEDEL. Do you think you should have approval of the FDA before you distribute the drug to so-called experts?

Mr. BEESLEY. We feel that we should supply FDA with the information about clinical investigations.

We feel that responsible companies will carry on the investigations in a very satisfactory way, and that approval per se is not necessary.

Mr. FRIEDEL. Do you perform these tests on animals, including pregnant animals, before distribution?

Mr. BEESLEY. Before thalidomide?

Mr. FRIEDEL. Before distribution.

Mr. BEESLEY. I think there is a very widespread movement now to test all drugs, or virtually all of them, at least, in pregnant animals.

I do not know the extent of those tests prior to some of the recent happenings.

Dr. Keefer and Dr. Scheele, who will follow me as witnesses, are well qualified to testify in this field.

Mr. FRIEDEL. Let me ask these questions, and I hope they will be pursued.

Mr. BEESLEY. Yes.

Mr. FRIEDEL. Just two more questions.

Are these experts required to advise the person to whom they intend to administer an investigational drug that the drug is investigational or experimental and has not been approved by the FDA?

What I mean by that:

Do they have to get the permission of a person to use it before it is approved by the FDA?

Mr. BEESLEY. No, they do not, and we feel that this should be left to the discretion of the physician. It should not invade the traditional physician-patient relationship.

And I think that, as a matter of general practice, probably most physicians would tell the patient that a drug that is in an investigational phase is being used.

However, there are situations where probably it would not be wise for the physician to tell the patient that an investigational drug is being used.

We feel that it should remain the prerogative of the physician to determine whether it is wise to tell the patient that an investigational drug is being administered in that patient's case.

Mr. FRIEDEL. For the record, I would like to have your reasons why in some cases a patient should not be told.

Mr. BEESLEY. Dr. Keefer will go into this in great detail, if you want to wait just a few moments for his testimony.

Mr. FRIEDEL. Thank you, Mr. Chairman.

That is all the questions I have at this time.

The CHAIRMAN. Mr. Bennett?

Mr. BENNETT. Mr. Beesley, is the law applied differently in respect to the testing of a new drug as distinguished from putting it on the market for general sale?

As I understand it, in the area of a drug that is regarded as experimental, manufacturers put it out on a clinical test basis rather than putting it out for general distribution.

Mr. BEESLEY. Yes.

Mr. BENNETT. Does the law have different requirements with respect to the procedure you follow in testing a drug and in putting it out on the market?

Mr. BEESLEY. The present law exempts investigational drugs from regulation.

Mr. BENNETT. Exempts the test of drugs?

Mr. BEESLEY. Exempts the testing, but it is subject to regulations to be promulgated by the Secretary.

Mr. BENNETT. What are the requirements of the law with respect to a new drug that is put out for general distribution?

Mr. BEESLEY. That new drug applications must be submitted with very extensive information about the experience with the drug, and that information, of course, is reviewed by the Food and Drug Administration.

Mr. BENNETT. While that is being reviewed, do you go ahead and sell it?

Mr. BEESLEY. No, indeed.

According to the food and drug law, not until the Administration has either 60 or 180 days in which to review this information, and either they ask for more information or permit the new drug application to become effective. That is the present law. Or they disapprove it; one or the other.

Mr. BENNETT. Do you file notice that you are going to put the drug on the market or desire to put the drug on the market, say, in 60 days, and if the Food and Drug does nothing, at the end of that time, do you then have authority to put it on the market?

Mr. BEESLEY. If the Food and Drug Administration does nothing, that is correct.

The CHAIRMAN. Will the gentleman yield?

Mr. BENNETT. Yes.

The CHAIRMAN. Maybe I misunderstood you, Mr. Beesley, or I am a little confused about it.

You say in testing under the law it is exempted?

Mr. BEESLEY. That is correct.

The CHAIRMAN. Then you say but it is subject to regulation.

If it is exempted, how can it be subject to regulation?

Mr. BEESLEY. Mr. Chairman, the Department of Health, Education, and Welfare just about 2 weeks ago for the first time issued regulations in this field.

I have here a statement that was issued by the Department of Health, Education, and Welfare which gives the objectives of these regulations.

First, the regulations require that the Food and Drug Administration be notified and given complete details on distribution of drugs for investigational use.

Second, the manufacturer is required to satisfy Food and Drug Administration that the investigations will be based on preclinical, chemical, and animal studies of such a nature as to assure safety for patients.

Third, the clinical studies would have to be properly planned, executed by qualified investigators and FDA kept fully informed of the progress of these investigations.

Now, that is a capsule statement of very long, detailed regulations.

Our association favors the general purposes of these regulations.

Mr. DINGELL. You say you favor the general purposes. Do you object to the regulations in any way?

Mr. BEESLEY. These regulations issued on August 9?

Mr. DINGELL. Yes. Do you have objection to the regulations?

Mr. BEESLEY. We have 60 days inw hich to try to study these regulations and present our views.

Now, then, we have not yet had time to thoroughly appraise and assess the implications of the individual regulations. I think that we probably will have some suggestions to make for changes.

Mr. DINGELL. In other words, you will have some objections to those regulations?

Mr. BEESLEY. Some of the details in them, I think we will have, yes, sir.

The CHAIRMAN. I am not getting into a discussion of the regulations. That is not our purpose at this time.

Mr. BEESLEY. Yes.

The CHAIRMAN. But how can they issue a regulation of this kind executively, if it is exempt under the law?

Mr. BEESLEY. May I ask Mr. Cutler to comment on that?

The CHAIRMAN. Maybe you had better let Mr. Cutler identify himself for the record.

Mr. BEESLEY. Mr. Cutler is a member of the law firm of Wilmer, Cutler & Pickering of Washington, and counsel for the Pharmaceutical Manufacturers Association.

The CHAIRMAN. Yes, if you could clear that up.

Mr. CUTLER. Yes, Mr. Chairman. Under section 505 of the present law, a so-called new drug, that is, one whose safety is not yet generally accepted, may not be introduced into interstate commerce until an

application has been filed with the Food and Drug Administration and the period of time Mr. Beesley referred to, which is either 60 or 180 days, has passed, and the Food and Drug Administration has either let the application become effective or has disapproved it, in which case, of course, the drug could not be marketed.

That section 505 has an exception in subparagraph (i) that permits the introduction into interstate commerce of new drugs for experimental purposes only, subject to such regulations as the Secretary shall issue governing the distribution of such drugs for experimental purposes.

The CHAIRMAN. Then it is not exempted?

Mr. CUTLER. It is not.

The CHAIRMAN. That is what I have been trying to get down to.

Mr. CUTLER. It is not exempted, that is correct.

The CHAIRMAN. All right. That is the answer I wanted.

Mr. BENNETT. Is it exempted under the present law, or are you speaking now——

Mr. CUTLER. Under the present law. Under the present law drugs may only be introduced into interstate commerce for experimental use under regulations issued by the Secretary.

Mr. BENNETT. What are those regulations presently?

Mr. CUTLER. Under the present regulations——

Mr. BENNETT. I do not mean the ones that were issued 2 weeks ago.

Mr. CUTLER. Yes. Under the present regulations the manufacturer is required to obtain a certificate from the clinical investigator, the distributor or whoever else it may be, certifying that he is qualified by training and experience to evaluate the safety of drugs, and the manufacturer is required to keep records of the distribution of drugs for experimental use. That is essentially the scope of the present regulations. The new, proposed regulations are much broader.

Mr. BENNETT. Let us not get into that for a minute or two.

Under the existing law and regulations, can the Food and Drug Administration refuse to permit a drug to be marketed for experimental testing purposes?

Mr. CUTLER. They are not marketed for this purpose, Mr. Bennett. They are distributed. But under the present regulations the Food and Drug Administration does not forbid the marketing for this purpose. Presumably it could.

Mr. BENNETT. I am asking you: Do they have the authority under the present law?

Mr. CUTLER. Under the present law?

Mr. BENNETT. To forbid.

Mr. CUTLER. They have the authority to forbid it, except under such conditions as they might choose to authorize.

I do not think you could read the present law so as to permit them to absolutely forbid any experimental work with new drugs, but they are entitled to set conditions that would adequately protect the public health.

Mr. BENNETT. Presently—and I am not speaking of the recent drug regulations—but, presently, does Food and Drug require you to obtain any affirmative approval from them before testing new drugs?

Mr. CUTLER. No, sir.

Mr. BENNETT. What you are required to do is to file the information that you talked about a few minutes ago and then you go ahead and do the testing?

Mr. CUTLER. You are required to maintain certain records under the present law, that is all.

Mr. BENNETT. Then in testing a new drug, you wish to leave it to the discretion of the physician, who has the drug in his possession, to determine whether or not it is not safe for the patients to use?

Mr. CUTLER. Yes, sir. And if I can turn for a moment to the proposed new regulations, the Food and Drug Administration now desires to be currently informed so that if they would disagree as to the safety of the proposed use, they could take measures.

Mr. BENNETT. They want to bring it within this discretion?

Mr. CUTLER. That is correct.

Mr. BENNETT. Rather than the discretion of the physician?

Mr. CUTLER. Right.

The CHAIRMAN. Mr. Jarman?

Mr. JARMAN. Mr. Beesley, you make a recommendation on page 9 that all manufacturers of drugs be subjected to mandatory inspection by FDA at least once every 2 years.

Mr. BEESLEY. Yes.

Mr. JARMAN. What is the situation at the present time as to inspection?

Mr. BEESLEY. It is to a large extent discretionary. There is no time interval that is specified.

I believe that the inspections occur, perhaps, all the way from an interval of once every 6 months up to perhaps once every 5 years—something of that kind.

This recommendation ties in with our proposal that all drug manufacturers be required to register, because there are supposed to be, according to the census of business, some 1,200 drug manufacturers in the country, and it seems to us that the identification of all of these manufacturers to the Food and Drug Administration and the inspection of all of the manufacturers would be in the public interest.

Mr. JARMAN. When an inspection is made by FDA, how thorough is the inspection? How much time is usually taken for an inspection?

Mr. BEESLEY. Well, our people tell me that it is very thorough; that when an inspector comes to visit us, he is likely to be there several days.

Mr. JARMAN. Thank you.

I think that is all.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Thank you, Mr. Chairman.

I would like to commend Mr. Beesley for his excellent statement.

Mr. BEESLEY. Thank you.

Mr. SCHENCK. I recall a very helpful and instructive visit we made to your laboratory several years ago.

Mr. BEESLEY. Thank you.

We certainly were happy to have the members of the committee visit us.

Mr. SCHENCK. All of us, Mr. Beesley, received a great deal of helpful information at that time, and we appreciated the very diligent care you observe in your plant to make sure of quality control at all steps of manufacture.

Mr. BEESLEY. Thank you.

Mr. SCHENCK. Now, Mr. Beesley, perhaps this is not a question you would care to answer, I do not know, but if you do not, it is quite all right.

Does Eli Lilly & Co., for example, spend a substantial amount of money in research on new drugs each year?

Mr. BEESLEY. Indeed, we do. This is information that we publicize in our annual report and other places, so I have no hesitancy in revealing the figures.

This year our research budget will be between $20 and $21 million, which is approximately 10 percent of our total sales.

In other words, we spend approximately 10 cents out of each sale's dollar in financing research.

Mr. DINGELL. How much do you spend on advertising out of each sales dollar?

Mr. BEESLEY. I do not have the figures in mind.

Mr. DINGELL. Will you submit it for the record?

Mr. BEESLEY. Indeed, I will.

Mr. DINGELL. Would you say it was equal to the 10 cents you spend on research?

As a matter of fact, it exceeds the 10 cents you spend on research, does it not?

Mr. BEESLEY. My opinion is that it does not, but I do not have the figures in mind, and I would prefer not to give a definite opinion on that.

(The requested information was subsequently received for the record:)

ELI LILLY & CO.,
Indianapolis, August 29, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: At page 271 of the transcript of my testimony before the Committee on Interstate and Foreign Commerce, I was asked by Congressman Dingell to submit for the record a statement of the number of cents out of each sales dollar our company spent on advertising during the last year.

During its calendar and fiscal year 1961, Eli Lilly & Co. and its subsidiaries spent approximately 3.2 cents out of each sales dollar on advertising. As pointed out in my testimony, this compares with about 10 cents of each sales dollar spent in financing research.

Respectfully yours,

EUGENE N. BEESLEY, *President.*

The CHAIRMAN. Mr. Schenck, any further questions?

Mr. SCHENCK. Yes, Mr. Chairman.

In the matter of research and the $20 to $21 million that you spend, which is a very substantial sum, it is spent by your company for the purpose of developing the best method of manufacture and also to improve the necessary quality control of both old and new drugs in the best public interest and safety.

Mr. BEESLEY. That is correct.

Mr. SCHENCK. And this is true of all the testing of new drugs?

Mr. BEESLEY. Yes.

Mr. SCHENCK. Now, Mr. Beesley, while I think you said that all of this is a part of your cost of manufacture——

Mr. BEESLEY. Indeed.

Mr. SCHENCK (continuing). As you develop new methods of manufacture, then I assume that these lower costs are reflected in and make lower prices possible?

Mr. BEESLEY. Yes.

We in our company maintain an index of prices, and in the last 10 years the index, which includes all of the drugs that we have, is now approximately 86 percent of the figure that it was at the beginning of the 10-year period.

Mr. SCHENCK. I have in mind, Mr. Beesley, that when insulin was first introduced, your company, I believe, was one of the key manufacturers of insulin?

Mr. BEESLEY. That is right.

Mr. SCHENCK. At that time it was quite expensive, was it not?

Mr. BEESLEY. Yes, it was.

Mr. SCHENCK. And it is now very much less in cost to the patient is it not?

Mr. BEESLEY. Yes.

It has been, I think, about 40 years since we first introduced insulin. We have had 13 price reductions during that period, and I believe the current price is about 6 percent of the price that prevailed in 1922.

Mr. SCHENCK. So that the users of the drugs manufactured do benefit, as you have increased your ability to develop drugs at lower cost?

Mr. BEESLEY. Indeed, that is correct.

Mr. SCHENCK. Now, I have one other series of questions here.

It has been suggested, Mr. Beesley, that the pharmacists, in filling a prescription, should somehow or other indicate on the prescription label itself the kind of drug that is in that prescription.

Is it not true that pharmacists buy drugs in, let us say, large quantities of a thousand, or so as an example, of a certain kind of tablet?

Mr. BEESLEY. Yes.

Mr. SCHENCK. They fill a physician's prescription for perhaps 25, 30, or 50 tablets and put them in a small container.

Now, the pharmacist then puts on that small container his own prescription number and the doctor's name, the date and the dosage.

Would it be a difficult proposition to require the pharmacist also indicate on the prescription label the generic of the drug that was included?

Mr. BEESLEY. I suppose it could be done, but I think it would be unwise and certainly would not be in keeping with the wishes of the great majority of the medical profession, because most patients are not familiar with the actual characteristics of the drug that the physician may think it advisable for them to take, and it is in the nature of the relationship of the physician with his patient and the relationship between the patient and the pharmacist that the physician and the pharmacist should have the information about the drug that is being used, being prescribed by the physician, but I would doubt the wisdom of putting that name on the actual label of the prescription package, sir.

Mr. SCHENCK. In some cases that would be difficult, anyhow, would it not, because of the very long and involved chemical name?

Mr. BEESLEY. Indeed.

Mr. SCHENCK. Or the generic term?

Mr. BEESLEY. It certainly would.

Mr. SCHENCK. There also are times when the pharmacist removes the label from the small container and merely puts on the prescription label, is that not true?

Mr. BEESLEY. That is correct.

Mr. SCHENCK. Is there any way for a pharmaceutical manufacturer to identify the capsule, the tablet, or what have you, so that in the event the patient becomes ill while he is away from his own home community and home physician, that another physician would know what he had been taking?

I am thinking of something for a heart condition or something for a respiratory condition, or something of that nature?

Mr. BEESLEY. I think the way that most physicians prefer to have this handled is for the pharmacist to give the patient a copy of the prescription, and the patient then carries the copy of that prescription with him regularly.

The manufacturer would be able, in most instances, to determine if it was that manufacturer's own product that had been used, but sometimes it would not be readily apparent without a chemical analysis.

Mr. SCHENCK. Mr. Beesley, I want to commend you for your splendid statement.

Mr. BEESLEY. Thank you.

Mr. BENNETT. The Chair asked me to recognize Mr. Dingell next. Do you have any questions, Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. Beesley, I want to compliment you on a very fine statement. We are honored to have you with us this morning.

Mr. BEESLEY. Thank you, Mr. Dingell.

Mr. DINGELL. I would like to go through briefly with you, if I may, to see what sections of the administration's bill you endorse and what you oppose, and then we will try and find out specifically why.

Mr. BEESLEY. Mr. Dingell, may I suggest that you have before you the list of witnesses, and they are going to discuss each of these sections in detail.

It was our hope that in order to handle the hearing expeditiously, that they might be permitted to discuss the appropriate provisions.

Mr. DINGELL. I see. Let me ask you this: Do you oppose the amphetamines and barbiturates section?

Mr. BEESLEY. No, we do not.

Mr. DINGELL. You endorse that?

Mr. BEESLEY. Indeed.

Mr. DINGELL. I see. Very good. So in our consideration of the bill we can dispose of those as being agreed upon by the industry, am I correct, those two sections?

Mr. BEESLEY. I think there are a few minor problems on language, but certainly nothing of substantial importance.

Mr. DINGELL. All right. Now, you mentioned penicillin has saved thousands of lives.

I think this is one of the great things. As a matter of fact, I happen to be living because of penicillin, too, but I was wondering about this: Penicillin is one of the drugs which is approved on a lot or a batch-by-batch basis, is it not?

Mr. BEESLEY. Yes.

Mr. DINGELL. There are five of these antibiotics which are endorsed or, rather, which are approved on a batch-by-batch basis. Those are the five that were named in the original statute, am I correct?

Mr. BEESLEY. That is correct, yes.

Mr. DINGELL. Subsequent to that time, there have been a number of new antibiotics which have come on the market?

Mr. BEESLEY. Yes.

Mr. DINGELL. The statute, of course, was silent on these and these are just treated as ordinary drugs as opposed to antibiotics, am I correct?

Mr. BEESLEY. That is correct.

Mr. DINGELL. The administration bill proposes to expand the treatment of antibiotics to cover all of these.

Now, do you endorse or do you oppose that section?

Mr. BEESLEY. We would oppose the extension of that certification.

Mr. DINGELL. On what ground?

Mr. BEESLEY. May I give a little background here, which I am sure you are quite familiar with, but I would like to recall it to lay the groundwork.

You will recall that batch certification was put in the act about the middle of World War II, and this was right in the beginning of the time when antibiotics were being used.

Certainly fermentation and the purification procedures were not at that time an exact science, and it was during that time that our industry cooperated with the Government in getting legislation enacted that would require the certification of at that time just penicillin, and later the other antibiotics were added.

However, since that time the whole thing has changed. Fermentation has become very much more an exact science, and today manufacturers can produce antibiotics with the same skill and definiteness that any other drug can be produced with, and, as a consequence, we do not feel that batch certification should be extended to include other antibiotics.

Mr. DINGELL. Then, as a matter of fact, you feel that batch certification should be stricken insofar as the five which have this requirement, am I correct?

Mr. BEESLEY. That is my personal opinion, yes.

Mr. DINGELL. Why do you feel this should be done, because it is costly?

Mr. BEESLEY. Costly and duplication, unnecessary.

Mr. DINGELL. Basically, though, it is cost, is that it?

Mr. BEESLEY. Yes. And it uses the time of highly skilled people, a group of individuals who are certainly in short supply.

Mr. DINGELL. The thing that concerns me is here I note that in 1962 penicillin had to be recalled, or one batch had to be recalled because it was contaminated with sulfonamides.

Apparently there was need for batch-by-batch certification in that particular case, was there not, because they found that one particular lot of penicillin was contaminated with sulfonamides?

This would indicate that there is some need for batch-by-batch certification, at least in the case of penicillin, and I would assume that these other newer antibiotics are really not much different in the method of preparation. Am I correct on this?

Mr. BEESLEY. Was that batch of penicillin certified?

Mr. DINGELL. I would assume that it was, if they are supposed to. I would assume that it had been. I do not know whether it was or not, but I assume it was supposed to have been.

Mr. BEESLEY. Do I understand that this was a recall of penicillin contaminated with sulfonamides by FDA from the market, is that correct?

Mr. DINGELL. That is correct. That is my understanding.

Mr. BEESLEY. Now, that would indicate, then, that batch certification did not do the job.

Mr. DINGELL. It would indicate that, but it would indicate we were better off with batch certification than without it, am I correct?

Mr. BEESLEY. The penicillin apparently here was certified. It was produced, and then certified by FDA?

Mr. DINGELL. Yes.

Mr. BEESLEY. Now, apparently—I am just guessing, now—I assume from the statement you have made that there was a contamination with sulfonamides in the tableting or whatever it was of the pharmaceutical form, so that we might get back to factory inspection or something like that.

Mr. DINGELL. I think this is also a good case for factory inspection.

Mr. BEESLEY. I agree.

Mr. DINGELL. Is it not?

Mr. BEESLEY. I would agree, yes.

Mr. DINGELL. But, to continue on this, you object to this because it is costly, am I correct, in the case of antibiotics?

Mr. BEESLEY. It is a duplication of effort.

Mr. DINGELL. But basically it is costly?

Mr. BEESLEY. Yes.

Mr. DINGELL. Duplication of efforts boils down to simply economic costs?

Mr. BEESLEY. That is right.

Mr. DINGELL. Does it not?

Mr. BEESLEY. That is right.

Mr. DINGELL. If I told you this costs a twentieth of a cent a dose, would you say that that was costly, a twentieth of a cent to certify the batch, a twentieth of a cent a dose? This is Food and Drug figures.

They say it costs a twentieth of a cent a dose to certify a prescription antibiotic.

Now, would you say that this is costly?

Mr. BEESLEY. It is just one more added cost.

Mr. DINGELL. I know, but let us compare this with advertising.

It is a great deal less than the amount of the advertising cost per dose of prescription antibiotics, is it not?

Mr. BEESLEY. May we carry this one step further?

Mr. DINGELL. Let us stay right where we are first, and then we will go a step further.

Mr. BEESLEY. All right.

Admittedly, of course, one-twentieth of a cent, in itself, per dose, is not much, but it is just that additional expense. Now, we might say that everything ought to be certified. That certainly would be a duplication and a costly procedure.

Our point, Mr. Dingell, is that we do not believe that antibiotics are in any different category than most other drugs.

Mr. DINGELL. For 5 years we have had certification on batch-by-batch basis on five.

Mr. BEESLEY. That is right.

Mr. DINGELL. And apparently it has worked well.

Mr. BEESLEY. Yes, but——

Mr. DINGELL. Apparently it has afforded protection to the people, and we have five which do have this protection that is standard to users, and then we have the balance of these antibiotics which have no similar protection extended to users.

Mr. BEESLEY. And may I point out that, so far as I know, there has been no difficulty that certification could have prevented with the balance of the antibiotics.

Mr. DINGELL. Let us talk factory inspection a little bit.

Do you oppose any additional factory inspection authority in the Food and Drug Administration?

Mr. BEESLEY. Now, may I point out that Mr. Connor will go into this in great detail.

Mr. DINGELL. I understand that, but I want to query you on it, too.

Mr. BEESLEY. General support for the provision.

Mr. DINGELL. You support the provision of factory inspection?

Mr. BEESLEY. In general, yes.

Mr. DINGELL. In general. Now, that means you have some specific reservation. Would you care to enumerate them briefly?

Mr. BEESLEY. As I pointed out in point No. 5, I think that is in my statement, Mr. Dingell, inspection powers should be broadened to cover all facilities, controls, and records that have a material bearing on violations of the law.

Mr. DINGELL. Then you do support expansion of the factory inspection provisions in the law?

Mr. BEESLEY. Expansion, yes, with certain reservations.

Mr. DINGELL. Last of all, do you support the requirements for adequate controls of manufacture?

Mr. BEESLEY. Yes.

Mr. DINGELL. Which is 101?

Mr. BEESLEY. Yes, we do.

Mr. Connor also will speak to that.

Mr. DINGELL. Thank you very much, Mr. Chairman.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

I do want to join in complimenting you, Mr. Beesley.

Mr. BEESLEY. Thank you.

Mr. YOUNGER. For a very fine statement.

I have only one question.

In the experience of your company, how many drugs have been removed from the market by the FDA?

Mr. BEESLEY. Of our company?

Mr. YOUNGER. Yes.

Mr. BEESLEY. We have had none.

Mr. YOUNGER. In your entire history you have had none?

Mr. BEESLEY. To the best of my knowledge, we have had none, that is correct.

We have had maybe one, two, or three voluntary recalls of a particular batch of a drug, but, as far as taking off the market by the Food and Drug Administration, we have had none as long as the Food and Drug Administration has been supervising the manufacture of drugs.

Mr. YOUNGER. For general information, do you know how many from other companies, or have you heard of how many have been withdrawn?

Mr. BEESLEY. I believe Mr. Connor has detailed statistics on that question.

I do not recall the figures specifically.

Mr. YOUNGER. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Moss, do you have any questions?

Mr. Moss. I have no questions at this time, Mr. Chairman.

The CHAIRMAN. Mr. Rogers?

Mr. ROGERS of Florida. Thank you, Mr. Chairman.

Mr. Beesley, your testimony has been helpful, and I think it is fine that the drug industry has set up a Commission on Drug Safety.

On page 8, your item No. 4, you mentioned that the FDA should have authority, if an item is not safe, to withdraw it after a hearing.

Is it not true that if an item is not safe now, that FDA can remove it from the market?

Mr. BEESLEY. Yes. Yes.

Mr. ROGERS of Florida. What additional authority is necessary?

Mr. BEESLEY. We fully support the position that a manufacturer's product should do what it is claimed to do. We feel, however, that the test should be whether or not there is substantial evidence that the drug will do what it is claimed to do.

I believe that answers the question.

Mr. ROGERS of Florida. What about your statement that in the light of new evidence it is now shown to be safe? That refers where there is a substantial doubt that it is safe?

Mr. BEESLEY. May I defer to Mr. Cutler?

Mr. CUTLER. Mr. Rogers, under the present law, the Food and Drug Administration may remove a drug from the market after hearing if the Food and Drug Administration can carry the burden of showing that the drug is not safe.

In other words, they must prove unsafety.

The proposed amendment would establish substantially the same test that exists when the drug is first allowed on the market, when the manufacturer must prove that the drug is shown to be safe, and we agree that the law should be amended so that in a recall case, a suspension case, the manufacturer must bear the same burden he had to bear in the first instance of proving in the light of new evidence that the drug is still shown to be safe.

That is the distinction.

Mr. ROGERS of Florida. So if there is a substantial doubt, then, on the part of FDA, once a drug has been approved and it is on the market, if there is substantial doubt, then, FDA could say:

"We want to remove this," have a hearing, as you propose?

Mr. CUTLER. Yes.

Mr. ROGERS of Florida. And the burden is then on the manufacturer?

Mr. CUTLER. Yes.

Mr. ROGERS of Florida. Before the drug would be removed?

Mr. CUTLER. Before the drug would be removed, yes, sir.

Mr. ROGERS of Florida. In other words, they must have a hearing before the drug would be removed?

Mr. CUTLER. Yes.

Mr. ROGERS of Florida. Suppose there is sufficient evidence to show it is not safe.

Could not FDA go ahead and remove it immediately without a hearing?

Mr. CUTLER. Under present law they could obtain a preliminary injunction in a court to remove it under those conditions, yes.

Mr. ROGERS of Florida. So that they do have some way of removing it?

Mr. CUTLER. Yes.

Mr. ROGERS of Florida. If it is not safe?

Mr. CUTLER. Yes.

And, of course, they are always free to notify the medical profession that they regard it as unsafe, which amounts to removal.

Mr. ROGERS of Florida. Yes.

Thank you, Mr. Chairman.

The CHAIRMAN. Carrying that one step further, the Administrative Procedures Act would have to be complied with in the course of the hearing, would it not?

Mr. CUTLER. Yes.

The CHAIRMAN. I am talking about with reference to withdrawing something that has been on the market.

Mr. CUTLER. Yes, that is correct, Mr. Harris.

Now, there is a provision in this bill which would allow the Food and Drug Administration to withdraw a drug from the market before a hearing, and without consultation with the manufacturer, if the Food and Drug Administration finds what is called an imminent hazard to the public health.

The CHAIRMAN. Do you support that?

Mr. CUTLER. We do not support that provision, sir.

We think that that provision gives the Food and Drug Administration more authority than it needs.

We think it already has ample power to remove a clearly unsafe drug from the market immediately, and that there should not be discretionary power, except in this one case of a clearly unsafe drug, where they already have all the power they need.

The CHAIRMAN. In other words, under present law you contend that the Food and Drug Administration can take any drug off the market that it determines to be unsafe?

Mr. CUTLER. Yes, sir, immediately, by going to a court and getting a preliminary injunction.

The CHAIRMAN. But they would have to go to a court to do it?

Mr. CUTLER. To get a preliminary injunction, yes sir, or under present law they could hold a hearing and determine, as a result of the hearing, that the drug was unsafe and remove it from the market.

Mr. BENNETT. Will you yield just to clarify that?

What is the difference between the present law, then, and the change that is being proposed here?

Mr. CUTLER. You are speaking now of the power to remove?

Mr. BENNETT. What you are talking about.

Mr. CUTLER. Because of the imminent hazard to the public health without a hearing?

Mr. BENNETT. You got me confused, and I think you have the chairman confused, too, about where the authority lies.

You say, on the one hand, that the Food and Drug has authority to remove an unsafe drug by going into court and getting an injunction; and, on the other hand, they can hold a hearing and enter an order themselves.

Mr. CUTLER. Yes, sir. They have the power——

Mr. BENNETT. Do they have those dual powers under the present law?

Mr. CUTLER. Yes, under the present law they have the power.

Mr. BENNETT. The dual power?

Mr. CUTLER. The power to hold an administrative hearing and, after the hearing, remove a drug administratively from the market as unsafe, or they have the power before an administrative hearing to go right to a court and get a preliminary injunction removing the drug from the market as unsafe.

Mr. BENNETT. All right.

Now, what additional or different authority would this bill give them?

Mr. CUTLER. This bill would give them the power by an order which the Secretary could sign this morning, without a hearing, without notice to the manufacturer, just ordering the drug removed from the market.

Mr. FRIEDEL. Mr. Chairman, will the gentleman yield?

Just one question on the same point.

You say that they have a right to have a hearing and then take a drug off the market?

Mr. CUTLER. Yes, sir.

Mr. FRIEDEL. Suppose they refuse. What happens?

Mr. CUTLER. It would be a criminal violation of law.

Mr. FRIEDEL. In other words, they would not have to go to court, then, to get a preliminary injunction?

Mr. CUTLER. No, sir.

Mr. FRIEDEL. That is all, Mr. Chairman.

The CHAIRMAN. I will go into that a little later.

Mr. Sibal?

Mr. SIBAL. Thank you, Mr. Chairman.

Mr. Beesley, on page 8 of your statement, the second point, FDA must have ample time to consider the safety and effectiveness of new drugs before they are introduced, but unnecessary delays in permitting valuable new medicines to reach the public must be avoided.

I think everybody would agree with that statement, but, on the other hand, there are interpretations which could differ substantially.

What is the present procedure if at the end of 60 days the FDA does not feel it is able to form an opinion as to the safety and efficacy of a drug?

Mr. BEESLEY. Then that time is extended to 180 days.

Mr. SIBAL. And suppose at the end of 180 days they still do not feel that they are qualified, considering the tremendously broad area of public health involved here, to have an opinion?

Mr. BEESLEY. They can turn it down on the grounds that there is not enough evidence of safety to permit the drug to go on the market.

Mr. SIBAL. Does the industry have any legal rights to require a decision anywhere along the line?

In other words, what right does the industry have to protect itself against perhaps dilatory treatment of its application?

Mr. BEESLEY. There is a provision giving the manufacturer the right to have a hearing after the verdict of the FDA, after the opinion has been formed.

Mr. SIBAL. You have a hearing before the FDA examiner?

Mr. BEESLEY. That is correct.

Mr. SIBAL. What happens then if the FDA is still uncertain?

Mr. BEESLEY. After the hearing it could be carried to the courts on appeal.

Mr. SIBAL. Has this ever happened?

Mr. BEESLEY. To the best of my knowledge, it has not.

Mr. SIBAL. Do you consider these 60- and 180-day provisions realistic?

Mr. BEESLEY. It has been proposed that the 60 days be extended to 90 days, and we have no objection to that, but, otherwise, we think the 90 and 180 days would be quite realistic.

Mr. SIBAL. Do you, based on your long experience in dealing with the FDA, feel that it has the personnel to meet these arbitrary deadlines, so to speak, without perhaps reducing the attention the personnel can give these drugs?

Mr. BEESLEY. Our association has long supported additional funds for Food and Drug Administration in order that they can have more personnel than they now have.

Mr. SIBAL. Do you feel they need it?

Mr. BEESLEY. Yes, indeed, we do.

Mr. SIBAL. Now, in these experimental cases which were referred to earlier in the testimony and also in the questioning of some of the other members, has there been any history of harmful effects in the past?

I am not talking about the immediate past which we are all aware of, but over the years, which resulted from the use of experimental drugs?

Mr. BEESLEY. I would answer that by saying that I think the record has shown that the present procedure is quite satisfactory, and it has only been in the last few weeks that there has ever been, so far as I am aware, any serious cloud thrown on the present procedure.

But Dr. Scheele, who is the former Surgeon General, and Dr. Keefer will follow me as witnesses, who can speak with more authority on that subject than I can.

Mr. SIBAL. Now, this procedure, as I recall, with the physician—would you mind repeating your testimony concerning what a physician must do when he is using a drug which has not been approved, but which is in an experimental stage?

Mr. BEESLEY. The physician signs an investigational use form which the manufacturer must keep on file. That is the present procedure.

The manufacturer has the responsibility of selecting careful, satisfactory investigators.

Now, then, the Food and Drug Administration just on August 9 issued the regulations that we have referred to earlier. Would you like for me to repeat the objectives of those regulations?

Mr. SIBAL. No, I recall them.

Mr. BEESLEY. Yes.

Mr. SIBAL. I was more interested in the actual mechanics of how it is done.

Mr. BEESLEY. Yes. I think that that is the extent of the present regulation.

Mr. SIBAL. The physician fills in a form and returns it to the manufacturer?

Mr. BEESLEY. And, of course, all records and reports that are submitted to the manufacturer then on subsequent investigations of the drug are retained.

They are available for inspection by the Food and Drug Administration.

Of course, most of this material is included in the new drug application that is eventually submitted if the manufacturer feels that the drug is worthy of such submission.

Mr. SIBAL. How long a period of time does this experimental phase last?

Mr. BEESLEY. Well, of course, it will vary from drug to drug. Perhaps as long as 5 years in some instances; sometimes as short a period as 1 year, perchance. Very seldom would it be less than 1 year.

Mr. SIBAL. There is no regulation which controls this. This is entirely at your discretion?

Mr. BEESLEY. There is no current legislation in force. There would be regulations under the proposal issued on August 9.

Mr. SIBAL. How do you feel about that?

Mr. BEESLEY. As I stated earlier, we are in favor of the objectives. We have 60 days from August 9 in which to develop our considered opinions, and we think we will have some suggestions for changes on specific language.

But we certainly are in accord with the general objectives of the regulation.

Mr. SIBAL. Now, is there any indication as to the breadth of your use of experimental drugs or the amount, the number of physicians, for example?

Mr. BEESLEY. There is no present statutory regulation or regulation promulgated by HEW or Food and Drug Administration that would limit that.

Mr. SIBAL. Including the August 9 proposed regulation, there is nothing in there?

Mr. BEESLEY. As I understand the regulations, there are no specific limitations in that field.

The manufacturer would be required to submit information to Food and Drug Administration on the extent of the investigation, and if the Food and Drug Administration is not satisfied with the amount of information that is being obtained, then the FDA has the power to ask the manufacturer to improve his test, and if the manufacturer does not do so, the regulation then states that if the conditions of exemption are not immediately met, the Commissioner shall notify the sponsor of the termination of the exemption.

But there is another specific point that perhaps we should mention in this connection, and may I just quote it:

> The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505(b) of the act or a statement that the investigation has been discontinued and the reasons therefor.

Mr. SIBAL. Is that in the present regulation?

Mr. BEESLEY. That is the proposed regulation, yes.

Mr. SIBAL. So that would tend, I suppose, to eliminate these five cases?

Mr. BEESLEY. Here let us take a cancer drug, for example, that would, very likely, be under investigation for a long time before it is ever put on the market, if ever, and quite properly so, and I am sure the Food and Drug Administration would agree in such case.

Mr. SIBAL. I just have one more question.

What must you show the FDA, or is there any requirement that you must show the FDA, before you use a drug in this experimental phase?

I mean is there a minimal amount of research which you must show?

Mr. BEESLEY. You mean currently or under the proposed regulation?

Mr. SIBAL. Currently.

Mr. BEESLEY. No, there is nothing.

Mr. SIBAL. So, theoretically—I know you are a company of repute which would not do this, but, as a matter of theory—a drug could be distributed to physicians in this country under the experimental phase of the law which had not actually had much research done on it, is that correct?

Mr. BEESLEY. I think that is correct.

I do not believe it would happen, but I think there would have been adequate tests performed, but technically I think you are entirely correct.

Mr. SIBAL. This is in the responsibility of the manufacturer?

Mr. BEESLEY. That is correct.

Mr. SIBAL. Do you think this is sound?

Mr. BEESLEY. This is the sort of thing that would be corrected under the regulations just proposed on August 9. That is one of the reasons why we support the objectives of these regulations.

Mr. SIBAL. Thank you very much, Mr. Beesley.

Thank you, Mr. Chairman.

The CHAIRMAN. I just want to pursue for one moment this question of withdrawing the drug when it is determined that it is unsafe.

In the past, when it was determined that a drug was unsafe and it was suggested that it be withdrawn, has the industry cooperated?

Mr. BEESLEY. That is right.

The CHAIRMAN. You will recall the figures in connection with the polio vaccine?

Mr. BEESLEY. Yes.

The CHAIRMAN. You will recall the concern created then, and of course there is the recent publicity having to do with thalidomide which caused great interest throughout the world.

I want to now recognize the presence of Dr. Kelsey. We appreciate Dr. Kelsey's interest in this program and we are glad to have you with us in these hearings today.

But thalidomide was never put on the market?

Mr. BEESLEY. No.

The CHAIRMAN. There were certain amounts of it that were given to doctors.

In other words, any manufacturer may develop a drug and then provide as much of it as he wants to doctors for experimental purposes?

Mr. BEESLEY. That is correct.

Mr. CUTLER. The statute, Mr. Harris, gives the FDA full power to set the terms and conditions on which drugs will be distributed for experimental use.

Until recently the FDA had not fully exercised that power.

The CHAIRMAN. In other words, there is plenty of authority?

Mr. CUTLER. Correct.

The CHAIRMAN. To deal with that insofar as the law is concerned?

Mr. CUTLER. Yes, sir.

The CHAIRMAN. But until a few days ago, the FDA has never taken such steps to control that particular phase of it?

Mr. CUTLER. They had taken some steps, but they had not utilized their full authority until the last few weeks.

The CHAIRMAN. In other words, under the law—and I think this should be made very clear and specific because of all the publicity that has been given to it—the agency does have authority to make certain requirements even for the dispensation of a new drug for testing purposes to physicians?

Mr. CUTLER. Yes, sir, section 505(i) of the present law.

The CHAIRMAN. And if the Department had utilized the authority it has under the statute, then thalidomide, which was given to certain doctors of the country, could have been withheld?

Mr. CUTLER. Whenever the Food and Drug Administration had wanted to withhold it.

The CHAIRMAN. Yes, that is what I am talking about.

Mr. CUTLER. The Food and Drug Administration would have had full and current information.

The CHAIRMAN. In other words, not only under present law does the Department have authority to withhold the drug thalidomide from being put on the market, but had it utilized fully the provisions of law and taken precautions which are authorized by law, they could have controlled the dispensing of thalidomide to the doctors?

Mr. CUTLER. Yes.

The CHAIRMAN. I wanted to make that very clear and definite.

Now, back to the present authority and what is proposed with reference to withdrawing a drug if it should be determined unsafe, after approval had been given.

A good many years ago, a polio vaccine had been approved and was dispensed to the general public. After a certain length of time there were reports as to the effect it had on certain people throughout the country.

Now, had not the industry cooperated by voluntarily withdrawing it or trying to withdraw it from the market—that was Salk vaccine then, was it not?

Mr. BEESLEY. That is correct.

The CHAIRMAN. Incidentally, I do recall the visit we had to your company back in those days.

Mr. BEESLEY. We were very privileged to have you, sir.

The CHAIRMAN. The visit was very revealing from the standpoint of the committee at that time.

Now, if the company had not cooperated—and I do not believe it was your company that was involved in that, either, was it?

Mr. BEESLEY. It was another company, sir.

The CHAIRMAN. If it had not cooperated, then before the Food and Drug Administration could have required it to be withheld, under the law it would have been necessary to have a hearing, No. 1, and the Administrative Procedures Act would have had to be followed, or else the FDA would have had to go to court to get an injunction?

Mr. BEESLEY. First, as you will recall, this is a biological product that you are referring to, and is under the jurisdiction of the Department of Biological Standards of the National Institutes of Health, and it is a different statute. But assuming the same circumstances, the rules are the same.

The CHAIRMAN. Now, you know, as one lawyer to another, although I have been removed from that practice for a good many years and would not maintain that I am on a par, but it requires time to process a case under the Administrative Procedures Act, does it not?

Mr. CUTLER. Yes, sir.

The CHAIRMAN. It could require a lot of time?

Mr. CUTLER. Yes, sir.

You could have an expedited hearing, if you follow the administrative hearing course. I would think you could have a hearing within a period of several months, but it would take at least several months.

The CHAIRMAN. It would take several months, and possibly much longer?

Mr. CUTLER. Right.

The CHAIRMAN. Now, you go into court and ask for an injunction. That would require some time?

Mr. CUTLER. That might require, at best, 48 hours, I would think, Mr. Harris.

The CHAIRMAN. Yes.

And if the judge had some questions in his mind as to what to do with it, it could require a longer time?

Mr. CUTLER. If you were on the bench and the Food and Drug Administration came to you requesting an injunction for what they deemed to be a clearly unsafe drug, I would think you would grant the preliminary injunction while you looked into the matter.

The CHAIRMAN. I would certainly consider it.

Mr. CUTLER. If I were on the other side, I do not know how we could stop you.

The CHAIRMAN. I was trying to develop and pinpoint the difference here—although it is somewhat technical—about the attitude of the industry toward temporary suspension of the use of the drug by injunction, and the request of the Administration to have this temporary authority within the agency.

Mr. CUTLER. We are asking, sir, only that there be some check on the arbitrary authority of one man without hearing and without even discussion with the manufacturer.

The CHAIRMAN. Even if that one man is the Secretary, himself?

Mr. CUTLER. Yes, sir.

He at least ought to be able to satisfy a judge in a court within 24 to 48 hours. He has any number of remedies available. He can notify all physicians immediately that he suspects the drug, and that will really do more by way of stopping immediate use than any kind of recall procedure.

He has plenty of weapons during the period while he has to check his judgment with somebody and give some kind of a hearing.

The CHAIRMAN. I think you should give serious consideration as to the result.

Now, let us go back and take the experience of withdrawing cranberries from the market several years ago, and see what happened throughout the country.

I suppose there is still debate going on whether that should have been done or should not have been done.

I am not going to ask you to comment on it, and I am not going to comment on it either.

But, using that as an example, you know, as a matter of fact, it did create a great deal of uneasiness and concern all over the country among business people, particularly those who had it on the shelves and others. Then a search went out to get the cranberries off the shelves.

In the case of experimental drugs sent to doctors the distribution would not be as wide but if it were to get to drugstores throughout the country, it seems to me there would be about the same turmoil.

It seems to me that serious consideration should be given to meet this problem without getting involved in such a public turmoil, which scares everybody to death.

Now, there are quite a lot of doctors in the country that had thalidomide dispensed to them. How many doctors have we got in the country?

Mr. BEESLEY. About 175,000 to 180,000.

The CHAIRMAN. 180,000 in the United States.

Well, with all the publicity that is given, I do not suppose there is any way of telling how many expectant mothers in the country were just put in a very, very unstable mental condition.

And I know and you know, as a matter of fact, thousands upon thousands of young mothers have been in terrible mental anguish during this stage of expectancy. It does seem to me that there should be some way to avoid that kind of a situation.

Thank you very much.

Mr. Moss. Mr. Chairman?

The CHAIRMAN. Mr. Moss.

Mr. Moss. I have just a couple of questions. One, I would like to have some clarification of this authority of the Secretary in the matter of investigative or experimental use of drugs. He may not deny the right to a drug for investigative or experimental purposes, may he?

Mr. CUTLER. I think that in an extreme case he probably could, Mr. Moss.

Mr. Moss. The law says that he shall promulgate such rules and regulations for its use.

Mr. CUTLER. Yes.

Mr. Moss. For this purpose.

Mr. CUTLER. Yes, but if the information which he required be furnished to him showed such a clear case of danger and lack of safety, perhaps he could even stop it under those circumstances.

Mr. Moss. That is a question that is unresolved at the moment.

Mr. CUTLER. It has never been attempted, but I don't think it could be challenged.

Mr. Moss. Now I am interested in the objection to granting the Secretary the authority to summarily remove, after approval, a drug where there is an imminent hazard to the public health. You indicate that in all probability a judge would grant a temporary order. He might not, however. It isn't totally inconceivable that he might not.

Mr. CUTLER. I think it would depend on the strength of the Secretary's case.

Mr. Moss. It is like the question I asked just a few moments ago. This is one of those things that is unresolved.

Mr. CUTLER. Yes.

Mr. Moss. What is so onerous about the language which requires, one, that there be an immediate notice upon the suspension of approval, and that the order state the finding upon which it is based?

Now if it were capricious, certainly you could go into court at that point on the basis of the order and challenge the action of the Secretary, could you not?

Mr. BEESLEY. May I comment on the question, Mr. Moss?

Mr. Moss. Certainly.

Mr. BEESLEY. We have here a situation where a manufacturer has a substantial investment in a product, usually millions of dollars in the research, in the development of that product, and here the manufacturer has launched it on the market again, with an investment of a lot of money. It seems to us that before a virtual death sentence can be passed on that activity, that the manufacturer should have a hearing for a temporary suspension is virtually a death sentence, because with the publicity that would be attendant to taking that product off the market temporarily, it would in effect be killing the drug completely.

Now if it is warranted, that is fine, but if it isn't warranted, then we think that that is really an arbitrary use of the power that is unjustified.

Mr. Moss. What would be the effect of the Secretary seeking a temporary injunction? Wouldn't there be the attendant publicity, and from the standpoint of a death sentence just about the same effect?

Mr. BEESLEY. Well, that could be, but at least a court of law would have to pass on the question.

Mr. Moss. Here we are discussing the finding of an imminent hazard to the public health.

Mr. BEESLEY. Yes.

Mr. Moss. Now if for that finding—and I would trust that it would not be capriciously made.

Mr. BEESLEY. Indeed.

Mr. Moss. If the evidence is such as to convince the Secretary, and of necessity before he is convinced the staff of the Food and Drug Administration must also be convinced that there is an imminent hazard, then we are talking about a most unusual case rather than the routine; are we not?

Mr. BEESLEY. Yes.

Mr. Moss. And at that point, having convinced the agency and the Secretary, shouldn't we be then concerned with the immediate protection of the public? There must be fairly persuasive evidence at hand for that conclusion to be reached.

Mr. BEESLEY. Mr. Moss, I would like to submit that in my judgment these occasions do not require such precipitate action.

Now then, may we take the recent unpleasant situation? I have no personal information on this, but judging from the newspaper reports, it is my understanding that the allged connection between thalidomide and deformities has been known for some 8 months. In fact, one magazine of national circulation, aside from the articles that had appeared in the medical journals, one lay magazine of national circulation published this in late February.

Mr. Moss. Mr. Beesley, we are not talking about the type of case that would be involved here. We are talking here of a preparation previously approved. Thalidomide was not in that category. Approval was withheld on thalidomide because of the vigilance of a member of the staff of the Food and Drug Administration.

Mr. BEESLEY. Correct, that which was marvelous.

Mr. Moss. Here we are discussing one where approval has been given, and on a broader use undoubtedly some development has emerged, in its totality, that must be very persuasive if the Secretary is to make a finding of an imminent hazard to the public health.

Mr. BEESLEY. Well, may I allude to another recent example that has been in all, or was in all, of the newspapers for several days, the preparation Enovid, made by a company with which I am not associated, but the company is a member of this association.

It is a marketed product. I am sure that company had made tremendous investment in the research that went into the development of this product. It has been, in the view of very competent clinicians, a worthwhile product.

Yet there was some publicity in medical journals and in newspapers and lay journals which would perhaps have given rise to the belief that this drug should be summarily taken off the market. Now fortunately the Food and Drug Administration did not reach that conclusion.

Mr. Moss. It acted with great restraint.

Mr. BEESLEY. Indeed, that is correct.

Mr. Moss. And with a very fine sense of responsibility for the role it plays.

Mr. BEESLEY. That is correct. May I point out, however, that in another country, Norway, the drug was actually taken off the market.

Now then, fortunately, here the Food and Drug Administration acted with great restraint, and I think acted very wisely. Yet I submit that the decision might have gone the other way, and if they had had this power——

Mr. Moss. And had it gone the other way, my point is that going in and seeking the temporary restraining order would have been just as damaging as the procedure here, the difference being that if they guessed right, in moving to remove it, that from the moment of a guess the product is off the market.

Mr. BEESLEY. We are laying great stress on judicial review.

Mr. Moss. Well, it is provided here inherently.

Mr. CUTLER. After the fact.

Mr. BEESLEY. After the fact, though. We are talking about before the fact.

Mr. Moss. Of course, counsel indicated that all the judges would very quickly respond to the request of the Secretary and grant the temporary restraining order.

Mr. CUTLER. Mr. Moss, it seems to me this is a matter of your philosophy. We can all think of cases where administrators should be allowed to act without hearings, without talking to the people whose lives and businesses they are affecting, and without going to any court first. But that hasn't been the philosophy of our Government. Wherever we can, we have always provided for some sort of review by a court or a hearing procedure on the discretion of one man.

Mr. Moss. No.

Mr. CUTLER. That is all we are asking for here.

Mr. Moss. I would say that there are any number of instances in administrative agencies, touching in my judgment upon less critical area than the public health, where the agency can move summarily, and the review is after, not before the fact. I chaired a subcommittee on the Home Loan Bank Board. They can seize a solvent institution and then provide for hearings, seize it whenever they have made certain determinations not as far reaching as the determination which must be made here, and there, because they are not subject to the Administrative Procedures Act, some of the review authority inherent here is not present.

So I don't think it goes to philosophy, because the history in some of these administrative agencies has already created a philosophy. I think the philosophy here is how far do we have to go to prudently protect the public health, at the same time maintaining a proper balance.

Mr. CUTLER. Yes.

Mr. Moss. Which does not destroy the industry.

Mr. CUTLER. Part of our problem here, Mr. Moss, is that of a standard of "imminent hazard to the public health." Now what is that? Is it such a clear case of unsafety that it is dangerous to permit the time necessary for a hearing. That would be one thing. But all of us could fill in the content of "imminent hazard to the public health" in different ways.

Mr. Moss. I would so interpret the use of the term "imminent hazard to the public health" to require a very clear showing of an immediate hazard.

Mr. CUTLER. I would think, sir, that the differences between us could well be resolved by further and more careful definition of the phrase we are talking about, the standard to be applied.

Mr. Moss. I think that is quite possible, and I don't think this would be violative of any philosophy or principle of government to which we both adhere.

Mr. CUTLER. Yes, sir.

Mr. Moss. That is all the questions I had, Mr. Chairman.

The CHAIRMAN. Mr. Beesley, thank you very much again for your presentation here this morning. The committee will be in recess until 2 o'clock, at which time Dr. Chester S. Keefer, will be the first witness.

(Whereupon, at 12:05 p.m., the committee recessed, to reconvene at 2 o'clock on the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

The first witness this afternoon is Dr. Chester S. Keefer.

Dr. Keefer, we are pleased to have you and we will be glad to have your testimony.

STATEMENT OF CHESTER S. KEEFER, M.D., SENIOR MEMBER, EVANS MEMORIAL DEPARTMENT OF CLINICAL RESEARCH AND PREVENTIVE MEDICINE AT MASSACHUSETTS MEMORIAL HOSPITALS

Dr. KEEFER. Thank you, sir.

My name is Chester S. Keefer. I am senior member of the Evans Memorial Department of Clinical Research and Preventive Medicine at Massachusetts Memorial Hospitals, and am also Wade professor of medicine at Boston University School of Medicine. I have held both of those posts for more than 20 years.

It may be a matter of special interest to this committee that during the early 1940's I was in charge of the nationwide collaborative clinical trials of penicillin and streptomycin, and that I served in 1953–55 as Special Assistant for Health and Medical Affairs to the Secretary of Health, Education, and Welfare. A more complete statement of my background has been submitted for the record.

For the past several years I have served on the board of directors of Merck & Co., Inc.

I do not appear before this committee as a representative of that company or of the drug industry, but as a doctor and professor of medicine.

I have been asked by Dr. I. S. Ravdin, vice president for medical affairs of the University of Pennsylvania and one of our most distinguished surgeons, to present for the record of these hearings a statement with respect to the legislation under consideration. That statement has been endorsed by 16 other outstanding physicians and surgeons, whose curricula vitae is furnished to the committee to be attached to this statement.

All of the sponsors of the statement hold or have held positions of responsibility in medical schools, in medical societies, and in hospitals throughout the country. I am pleased to join with them in their statement and ask that it be included in the record at this point.

This committee is today hearing testimony on legislation to amend the laws with respect to new drugs. The widespread publicity on congenital malformations in infants—malformations which have been attributed to the drug thalidomide—has intensified public interest in our drug laws.

While we can be glad that our present system worked to prevent the general introduction of the drug into this country, we should heed the warning implicit in the tragedy and conscientiously examine the laws and regulations under which we operate.

This committee has demonstrated in its long experience with drug legislation an ability to deal in such sensitive areas with perspective

and perception. Those qualities are urgenty needed today if we are to have legislation which will in fact advance the interests of the health of the Nation without at the same time jeopardizing the steady flow of new and improved drugs which enable the medical profession to carry on its never-ending battle against the critical and crippling diseases for which we now have no adequate prevention, treatment, or cure.

I have recently been asked by Dr. Lowell T. Coggeshall, a vice president of the University of Chicago, to serve with him and other scientists on a commission for drug safety.

The purpose of the commission is to advance scientific knowledge of the predictability of action in human beings of new pharmaceuticals, and I am confident that its work will result in increased safety in clinical testing.

The need of advances in testing procedures for the safety of new drugs, while always a matter of concern, has been dramatized by the reports that the drug thalidomide has been associated with the death or deformity of newborn babies in Germany, in England, and in other countries where the drug was released for general use.

Historically, pharmacological testing of new drugs in animal experiments has been quite a reliable yardstick in determining whether the drug is sufficiently safe to warrant clinical testing in human beings.

However, the need for tests to detect the possible relationship between therapeutic use of the drug and the occurrence of congenital malformations had never before been generally recognized.

That can be classified as a gap in scientific knowledge.

Even after the fact, no one knows the precise nature or extent of the relationship between the drug and the deformities. As has been stated by Senator Humphrey:

> All we know is we do not know enough.

Among the purposes of the commission on drug safety will be to study ways of improving pharmacological testing so that the risks in clinical investigation may be minimized.

Although the bill before this committee deals with drugs in general use and does not deal specifically with the investigational use of drugs, I wish to say a word at this point to help lay at rest a distortion that has crept into the current discussion of the testing of drugs.

That is the human guinea pig concept, a term that lends itself to abuse and misunderstanding. Every advance in science requires trial and experimentation.

The law requires that prior to marketing, a drug be extensively tested for its effect on human beings. Before that is done extensive pharmacological testing on animals is required.

There is, however, no substitute for the trial of drugs in man. I think it should be emphasized, as stated by Mr. Larrick and Dr. Kelsey of FDA, that the responsibility for the administration of drugs to a patient, whether the drugs are on the market or in an experimental stage, is that of the physician.

It is most important to see the thalidomide tragedy in perspective, and to act with knowledge and understanding of that perspective.

During the past several decades, tremendous progress has been made in drug therapy. This has been due in large measure to the dynamic

research programs of the American drug industry. Countless lives have been saved.

Millions have been helped to live happier, more productive lives.

But there is no such thing as absolute safety or absolute effectiveness. And progress does not come without the payment of some price.

We have been extremely fortunate in this country in the low price we have paid for tremendous progress in drug therapy. I think the Food and Drug Administration and the drug industry deserve tremendous credit for the advances which have been achieved under our present laws as compared with the almost minimal occurrence of serious side effects.

I think the Food and Drug Administration has been improperly criticized for permitting certain drugs to be marketed which later were recalled.

Medicine is at best an uncertain science. There is no way of putting a new drug application through a computer and knowing what adverse side effects may occur. Despite this fact the safety tests for new drugs in this country have proven remarkably effective.

In the past 4 years, according to the records of the Food and Drug Administration, approximately 784 new drugs have been marketed and only 15 have been withdrawn (generally on the basis of information as to side effects provided by the manufacturer).

The combined incidence of unwanted effects of all of those 15 drugs did not approach the incidence of effect associated with thalidomide. That seems to me to be an exceptional record of responsibility, rather than one which merits censure for the handful of withdrawals.

I recognize in the legislation presently under consideration by this committee an effort at a constructive approach to some of the problems faced by the drug industry and the FDA.

Since they are at the same time problems of American medicine and of the American people, I know this committee will approach them objectively and will not recommend legislation which would unduly obstruct research in new drugs which are vitally needed by the doctors and the people of the country.

Today tuberculosis, pneumonia, and other scourges of the recent past are no longer among the top 10 killers, due largely to breakthroughs in drug therapy.

But we are still confronted with the scourge of diseases such as heart disease, cancer, mental illness, neurological disorders and many others.

I am sure no one of us would wish to retard much-needed research leading to new drugs or in any way to delay the availability of existing drugs for cancer and other uncured ailments. Keeping a useful drug off the market or unduly delaying its marketing may frequently in itself be a great detriment to public health.

Today we regard the drugs of 1942 as outmoded. It is to be hoped that the doctors of 1982 will consider the drugs of 1962 just as outmoded. That can be accomplished only by continuation of the present dynamic drug research program.

My concern is that there is danger in the present legislation of overregulating the drug industry, the research it conducts and the clinical investigation it fosters. I am also concerned that it should not place so much authority and responsibility for recordkeeping and review in the Food and Drug Administration as to weaken and perhaps destroy its ability to carry out its assigned tasks.

As this committee is well aware, legislating in the area of new drugs requires objective perspective and mature judgment. The drug industry, the FDA, and the conscientious physician are all vitally interested in the discovery, development, and applications of new and useful drugs. They are also interested in making new drugs accessible to all patients who need them as promptly as possible—because drugs are for patients who need them.

I should like to read the statement by Dr. Ravdin, if I may.

STATEMENT OF DR. I. S. RAVDIN

The subscribers to this statement are doctors of medicine. We hold, or have held, positions of responsibility in medical schools, in medical societies, and in hospitals throughout the country. We represent one or more of the many fields of medicine, and for this reason we feel a responsibility to comment on H.R. 11581.

The tragic thalidomide experience of recent weeks has understandably focused attention on drug research as a whole. Improvements, particularly in the areas of clinical investigations, may be made through the strengthening of certain regulations.

However, broader legislation conceived in an emotional atmosphere must be viewed in the light of its possible detriment to independent and creative research by the pharmaceutical industry of this country.

In our opinion, H.R. 11581 raises a serious medical issue by providing that, in addition to showing that a new drug is safe, a manufacturer must also prove to the Food and Drug Administration that it is "efficacious." Proof of efficacy is desirable only if the "efficacy" requirement is taken to mean that a manufacturer should produce substantial evidence that a drug has the effect the manufacturer claims for it.

If proof of efficacy is interpreted as meaning more than this, then there is a serious danger that this provision of the bill would keep many valuable new medicines from the American people.

We ask the committee to consider the following points:

(1) Medicine is in part an uncertain science. There is at the present time no precise method for determining absolute efficacy or effectiveness. Such a determination must frequently be based upon medical opinion, and medical opinion is not always unanimous.

(2) Physicians very often have differing opinions about the usefulness of an agent in treating a particular disease. Many eminent physicians, for example, favor the use of the corticosteroids in the treatment of rheumatoid arthritis, but others believe that the corticosteroids are not the drug of choice for this purpose.

Under such circumstances, it is difficult, if not impossible, to determine the exact effectiveness of the corticosteroids in treating rheumatoid arthritis. It would be an appalling development to have the FDA, directly or indirectly limiting the rights and responsibilities of a prescribing physician by determining, for example, the corticosteroids should not be marketed because of the FDA's opinion that they lack efficacy.

(3) Drugs are not uniformly effective in individual patients even with the same disease. In the case of epilepsy, some of the available drugs are useful in treating perhaps only 20 percent of the patients suffering from this disease.

But we believe it would be wrong to deny a drug to this 20 percent because that drug is ineffective in the treatment of the remaining 80 percent of those suffering from epilepsy.

If a drug company should be required to submit a preponderance of evidence as to the effectiveness of a new drug, it is highly doubtful that any drug which is effective in treating a limited percentage of patients would ever be marketed.

(4) To be truly effective, the medical profession needs an expanded and improved arsenal of drugs. We have confidence that the American prescription drug industry, if permitted to operate in an atmosphere of freedom, can supply that need.

In our judgment, both the industry and the medical profession—and ultimately the American people—would suffer if Government were to require anything more than substantial evidence that a drug is effective for the use claimed for it. By "substantial" evidence we mean that the clinical testing data submitted to the FDA should be performed by truly competent and qualified clinical investigators and that the medical evidence supporting the claim of effectiveness should be significant.

(5) To require a drug company to submit a preponderance of evidence as to the effectiveness of a new drug is, in our judgment, unreasonable. It is a well-known fact that the majority of expert opinion has at first often been opposed to what later was proven to be valuable new discoveries in medicine. Yet such discoveries have, in the long run, greatly benefited our people. Under this bill, a finding by the FDA that a company has not submitted a preponderance of evidence as to the effectiveness would for all practical purposes keep that drug—possibly a lifesaving one—from being marketed.

We believe that the Food and Drug Administration should continue as the protector of public safety. When a new drug is under consideration, we think it should insist that substantial evidence of effectiveness be demonstrated before the product is released for marketing. But we believe it is the physician's responsibility, and his alone, to decide whether a drug will be effective in treating his patients.

There is one other major provision of the bill that we feel is not in the public interest—that relating to trademark names.

It is our opinion that trademarks are of great value to the physician. It is often said that all prescribing should be done by generic names, but such a suggestion overlooks the realities of medical practice.

In the course of his experience, the physician gradually builds up confidence in certain pharmaceutical firms because he knows that they will supply him with drugs of reliable quality. He identifies certain trademark names with the firms he favors, and these names serve as a shortcut for writing prescriptions.

Moreover, there is evidence that the same generic-name drug, produced by two different companies, may react quite differently in a patient. This occurs not because of differences in the active ingredients, but because of variations in the inert ingredients used. For this reason, the doctor comes to rely on trademark names.

In our opinion, therefore, the provision of H.R. 11581 that calls for generic names to take precedence over trademark names on the label will, we believe, only complicate normal procedures in the day-to-day practice of medicine.

This statement, Mr. Chairman, has been signed by Dr. Henry Bockus, of Philadelphia; Dr. Wallace M. Yater, Yater Clinic, Washington, D.C.; Dr. William A. Sodeman, dean, Jefferson Medical College, Philadelphia; Dr. William A. Altemeier, Cincinnati, Ohio; Dr. Loyal Davis, Northwestern Medical School, Chicago, Ill.; Dr. Reed Nesbit, University of Michigan Medical School, Ann Arbor, Mich.; Dr. George E. Armstrong, New York University School of Medicine, New York, N.Y.; Dr. Julian P. Price, Florence, S.C.; Dr. Francis Wood, Philadelphia, Pa.; Dr. Michael E. DeBakey, Baylor University, Houston, Tex.; Dr. Harold Glendon Scheie, University of Pennsylvania, Philadelphia, Pa.; Dr. Howard Mahorner, director, Mahorner Clinic, New Orleans, La.; Dr. Clifford Barborka, Chicago, Ill.; Dr. Joseph Marchant Hayman, Jr., dean, Tufts University School of Medicine, Boston, Mass.; Dr. Cecil J. Watson, University Hospitals, Minneapolis, Minn.; Dr. Alton Ochsner, New Orleans, La.; Leroy E. Burney, M.D., vice president of health sciences, Temple University School of Medicine, Philadelphia, Pa.; Warren Henry Cole, M.D., professor and department head of surgery, University of Illinois, Research and Educational Hospital, Chicago, Ill.; Thomas Morton Durant, M.D., Temple University School of Medicine, Philadelphia, Pa.; William M. M. Kirby, M.D., University of Washington Medical School, Seattle, Wash.; George Widmer Thorn, M.D., Peter Bent Bringham Hospital, Boston, Mass.; Barnes Woodhall, M.D., dean, Duke University, School of Medicine, Durham, N.C.; Paul Dudley White, M.D., Boston, Mass.; and myself.

Thank you very much, sir.

The CHAIRMAN. Thank you, Doctor, for your statement, and the statement from other well-known medical people in the country.

I am sure the committee appreciates your concern with reference to the problem as you have very appropriately outlined in your statement to the committee. I am certain that the committee will give very careful and close attention to these problems, keeping in mind our objective in this legislation, which is to provide the appropriate authority, without doing irreparable harm, to the continued research and development of drugs and that will alleviate human suffering.

Any questions of the committee?

Mr. DINGELL. I have several but I would be happy to yield to Mr. Schenck.

The CHAIRMAN. Mr. Schenck.

Mr. SCHENCK. I listened with great interest, Mr. Chairman, to the statement of Dr. Keefer, and I know that Dr. Keefer is very distinguished, able and a highly recognized member of the medical profession.

Dr. KEEFER. Thank you, sir.

Mr. SCHENCK. And, therefore, the statement is very important to this committee.

Of course, I am not a trained person in medicine, pharmacology or any of the allied fields. I am wondering, Dr. Keefer, as a member of the medical profession, whether or not you know if the pharmaceutical companies are using a great deal of care in the selection of the doctors to whom they allot certain quantities of a drug to be tested?

Do the drug manufacturers carefully select those men or women?

Dr. KEEFER. Mr. Schenck, I would say that they used extraordinary care in selecting highly trained clinical investigators when they attempt to place an important drug on the clinical trial basis. There are a number of highly qualified clinical investigators in the United States. In fact, there is a 50-year-old society known as the American Society of Clinical Investigation, and these young men, I say young men, because they must join the emeritus list at the age of 45, have all been highly trained in our university and hospital clinics in the techniques of clinical investigation.

So, that I would say that in my own experience these investigators have been selected with great care and with great critique.

Mr. SCHENCK. That is very reassuring. Dr. Keefer, do these investigators make a rather careful case study of the patient prior to prescribing of new drugs?

Dr. KEEFER. Yes, sir.

Mr. SCHENCK. Is that a general procedure?

Dr. KEEFER. Yes, sir. They certainly do, and they prescribe such an investigational drug only to patients to whom they feel might be benefited by such a drug.

They take a careful history and decide after physical examination, whether or not such a drug would be suitable for clinical trial in that individual patient.

Mr. SCHENCK. As you have pointed out, Dr. Keefer, in your statement or in this additional statement from others which you presented here, that different individuals react differently to the same drug.

Dr. KEEFER. Yes, sir.

Mr. SCHENCK. And also the inert or filler part of the medicine is quite often a determining factor.

I am told that the drug which has been recently discussed in the press as one of the contraceptives, as having developed some thrombophlebitis, that that situation would be likely to occur if the patient had had a rheumatic type injury or illness to his or her heart.

Therefore, such condition or other conditions should be shown up in the history of the patient if the investigating or the clinical doctor had made a very careful case study of that, is that true?

Dr. KEEFER. That is true, sir.

Mr. SCHENCK. So it may well be that thrombophlebitis cases which have developed because of inadequate case histories, perhaps?

Dr. KEEFER. No, sir. I don't think that that necessarily follows, because thrombophlebitis is a very common disorder and can occur under a wide variety of circumstances, and is certainly one of the major problems in the study of diseases of the blood vessels and particularly the veins.

So that occasionally—some patients, whether they are taking drugs or not, will develop thrombophlebitis, and it is particularly true if they have an illness and are confined to bed or have some slight injury to an extremity. These factors must all be taken into account when a patient develops thrombophlebitis. It may not be related to any medicines that the patient has been taking at all.

It is only when a side effect, or an unwanted effect or a complication arises during the treatment of a patient which appears with regularity and frequency, and is unrelated to anything other than what one may determine as drug therapy, that one is justified in drawing the conclusion that the drug therapy itself has promoted the development of the thrombophlebitis.

Mr. SCHENCK. Mr. Chairman, I have just two brief questions.

It has been suggested that the pharmaceutical companies must include in their advertising in medical journals all of the side effects and contraindications. Do you feel that would be necessary or proper or helpful?

Dr. KEEFER. Sir, Mr. Cain is going to discuss this matter this afternoon.

Personally, I do not think that it is necessary to include all of those facts in advertising, because it would really mean that so much space would be devoted to repeating what is in the usual package inserts or the monographs of drugs that advertising would lose its effectiveness, particularly since advertising is mainly for reminding the doctor of products.

Mr. SCHENCK. Each of the physicians then, Dr. Keefer, do receive rather complete monographs or the information packaged with the drug, do they not?

Dr. KEEFER. Yes, sir.

Mr. SCHENCK. And that is rather complete?

Dr. KEEFER. And these are all approved by the Food and Drug Administration.

Mr. SCHENCK. And that is required by the Food and Drug Administration?

Dr. KEEFER. Yes, sir; it is.

Mr. SCHENCK. All right. Now, just this one final question, Dr. Keefer.

On page 4 of Dr. Ravidin's statement, and endorsed by others, line 2 and later down, he uses the same word again, you discuss the preponderance of evidence as to the effectiveness of the new drug.

Now, are you interested only in the effectiveness or are you also interested in the safety?

Dr. KEEFER. Well, sir, we are very much interested in safety as well as effectiveness.

Mr. SCHENCK. Wouldn't you feel then that this statement might well be revised to that extent that you might include "effectiveness" and "safety"?

Dr. KEEFER. Yes, indeed. The reason it was not included in the statement, sir, was that we took this for granted, really, that we are concerned primarily with safety as well as effectiveness.

Mr. SCHENCK. Thank you very much, Dr. Keefer.

Thank you, Mr. Chairman.

Dr. KEEFER. Thank you.

Mr. DINGELL. Doctor, you indicate in your statement that you feel it is unwise to require a drug to be labeled with the generic name, is that your position?

Dr. KEEFER. No. No——

Mr. DINGELL. You say:

> There is one other provision of the bill that we feel is not in the public interest—that relating to trademark names. It is our opinion that trademarks are of great value to the physician. It is said that all prescribing should be done by generic names.

Where in the bill does it appear that all prescribing should be done by generic names?

Dr. KEEFER. Well, it does not appear in the bill.

Mr. DINGELL. It does not appear in the bill.

Dr. KEEFER. No, sir.

Mr. DINGELL. Then you have no objection to the bill on its language dealing with generic names?

I assume you have read the bill and are familiar with it, aren't you, Doctor?

Dr. KEEFER. Yes. I am familiar with the bill. It says here:

> In our opinion the provision of H.R. 11581 that calls for generic names to take precedence over trademark names on the label we believe will only complicate normal procedures in the day-to-day practice of medicine.

Mr. DINGELL. All right.

Let's take a look at that.

If this bill is passed, you will get a bottle with a label first of all giving the generic name and then the trademark name, am I right?

Dr. KEEFER. Yes.

Mr. DINGELL. All right.

How is that going to complicate the practice of medicine?

Dr. KEEFER. Well——

Mr. DINGELL. You will still be able to prescribe by trademark name if you are so minded, wouldn't you?

Dr. KEEFER. I hope so.

Mr. DINGELL. All right.

You will have available to you one additional piece of information, will you not? You will have available to you not only the trademark name but you will also have the generic name available to you, isn't that right?

Dr. KEEFER. The doctor has that information available before he writes the prescription.

Mr. DINGELL. I am aware of that, but that will be on the label of the commodity that he prescribes. What is bad about that?

Dr. KEEFER. Well, I don't think there is anything bad about it.

Mr. DINGELL. All right.

So you then have no objection to it?

Dr. KEEFER. It is just required by law. All right.

Mr. DINGELL. But you have no objection to it then because it is not bad?

Dr. KEEFER. No.

Mr. DINGELL. Then your statement with regard to this point you might like to revise at this point by indicating to the committee that you have no objection to this section then?

Dr. KEEFER. I have no objection, it is a matter of precedence.

Mr. DINGELL. I see. But you have no objection to it?

Dr. KEEFER. No.

Mr. DINGELL. As a matter of fact, you do not feel then that this section is not in the public interest, as you have indicated on page 4 of your statement?

Dr. KEEFER. It is largely a question in my mind and in the mind of the committee——

Mr. DINGELL. Just a minute, Doctor. You are an intelligent man, you are schooled in pharmacology, and I assume you are schooled in the drug trade and also in medicine.

I am a layman, but I am able to read a statement and you are, too. You state this is not in the public interest and then you state you have no objection. Which of the two is true?

Dr. KEEFER. It is simply a matter of precedence.

Mr. DINGELL. But you have no objection to it, as you indicated?

Dr. KEEFER. No, I have no objection.

Mr. DINGELL. I would like to talk to you a little here about efficacy; you devoted a great deal of your statement to efficacy.

Do you feel the drug industry should be able to market new drugs with claims that are not supported by medical evidence?

Dr. KEEFER. No.

Mr. DINGELL. You don't think that is sound or in the public interest?

Dr. KEEFER. No, I do not.

Mr. DINGELL. All right.

It has been said up to 20 percent of the new drugs studied by the AMA's Council on Drugs since 1956 are being promoted by one or more claims unsupported by reliable evidence.

In your view is this a situation that should remain unchanged by this new legislation?

Dr. KEEFER. Who says this?

Mr. DINGELL. I just say—well, let's make first of all, the assumption, let's just say for purposes of the argument then, that this statement is true [laughter] do you think that this [laughter] do you think that this situation should continue?

Dr. KEEFER. Why, no; I don't think it should continue.

Mr. DINGELL. I think, by the way, if you would check the Celler hearings, I think you will find something to this effect in there. All right.

Now, is what you are saying that the drug manufacturer should be allowed to claim that his drug will prevent heart attacks if he has medical study to support it even though the preponderance of evidence shows the claim is false?

Dr. KEEFER. Certainly not. If the preponderance of evidence would show that the claim is false he certainly should not be justified in saying that it was true.

Mr. DINGELL. I see. Would he be justified in marketing a drug where the preponderance of the medical evidence showed that his claims of efficacy were not true?

Dr. KEEFER. Well, this is a matter of opinion, and a question on the part of the experience of a doctor who uses these drugs as to whether or not, in his experience, it has prevented heart attacks or not.

Mr. DINGELL. All right. Well, then, you say—you say, then, that the drug manufacturer should be allowed to market a drug based on claims of efficacy even though the preponderance of sound medical evidence shows that the drug has no efficacy?

Dr. KEEFER. Well, if the evidence is substantial that it has prevented, let us say, heart attacks in 20 percent of cases over a period of 5 years compared to a group who have not received similar therapy, I think that that is substantial evidence.

Mr. DINGELL. Let's go one notch further here. Which one of the manufacturers do you work for as a consultant?

Dr. KEEFER. I don't work for any manufacturer.

Mr. DINGELL. You don't work for any of them at all.

Let's assume you were a manufacturer and you had an unfair labor practice case before the NLRB, and you said that there was an unfair labor practice and the union said there was not.

Would you regard it as appropriate that the NLRB should find against you because there was some substantial evidence on the other side even though you presented a preponderance of evidence?

Dr. KEEFER. Mr. Dingell, I am not a lawyer and I am not an expert in labor relations, so I don't know how I could answer that question adequately.

Mr. DINGELL. Well, now, you see, here we are, we are going to say we can market these drugs even though we can say there is only substantial evidence.

Yet you will concede that circumstances under your testimony will arise in the course of events whereby the preponderance of evidence will say that the drug has no efficacy, and where you say, or rather where the person who wants to market it has only some substantial evidence to show that the drug has efficacy, is it your feeling that all of these where the preponderance of the evidence shows there is no efficacy should be marketed even though there is just some substantial evidence to show that the drug does have efficacy?

Dr. KEEFER. Well, I think that this is a matter of relative judgment and experience with the deportment of any drug, and I don't think that drugs are ever marketed that have been in clinical trial that have no efficacy.

Mr. DINGELL. How many drugs are marketed for the treatment of arthritis?

Dr. KEEFER. Well, I wouldn't know, but I would say that there are a great many.

Mr. DINGELL. A great many. How many of these actually have efficacy in the treatment of arthritis?

Dr. KEEFER. Well, this is a matter of opinion and statistics developed by the doctor who observes the patient and follows the course of his illness, who knows the patient and knows the course of the disease.

So that some drugs are much more effective in the treatment of arthritis than others. It depends upon the stage and type of the arthritis.

Mr. DINGELL. Do you think that a drug ought to do what the manufacturer says when he goes to put it on the market?

Dr. KEEFER. I do.

Mr. DINGELL. All right. If we take this as being the test of efficacy, do you think that the efficacy should be supported just by substantial evidence or should it be supported by the preponderance of evidence?

Dr. KEEFER. I think it should be supported by substantial evidence.

Mr. CUTLER. Mr. Dingell, if I can break in for a moment, sir, Dr. Klumpp has some 10 pages of detailed discussion on this precise point which we would be reaching very precisely.

Mr. DINGELL. I see. I had read this gentleman's testimony and it was my impression he was here speaking on efficacy.

Mr. CUTLER. He is speaking as a doctor; Dr. Klumpp is speaking as a manufacturer and as a doctor.

Mr. DINGELL. Thank you, Mr. Chairman, no further questions.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

It has been suggested that a doctor should notify his patient if he is administering the drug in an experimental manner.

What is your feeling on that?

Dr. KEEFER. Well, Mr. Younger, I would say in my own experience that the vast majority of physicians inform patients that they are using an investigational drug, and since he is not able to prescribe that drug, and the patient is not able to buy it, he usually gives it to the patient and informs him. If he happens to be an ambulatory patient, he instructs the patient how to take it, and then gives him all the instructions and tells him usually what it is. Also he asks the patient to report any symptoms that may be considered to be unwanted, and also observes this patient to determine what effect the drugs have actually had.

For example, if it is a new drug for the treatment of hypertension, usually he prescribes it, the patient takes it, and he takes his blood pressure periodically, patients often take their own blood pressure at home, and then they return. Patients often keep very good records in the form of a diary, and bring it to the doctor for examination.

If the patient is being treated in the hospital, similar records are kept, so that they can be examined thoroughly and unwanted symptoms looked for, and also determine what the action of the drug has been in the patient.

Mr. YOUNGER. As you know, when you go to the hospital for an operation you sign a statement that you consent to the operation, and so forth.

What would be the attitude of the doctors, perhaps, of having some kind of a statement signed by the patient acknowledging that this drug was administered to him for experimental purposes?

Dr. KEEFER. Well, Mr. Younger, this is a suggestion that has been made on a number of occasions and I believe that some doctors make it a practice to get such a statement from the patient. It is not universal.

Mr. YOUNGER. On page 5 of your statement, one more question, you mention about 15 incidents where the drug has been withdrawn.

Dr. KEEFER. Yes, sir.

Mr. YOUNGER. Was that withdrawal by the order of the Food and Drug or was that a voluntary withdrawal or what were the circumstances, do you recall in these occasions?

Dr. KEEFER. Mr. Younger, that is usually a voluntary withdrawal after discussion with the Food and Drug Administration.

Mr. YOUNGER. Those are not the cases, as you recall, I asked Mr. Beesley this morning and he could give no incidence of where the drug was withdrawn by order of the FDA.

Dr. KEEFER. Well, I do not know of any, sir.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Sibal.

Mr. SIBAL. Dr. Keefer, I hesitate to examine you on Dr. Ravdin's statement, but I don't know how else to approach this. He discusses on page 5 of his statement the fact that there is evidence that the same generic drug produced by two different companies might react differently on a patient because of differences in the inert ingredients used.

Could you expand on that a little bit so that those of us who are laymen in this field follow that a little better?

Dr. KEEFER. Well, by insert ingredients is usually referred to the binder or the chemical substances that make a tablet so that it is more soluble, or less soluble depending upon its desired effect after, let us say, a tablet is taken. These binders are different, and have been developed through pharmacy research so that some of these ingredients which are inert as far as having some unwanted effects are concerned, may in some instances cause the drug not to dissolve so it will not be absorbed.

Others will have other side effects. This subject has been studied extensively by the profession of pharmacy and I believe that this is going to be discussed later this afternoon in greater detail.

Mr. SIBAL. Well——

Mr. SCHENCK. Mr. Chairman, will the gentleman yield?

Mr. SIBAL. Yes.

Mr. SCHENCK. As I understand some of these active ingredients are in such a small quantity that unless some so-called inert material is added as a filler you couldn't even handle it?

Dr. KEEFER. Yes, sir.

Mr. SIBAL. I understand that, but the point I am getting to is, does the Food and Drug Administration, in the licensing of a drug, take into consideration the binder, if you will, which is used with the drug?

Dr. KEEFER. With every new drug; yes, sir.

Mr. SIBAL. In other words, when an application is made and a testing goes on and ultimately approval is given by the FDA it is given to the whole package?

Dr. KEEFER. Right.

Mr. SIBAL. Including the inert material, if you will, and the manufacturer is required thereafter, is he not, to continue to use the same inert material along with the active material; in other words, he does not have the leeway of changing his binder or changing——

Dr. KEEFER. That is correct, sir.

Mr. SIBAL. In effect, then, the point that Dr. Ravdin makes is that so far as the reaction of the patient to a particular generic drug it might be quite different between trade names?

Dr. KEEFER. Yes. That is correct.

Mr. SIBAL. So the trade name becomes important as well as the generic name as the doctor prescribes?

Dr. KEEFER. That is correct, sir.

Mr. SIBAL. Thank you very much.

The CHAIRMAN. What should be used, the trade name, the generic name, or both?

Dr. KEEFER. I beg your pardon, sir?

The CHAIRMAN. What should be used, the generic name, or the trade name, or both?

Dr. KEEFER. Well, sir, I think that this is a matter of the judgment of the physician.

Very often he can prescribe with a generic name and place after it which company he would like to have provided, whose product he would like to have provided.

The CHAIRMAN. You are talking about prescription drugs now?

Dr. KEEFER. Yes, sir.

The CHAIRMAN. What about proprietary drugs?

Dr. KEEFER. Well, I think that all, practically all of those drugs are sold under a trade name.

The CHAIRMAN. Thank you very much, Dr. Keefer.

Mr. SCHENCK. Mr. Chairman, I would like to say just one other thing here. Brand names are important in many, many different things other than medicine, are they not?

Dr. KEEFER. I would say they were most important, sir.

Mr. SCHENCK. You buy food and you buy automobiles and you buy suits and you buy everything else by brand names, do you not?

Dr. KEEFER. Yes, sir.

The CHAIRMAN. Dr. Leonard A. Scheele.

Dr. Scheele, let me, on behalf of the committee, welcome you back to the committee. We recall your numerous appearances in the past.

I see that you are a member of the Warner Lambert Pharmaceutical Co.

STATEMENT OF DR. LEONARD A. SCHEELE, MEMBER, BOARD OF DIRECTORS, WARNER LAMBERT PHARMACEUTICAL CO.

Dr. SCHEELE. Mr. Chairman, and members of the committee, it is indeed a pleasure to be back here after 5 years and to see several friends and new friends.

I am a member of the board of directors of Warner Lambert Pharmaceutical Co., which is our parent, and in addition I work with the research program of our company and with the ethical drug operation which is Warner-Chilcott Laboratories.

As you know, I am a physician, having graduated from Wayne State University, the medical school of that university. I joined the U.S. Public Health Service and spent 23 years as a career officer in that service, serving from 1948 until I retired in 1956 as Surgeon General.

I am here today, as you know, on behalf of the Pharmaceutical Manufacturers Association directing my comments to section 103 and section 106 of H.R. 11581. Those sections would require reporting by drug manufacturers on new drugs being placed in clinical trial and during their trial period prior to the filing of a new drug application, as well as after a new drug application has become effective.

These sections have attracted particular attention, Mr. Chairman particularly in the light of the intense public interest that is now being focused on the testing of a new drug, and the steps that are being taken to protect the public health while new drugs are being tested.

This committee is keenly aware of the major disease problems of our country and the world. You have held many hearings and issued many excellent reports on the toll of our major diseases, their causes, prevention, and control. And, of course, you have dealt over the years with the creation of laws which enable the health agencies of the Department of Health, Education, and Welfare to play major roles in improving man's health.

We recognize, Mr. Chairman, that it is at once the strength and the weakness of a democratic society that it takes crisis to give impetus for major legislative change. We recognize that since we discover, develop, test, produce, and market drugs that have a direct bearing on the physician's ability to save life and protect health, we have special responsibilities to accept regulation and to regulate ourselves.

We believe we have met our responsibilities well in the past, and that our record of accomplishment is one of which we and the Nation we serve can be proud. The industry is constantly striving to make more uniform throughout the industry those practices which now characterize the best of the industry.

You are aware, as I am, that dramatic progress has been made in controlling some diseases, especially those caused by bacteria, but that, like an iceberg with seven-tenths of its mass submerged, the large-scale cripplers and killers, including the chronic afflications which plague our senior citizens more and more, as the lifespan increases, are still very much untouched. Too frequently we are limited to relief of symptoms and lack knowledge and drugs to prevent more illnesses and provide more cures.

Amendments to the Food, Drug, and Cosmetic Act should be designed to close existing gaps while at the same time assuring maximum effort by the Public Health Service, the National Science Foundation, in its grants program, and the Nation's private laboratories, including those in universities, pharmaceutical companies and elsewhere, to continue and, for that matter, speed the flow of new, safe, and useful drugs.

In general the pharmaceutical industry has been the principal producer of new drugs while other laboratories have been producing much of the flow of basic knowledge which enables us better to understand body processes in health and disease and makes it easier to produce needed drugs.

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One example of the Congress recognition of this is the support you give to cancer research through provision of large numbers of grants to universities and others to do general research and through provision for contracts with pharmaceutical companies to produce drugs for testing in animals which, hopefully, can lead to testing in humans.

This committee has demonstrated its awareness of the problem of shortages of physicians, dentists, and clinical investigators in many ways. One of the most recent was its consideration and action on H.R. 4999, to provide for grants to medical and related schools for the creation of new facilities for medical education. An expression of PMA's interest in this legislation was submitted to this committee by letter dated February 2, 1962.

A recent Public Health Service program, which the Congress has also fostered, is directed to improving our capacity for sound clinical investigation by awarding grants to assist in the construction, staffing and operation of clinical research centers in medical schools and leading research hospitals across the country.

These and many other actions taken on many fronts suggest that the long-range solution to the problem of clinical investigation is to improve clinical research facilities, increase the number and broaden the competence of clinical investigators, and accord more general stature and recognition to those whose lifework is centered in the selection, testing, and evaluation of new therapeutic agents.

It is of fundamental importance that new drugs, before being used widely in research and being marketed, should be adequately tested for safety. Of equal importance is the fact that there be a continuous flow of new and improved drugs. Any legislation on this subject, therefore, needs to strike a fine balance. On the one hand, it properly seeks to broaden and strengthen controls over drugs both new and old, to protect the public interest. On the other hand, it must encourage rather than obstruct the continuing flow in the number and kind of new drugs that are needed for better health. It is with this goal in mind that I wish to address myself to the provisions of H.R. 11581, which I mentioned earlier.

Certainly the pharmaceutical industry and its Government do not disagree on the objectives that underlie section 103(b) and section 103(a) of the bill. The objective of section 103(b) is to permit the Food and Drug Administration to obtain information about the investigational testing of a new drug so as to enable them to evaluate its safety and efficacy in the event a new drug application should be filed. The objective of section 103(a) is to provide the FDA with continuous and current information on the safety of a drug after it is released.

We share these objectives, Mr. Chairman.

I do wish to point out that Secretary Celebrezze and Commissioner Larrick, I am sure on advice of departmental counsel, apparently feel the Department already has the legislative authority to pursue the objective of section 103(b). As the committee knows, it was referred to by Mr. Beesley this morning, the Department on August 9 announced that it would exercise its existing authority to issue proposed new regulations covering the investigational use of drugs, and on August 10 published an extensive series of proposed amendments.

Under established procedures, 60 days are allowed for comments, and after that comment is taken into account, the regulations are published in final form. I submit herewith a copy of the proposed regulations for the record.

The CHAIRMAN. Let it be received.

(The document referred to follows:)

[Published in the Federal Register of August 10, 1962]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

[21 CFR Part 130]

NEW DRUGS FOR INVESTIGATIONAL USE

NOTICE OF PROPOSAL TO AMEND REGULATIONS

The Commissioner of Food and Drugs, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 505, 701, 52 Stat. 1052, 1055; 21 U.S.C. 355, 371) and under the authority delegated to him by the Secretary of Health, Education, and Welfare (25 F.R. 8625), proposes to amend the new-drug regulations (21 CFR 130.3) as hereinafter set forth. The Commissioner hereby offers an opportunity to all interested persons to submit their views in writing with reference to this proposal to the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue S.W., Washington 25, D.C., within 60 days from the date of publication of this notice in the FEDERAL REGISTER. Views and comments should be submitted in quintuplicate.

It is proposed to amend § 130.3 to read as follows:

§ 130.3 New drugs for investigational use; exemptions from section 505(a).

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use."

(2) The person seeking the exemption has filed with the Food and Drug Administration a completed and signed "Notice of Claimed Investigational Exemption for a New Drug" in triplicate, with the following information:

"Form FD 1571.

"Department of Health, Education, and Welfare,
"Food and Drug Administration.

"NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION FOR A NEW DRUG

"Name of sponsor_____
"Address _____
_____
"Name of investigational drug_____

"TO THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
"*For the Commissioner of Food and Drugs,*
Washington 25, D.C.

"DEAR SIR: The undersigned _____ submits this notice of claimed investigational exemption for a new drug under the provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3.

"Attached hereto are:

"1. Name of drug and description of dosage form.

"2. Complete list of components of drug.

"3. Complete statement of quantitative composition of drug.

"4. Description of source and preparation of any new-drug substances used as components, including the name and address of each supplier or processor, other than the undersigned, of each new-drug substance.

"5. A brief statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and main-

tain appropriate standards of identity, strength, quality, and purity as needed to give significance to clinical investigations made with the drug. If any of these operations are performed by a person other than the undersigned, each such person is identified and his signed statement covering the part of the operations he performed is attached.

"6. Adequate information about the preclinical investigations, including studies made on laboratory animals, which show that it is reasonably safe to initiate clinical investigations with the drug. Such information should include identification of the person who conducted each investigation; identification and qualification of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical investigations with the drug; and an explanation of where the investigations were conducted and where the records are available for inspection. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of proposed clinical testing such as, for example, whether the drug is for short- or long-term administration or whether it is to be tested or used in infants, children, pregnant women, premenopausal women, or geriatric patients.

"7. Five copies of all informational material to be supplied to each investigator. This shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigations. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe all relevant hazards, contraindications, side effects, and precautions suggested by prior investigations and experience with the drug for the information of clinical investigators.

"8. The scientific training and experience considered appropriate by the sponsor to quality the investigators as suitable experts to investigate the safety of the drug, bearing in mind the pharmacological action of the drug and the conditions of use contemplated by the plan of clinical investigation.

"9. The names and a summary of the training and experience of each investigator and of the individual charged with monitoring the progress of the investigation and evaluating the evidence of safety of the drug as it is received from the investigators, together with a statement that the sponsor has obtained from each investigator a completed and signed form, as provided in subparagraph (12) of this paragraph and that the investigator is qualified by scientific training and experience as an appropriate expert to investigate the safety of the investigational drug under the criteria outlined in section 8 of the 'Notice of Claimed Investigational Exemption for a New Drug.'

"10. An outline of the planned clinical investigations of the drug including the following:

"(*a*) Planned stages of investigation, if any, that will be completed and evaluated prior to determining whether the next stage or stages will be initiated.

"(*b*) The names of the investigators to be engaged in each stage and kind of investigation.

"(*c*) The specific nature of the investigations to be conducted in each stage, together with the specific information or forms showing the scope and detail of the clinical observations and clinical laboratory tests to be made and reported.

"(*d*) The approximate number and any specific criteria as to the selection of patients by age, sex, and condition, to be employed in each stage of the investigation.

"(*e*) The estimated duration of the clinical investigation by stage, and the intervals, not exceeding 1 year, at which progress reports showing the results of the investigations will be submitted to the Food and Drug Administration. (This part of the statement may be limited to the plan for one or more stages of the investigations, provided that shipments or deliveries of the drug for use in additional stages of the investigations are not made until a supplemental statement recording results of the prior investigations and outlining the plan for following stages of investigations has been submitted to the Food and Drug Administration.)

"Ordinarily a plan of investigation will not be regarded as reasonable unless, among other things, it provides for more than one independent competent investigator to maintain complete case histories of an adequate number of patients, designed to record observations and permit evaluation of any and all discernible effects of the drug on each individual treated, and comparable records on any

individuals employed as controls. These records shall be individual patient records maintained to include full information pertaining to each individual, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all clinical observations and laboratory examinations made, full information concerning any other treatment given and a full statement of any adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation.

"11. A statement as to whether or not the drug will be sold; and if so, a full explanation why sale is required and should not be regarded as the commercialization of a new drug for which an application is not effective.

"Very truly yours,

_____
(Sponsor)

"Per _____

_____
(Indicate authority)

(3) Each shipment or delivery is made in accordance with the commitments in the "Notice of Claimed Investigational Exemption for a New Drug."

(4) The sponsor maintains complete records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application becomes effective for the drug; or, if an application does not become effective, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of any officer or employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in subparagraph (2) of this paragraph available for inspection, and upon written request submits such records or copies of them to the Food and Drug Administration.

(5) The sponsor closely monitors the progress of the investigations and currently evaluates the evidence relating to the safety of the drug as it is obtained from the investigators. Accurate progress reports of the investigations and significant findings shall be submitted to the Food and Drug Administration at reasonable intervals, not exceeding 1 year. All reports of the investigation shall be retained until 2 years after a new-drug application becomes effective for the drug; or, if an application does not become effective, until 2 years after shipment and delivery of the drug for investigational use is discontinued. Upon request of any officer or employee of the Department, at reasonable times, these reports shall be made available for inspection, and on written request copies of these reports shall be submitted to the Food and Drug Administration.

(6) The sponsor shall immediately report to the Food and Drug Administration and to all investigators any findings associated with use of the drug that may suggest hazards, contraindications, side effects, and precautions pertinent to the safety of the drug.

(7) If the investigations adduce facts showing that there is substantial doubt that they may be continued safety, the sponsor shall promptly discontinue the investigation, notify all investigators and the Food and Drug Administration, recall all stocks of the drug outstanding, and furnish the Food and Drug Administration a full report of the reason for discontinuing the investigation.

(8) The sponsor shall discontinue shipments or deliveries of the new drug to any investigator who fails to maintain or make available complete records or reports of his investigations.

(9) The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505 (b) of the act or a statement that the investigation has been discontinued and the reasons therefor:

(i) With reasonable promptness after finding that the results of such investigation appear to establish the safety of the drug; or

(ii) Within 60 days after receipt of a written request for such an application from the Commissioner of Food and Drugs.

(10) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any labeling, advertising, public relations statements, or news releases, representing the drug to be safe or useful for the purposes for which it is offered for investigation.

(11) The sponsor shall not commercially distribute nor test-market the drug until a new-drug application has become effective pursuant to section 505(b) of the act.

(12) The sponsor shall obtain from each investigator a signed statement in the following form:

"Form FD 1572.

"Department of Health, Education, and Welfare, Food and Drug Administration.

"STATEMENT OF INVESTIGATOR

"Name of investigator_____
"Date _____
"Name of drug_____
"To supplier of drug:
"Name _____
"Address _____

"DEAR SIR: The undersigned _____ submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of the regulations as a condition for receiving and conducting clinical investigations with a new drug limited by Federal (or United States) law to investigational use.

"1. The following is a statement of my education and experience:

"a. Colleges, universities, and medical schools attended, with dates of attendance, degrees, and dates degrees were awarded.

"b. Post-graduate medical training: Dates, names of institutions, and nature of training.

"c. Teaching or research experience: Dates, institutions, brief description of experience.

"d. Experience in medical practice: Dates, institutional affiliations, nature of practice.

"e. Medical publications: Titles of articles, names of publications and volume, page number, and date.

"2. The following facilities will be used for investigating the safety of the new drug (including a statement of hospital, institutional, and clinical laboratory facilities, etc., which are available and will be employed in connection with the investigation) _____:

"3. The investigational drug will be used by the undersigned or under his supervision in accordance with the plan of investigation described as follows:

"(Outline the plan of investigation, including approximation of the number of patients to be treated with the drug and the number to be employed as controls, if any; clinical uses to be investigated; characteristics of patients by age, sex, and condition; the kind of clinical observations and laboratory tests to be undertaken prior to, during, and after administration of the drug; the estimated duration of the investigation; and a description or copies of report forms to be used to maintain a complete record of the observations and test results obtained.)

"4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipt and use of this investigational drug:

"a. The sponsor is required to supply the investigator full information concerning the preclinical investigations that justify clinical trials, together with fully informative material describing any prior investigations and experience and any possible hazards, contraindications, side-effects, and precautions to be taken into account in the course of the investigation.

"b. The investigator is required to maintain complete records of the disposition of all receipts of the drug, including dates, quantities, and use by patients.

"c. The investigator is required to prepare and maintain complete and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the drug or employed as a control in the investigation.

"d. The investigator is required to furnish his reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained by various investigators. The sponsor is required to present progress reports at appropriate intervals not exceeding 1 year. Any adverse effect associated with

use of the new drug shall be reported to the sponsor immediately. A complete report of the investigation should be furnished to the sponsor shortly after completion of the investigation.

"e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new-drug application becomes effective for the drug; or if the application does not become effective, until 2 years after the investigation is discontinued. Upon the request of any officer or employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying.

"Very truly yours,

"(Name of investigator)

"(Address)"

(b) A shipment or other delivery of a new drug that is being imported or is offered for importation into the United States shall be exempt from the requirements of section 505(a) of the act if the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use";

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States, which agent and exporter have prior to such shipments and deliveries completed and submitted signed copies to the Food and Drug Administration of the "Notice of Claimed Investigational Exemption for a New Drug"; and

(3) The agent acts as the sponsor of the clinical investigation to assure compliance with the conditions prescribed by paragraph (a) of this section; or

(4) The drug is shipped directly to a scientific institution with facilities and qualified personnel to conduct the investigation and is intended solely for investigational use in such institution.

(c) Whenever there is submitted to the Commissioner the name of an investigator who has previously failed to comply with the conditions of these exempting regulations, the Commissioner will notify the sponsor that the investigator is not entitled to receive investigational-use drugs, and such investigator shall not be supplied any investigational-use drug until adequate assurance is provided to and accepted by the Commissioner that the conditions of the exemption will be met.

(d) If the Commissioner of Food and Drugs finds that:

(1) The submitted "Notice of Claimed Investigational Exemption for a New Drug" contains an untrue statement of a material fact or omits material information required by said notice; or

(2) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(3) There is substantial evidence to show that the drug is unsafe for the purposes for which it is offered for investigational use; or

(4) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed to give significance to clinical investigations made with the drug; or

(5) The plan for clinical investigations of the drug described under section 10 of the "Notice of Claimed Investigational Exemption for a New Drug" is not a reasonable plan in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe for use; or

(6) The clinical investigations are not being conducted in accordance with the plan submitted in the "Notice of Claimed Investigational Exemption for a New Drug"; or

(7) The drug is not intended solely for investigational use, since it is or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(8) The labeling submitted for the drug as required by section 7 of the "Notice of Claimed Investigational Exemption for a New Drug" or any other labeling of the drug disseminated within the United States by or on behalf of the person who signed such notice fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contra-

indications, side-effects, and precautions; or any labeling, advertising, public relations statements, or news releases disseminated within the United States by or on behalf of the sponsor contains any representation or suggestion that the drug is safe or that its usefulness has been established for the purposes for which it is offered for investigations; or

(9) The person who signed the "Notice of Claimed Investigational Exemption for a New Drug" fails to submit accurate reports of the progress of the investigations with significant findings at intervals not exceeding 1 year; or

(10) The person who signed the "Notice of Claimed Investigational Exemption for a New Drug" fails to promptly inform the Food and Drug Administration and all investigators of newly found serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug;

he shall notify the sponsor and invite his immediate correction. If the conditions of exemption are not immediately met, the Commissioner shall notify the sponsor of the termination of the exemption.

(e) Where drugs are under investigation on man on the date of publication of this notice of proposed rule making, the sponsor shall, within 60 days after these regulations become effective, submit the completed "Notice of Claimed Investigational Exemption for a New Drug" to the Food and Drug Administration. Failure to do so shall automatically terminate the exemption.

(f) A shipment or other delivery of a new drug for laboratory research or animal tests only shall be exempt from section 505(a) of the act if it is labeled: "Caution: New drug—Limited by Federal (or United States) law to laboratory research and tests on animals. Not for human use." No animals used in such tests shall be used for food purposes.

Dated: August 7, 1962.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

Dr. SCHEELE. I do not propose here to comment on those regulatory proposals. Both my company and the industry are studying them carefully and will make our views known to the Department after our study is completed. But the proposed changes in regulation are relative to the consideration of H.R. 11581 since section 103(b) appears to be directed to giving the Department powers it already has.

The clinical trial process involves practicing physicians and patients. The investigational use of a new drug is an integral part of the practice of medicine and of health sciences. It should, therefore, be noted that the views of the clinical investigators themselves, who will be directly affected by the proposed regulations, should carry a great deal of weight, and I say, they probably should carry a great deal more of weight than the opinions of those of us who are administrators in the pharmaceutical industry.

Since the proposed changes in section 103(b) appear to us to be directed at giving the Department powers it already has, we urge the committee to study the existing law and proposed new regulations in order to ascertain whether or not the amendment proposed in section 103(b) is necessary.

In the event this committee should decide that the present law of the FDA requiring recordkeeping and reporting on new drug investigations is inadequate, we urge the committee to consider adding the proviso contained in section 7(a)(3) of S. 1552 to section 103(b) of H.R. 11581. That proviso reads:

Provided, however, That regulations issued under this subsection and under subsection (j) shall have due regard for the professional ethics of the medical profession and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations are applicable, of similar information received or otherwise obtained by the Secretary.

That proviso is necessary in order to insure a proper regard for the confidential relationships of the medical profession and its patients and also to provide, under certain conditions, for examination by those to whom the regulations apply of similar information received or otherwise obtained by the Secretary, or by the Department.

When regulating on the complex subject of recordkeeping and reporting by clinical investigators, the touchstone should be to place as few additional recordkeeping and reporting burdens on the clinical investigators as are absolutely required to insure a reasonable degree of safety.

Section 103(a) of H.R. 11581 would add a new subsection 505(j) to the act which would permit the Secretary to have access to data of manufacturers containing clinical results from the use of new drugs which are on the market pursuant to new drug applications. We favor this amendment in principle, but again suggest the adoption of the proviso contained in the Senate bill which I previously quoted, which also applies to subsection (j).

The comments in this statement on section 103 (b) and (a) of H.R. 11581 apply equally to sections 106 (b) and (a) of H.R. 11581, which relate to recordkeeping and reports about investigational use of antibiotics and clinical data for antibiotics which have been certified or released. Sections 106 (b) and (a) of H.R. 11581 would amend sections 507 (d) and (g) of the act.

My experiences lead me to the conclusion that the public health of this Nation has been well protected under the existing drug and biological laws.

I hope that the committee, should it report out a bill, will in its report call attention to the urgent need for a continuing flow of new and useful drugs and will emphasize the importance of requiring only those records and reports that are necessary to help assure safety without overburdening clinical investigators with nonessential paperwork.

Finally, members of the Pharmaceutical Manufacturers Association wish to cooperate fully with the FDA in providing essential information with respect to the investigation of new drugs and reports on already approved drugs, and we wish to assure the greatest possible safety for all people for whom drugs are prescribed.

The CHAIRMAN. Doctor, thank you very much for your statement on these two sections of the bill. We are very glad to have your advice and your suggestions.

Mr. Dingell, any questions?

Mr. DINGELL. No questions, Mr. Chairman, thank you.

The CHAIRMAN. Mr. Schenck.

Mr. SCHENCK. Thank you, Mr. Chairman.

I appreciate seeing Dr. Scheele again and having him before our committee.

Dr. Scheele, there is one aspect of your statement which bothers me a little, and that is at pages 6 and 7 you seem to emphasize that reporting should be kept to the basic necessary minimum.

All of us who have had a great deal of experience with the law of various and sundry reports that have to be made at various times, and they do require a tremendous amount of time, yet it would seem to me it is quite essential, and I do not know how you can determine which is nonessential paperwork. I do not know whose judgment

will decide nonessential paperwork, and it would seem to me that it would be very important to have full and complete reports in order to evaluate some of the experiences with these drugs.

Dr. SCHEELE. I agree with you, Mr. Congressman.

Actually, of course, the amount of recordkeeping that will be required is going to be determined by the Food and Drug Administration.

I think our plea here is to them not to develop a lot of, say, pro forma reporting which may not be applicable to a drug on trial of a certain type and in a certain kind of field.

The kind of records required, the kind of reports on patients will vary depending on the disease being treated or the patient being treated.

It would not be appropriate, for example, to ask for a chest X-ray on every person being treated with a new drug.

Our plea, Mr. Congressman, here is for the exercise of scientific reason and requiring only those things necessary to enable the Food and Drug Administration to make a judgment on the safety aspects of a drug, and the other aspects they wish to consider.

Mr. SCHENCK. Dr. Scheele, we have been hearing a discussion about inadequacy of information going back and forth between various nations of the world in the development of drugs and the treatments.

Now, is not the World Health Organization supposed to be an organization to improve, encourage, and do this sort of thing? Weren't you very closely connected with that operation?

Dr. SCHEELE. Yes, sir; I was. I served as chairman of the U.S. delegation to that Organization's annual meeting for many, many years.

The World Health Organization, of course, could play a role. I think all of us here would have to say that something does remain, something is desired, in communication as between countries, as between physicians in countries, as between pharmaceutical companies in various countries, and as between health departments and the World Health Organization in that same role.

I think that the recent events on thalidomide will certainly help everyone now be more acutely aware of this problem, and I think in the future we will see a lot more flow of information.

On the other hand, I must point out that information develops in a sort of scattered way. We may have a drug which seems completely safe, and after using this in very large numbers of patients, a physician may see a certain kind of side effect which no one else has paid much attention to or maybe nobody else has seen. He probably will not pay much attention to it either because he sees many side effects that are not side effects of the drug. He know that people on sugar pills have side effects.

So until someone becomes acutely enough aware to recognize that there may be some drug relatedness, no word is spoken. The company does not know, other physicians do not know.

In the ordinary course of events, one or two or three people may become suspicious, they may compare notes. At this point it becomes apparent that several factors are coming up in common.

Then again depending on the interests of that physician or those physicians, this may come into open medical records, shall we say, or it may not.

If they are men who feel they must make a public report of this, that is to the medical profession, they may go before a scientific society, they may send a letter to a journal, and by this device the effect may be reported.

So there is a timelag in this process, but I think that the job is to minimize that timelag and is to exchange as much information as we can.

Mr. SCHENCK. You have to develop a better common denominator.

Dr. SCHEELE. That is right. There are dangers, however, of course, that must be recognized, too, in trying to find a lot of side effects and communicating a lot, too.

Many times there may be what are thought to be side effects in a drug which are not or which may be unimportant, and a great deal of harm can be done. We can take away from the patient some of the confidence the patient has in his physician and drugs.

We can make patients afraid even of good things and things without serious side effects.

We must also recognize—and this is something I said to a House appropriations subcommittee quite a few years ago when a certain tranquilizing drug was developed—that as we go forward in treating and curing some of man's serious illnesses, it is going to be very difficult to find ideal drugs which will operate only on that one condition.

The body is a very complex biochemical mechanism. There are a multiplicity of reactions which go on in a very short time. The body can take basic building chemicals, building blocks, and pass them through various chemical processes literally by the hundreds, literally in seconds, literally in minutes that in test tubes may take hours, days and weeks to do. So it is not very likely that ideal things will come along that will not cause some side effects.

So this is why it is very difficult sometimes to explain these things to the public or to the patient.

These are very highly complex scientific matters, and when we say side effects, we always have to say on which drug, treating which condition.

As a matter of fact, the very drug that I am referring to that I mentioned to the appropriations subcommittee a number of years ago, was a drug that was at first rejected by a series of pharmaceutical companies in the United States. It was developed overseas to be an antihistamine, and they found that it was not enough better than, in fact, it seemed to be inferior to, antihistamines then available on the U.S. market for physicians to use, hence they rejected it.

It turned out that a side effect of the drug, a tranquilizing effect, a drowziness-causing effect, was accidentally discovered by two French clinicians who were testing it for the other purpose on mental patients in two mental institutions, one in Paris and one adjacent to Paris, and showed the great virtues of this drug as a tranquilizer. Suddenly there was born a whole new field of medical drug therapy which has kept the number of beds and patients in mental hospitals from growing.

So we cannot—we have to be very careful about this absolutism of all black and all white. There are many shades of gray and this, I think, is what Dr. Keefer was referring to as judgmental matters. This is why, I know, it is very difficult for this committee in a sense to set up all the safeguards necessary to assure absolute protection.

You cannot legislate out all side effects. We may want to use them as methods of therapy.

We may sterilize our progress in the United States, in part, if we work too hard to make everything safe. So we have to depend then on the judgment of competent scientific people, competent physicians, who understand clinical investigation, understand the application of biostatistical procedures and on our folks in the Food and Drug Administration to arrive at these judgments soundly and scientifically.

Mr. SCHENCK. Thank you very much.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

Just one question, Doctor.

We are glad to see you back.

Dr. SCHEELE. Thank you, sir.

Mr. YOUNGER. On page 6, the proviso that you propose, will you enlarge a little bit on "shall have due regard for the professional ethics of the medical profession"?

What do you mean by that?

Dr. SCHEELE. In the relationship between a physician and a patient, even as in the relationship between an attorney and his client, certain matters are confidential. We take a drug to a group of clinicians and we ask them to test it on patients on a protocol, a study design, and we ask them then to send us detailed clinical records on those patients.

Those records will probably contain the name of the patient, age of the patient, the vocation of the patient, data on where the patient lives, a lot of information on the patient.

Some patients, of course, would not mind having all this information become fairly public. Others would prefer to have things they tell the doctor remain confidential.

So this, in a sense, would be an instruction in the law to the Commissioner of Food and Drugs, to whom we give these data or who ask for these data in the preclinical testing period, to hold that as confidential, even as today, under the Food and Drug Act and under the Biologics Control Act, the Food and Drug Administration and the Public Health Service are forced to hold any data they get on manufacturing processes, and so forth, as confidential.

We primarily want this patient data to remain confidential as far as actual names go.

That is what the safeguard is that is asked for here, sir.

Mr. YOUNGER. If you had an agreement with the patient to start with, where he knew that he was a guinea pig in taking an experimental drug, would it be any easier to get that confidental information made available?

Dr. SCHEELE. Mr. Younger, the reason I am smiling is because if the patient is a perfectly healthy patient and all he has is a headache and that is what the physician is trying the new drug for, I am sure he probably would not care.

But if the patient, in addition to that, had a certain kind of illness, if his illness might, if it became public information, cause him to lose his job or somebody not promote him, or whatever it might be, it might embarrass him among his friends, he might prefer not to be identified.

Many patients do not like to even admit that they have cancer, for example. If we are trying a drug for something else, and the patient

has cancer of the lip or tongue or rectum, or whatever it may be, is it not in the best interest of the patient not to have his name made public with the clinical report?

To the Food and Drug Administration giving the record without a name is all right.

Mr. YOUNGER. Thank you, Doctor.

The CHAIRMAN. Doctor, thank you very much. It is a pleasure to have you back with us.

Dr. SCHEELE. Thank you. It is a pleasure being here.

The CHAIRMAN. Dr. Theodore G. Klumpp?

STATEMENT OF THEODORE G. KLUMPP, M.D., PRESIDENT OF WINTHROP LABORATORIES, AND A MEMBER OF THE BOARD OF DIRECTORS OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY LLOYD CUTLER, ESQ.

Dr. KLUMPP. Mr. Chairman, I will not take your time to recite my training and experience.

That is here on this mimeographed form, except to add that since this was mimeographed, President Kennedy announced my appointment to his Health Resources Advisory Committee.

The CHAIRMAN. Your background and experience will be printed in the record at this point.

(The biographical sketch referred to is as follows:)

THEODORE G. KLUMPP, M.D.

Born May 15, 1903. Married 1934, four daughters, two sons.

Bachelor of science from Princeton; doctor of medicine, Harvard; honorary doctor of science from Philadelphia College of Pharmacy and Science and New England College of Pharmacy; honorary doctor of laws, University of Chattanooga.

Internship at Peter Bent Brigham Hospital, Boston. Residency at Lakeside Hospital, Cleveland. Served in various capacities with New Haven Hospital and as instructor in internal medicine at Yale, prior to joining Food and Drug Administration in 1936 as Chief, Drug Division.

Joined staff of American Medical Association in 1941 as director of drugs, food, and physical therapy and secretary of council of pharmacy and chemistry. In 1942 became president and director of Winthrop Laboratories; is now in addition director and vice president, Sterling Drug, Inc.

Has served or is now serving Federal governmental bodies as member, Medical Advisory Committee, Office of Vocational Rehabilitation, Department of HEW; chairman, Medical Services Task Force, Hoover Commission; member, Study Committee on Federal Aid to Public Health, Commission on Intergovernmental Relations; chairman, Task Force on Employment of the Handicapped (Office of Defense Mobilization).

Service to private and civic organizations includes: vice president, U.S. Pharmacopeia Convention, Inc., and member of its board of trustees; member of the board of directors of Pharmaceutical Manufacturers Association; member committee on rehabilitation, American Heart Association; various committees of the American Medical Association; director, World Medical Association; member, board of directors, American Foundation for Tropical Medicine; numerous other organizations.

My name is Theodore G. Klumpp. I am president of Winthrop Laboratories, and a member of the board of directors of the Pharmaceutical Manufacturers Association. I was graduated from the medical school of Harvard University in 1928 and practiced at various hospitals in Boston, Cleveland, and New Haven, where I was on the faculty of the Yale University Medical School. I was adjunct professor of clinical medicine at the George Washington University

Medical School and attending physician at the Gallinger Municipal Hospital from 1938 to 1941. In 1936 I was appointed Chief Medical Officer and in 1938 became Chief of the Drug Division of the U.S. Food and Drug Administration and served in this capacity until 1941. I was vice president of the U.S. Pharmacopeia from 1950 to 1960 and was reelected to a second term, running from 1960 to 1970. I also served as Chairman of the Medical Service Task Force of the Hoover Commission and am presently a member of the Medical Advisory Committee of the Department of Health, Education, and Welfare's Office of Vocational Rehabilitation. In addition, I was Chairman of the Office of Defense Mobilization's Task Force on Employment of the Handicapped. I am a member of the Panel on Aging of the Department of Health, Education, and Welfare, and Chairman of its Subcommittee on Physical Fitness. I am a director of the U.S. Committee of the World Medical Association, a director of the American Heart Association, and chairman of its Committee on Rehabilitation. I am a fellow of the American College of Physicians and the New York Academy of Medicine.

Dr. KLUMPP. Mr. Chairman, I would also like to say at the outset that I recognize that this statement is long. It is the longest that you will be confronted with, so far as I know, today.

We regret that very much, and my collaborators and I have gone over this thing to chop it down and try to reduce it to its least common denominator, but, as it stands here, the thread of reasoning is such that we could see no way in which it could be further shortened except that, as I go along, I will try to eliminate some of the examples and extemporaneously try to shorten it.

I shall testify in behalf of the Pharmaceutical Manufacturers Association concerning section 102 (a) and (b) and section 104 (a) and (b) of H.R. 11581, which relate to the safety and effectiveness of new drugs, the definition of "new drugs," the filing of new drug applications and their suspension or withdrawal.

By way of introduction, let me say that the new drug provisions of the present Food, Drug and Cosmetic Act which were enacted in 1938 were drafted in close collaboration with the Food and Drug Administration. As Chief Medical Officer I participated in the discussions and councils that led to the adoption and enactment of these provisions. As Chief of the Drug Division I also participated in the formulation of the administrative policies and regulations by virtue of which the "new drug" and other sections of the law were enforced. I have had, therefore, the somewhat uncommon experience of working closely with the food, drug, and cosmetic law from two points of view: first, that of a law enforcement official, as Dr. Scheele was; and then as chief executive officer of a company whose responsibility it was and is to comply with this law and the administrative rulings pertaining to it.

Under the current law and system the drug industry has made great strides, particularly since World War II, and its discoveries have helped materially to make the health of the American people unequaled in the world. We of the drug industry accordingly believe that the matter of any changes should be approached with care, with full understanding of the philosophy of existing law, and with appreciation of the implications and consequences of proposed changes. At the same time, we recognize our public responsibilities and are not opposed to change as such, so long as it is constructive and maintains a proper balance between needed regulation and industrial freedom which together make up the public interest, the balance to which Mr. Beesley has referred. It is in this light that I intend to discuss the amendments proposed in sections 102 (a) and (b) and 104 (a) and (b) of the bill.

In substance and effect these provisions of H.R. 11581 broaden the definition of the term "new drug" to include drugs not generally recognized as efficacious; require that a new drug application must be affirmatively approved by FDA before it can become effective and before the new drug can be marketed; grant FDA the authority to reject a new drug application if the manufacturer has not convinced FDA that the drug is efficacious for use; and, give FDA the power to withdraw an effective new drug application if FDA entertains a substantial doubt as to the drug's safety or efficacy—such withdrawal to be effective in advance of a hearing if FDA feels that the drug presents an imminent hazard to the public health.

Let me state very clearly—these are radical, even revolutionary, proposals. The basic philosophy of our food and drug laws—the philosophy that was incorporated in the first Pure Food and Drug Act of 1906 and consistently and repeatedly reaffirmed ever since by the Congress, and particularly by this committee—is changed by these provisions of H.R. 11581 concerning "efficacy," "substantial doubt," and "affirmative approval."

That the Pure Food and Drug Act of 1906 did not seek to establish the Government as the arbiter of scientific or medical opinion was expressly stated in 1911 by Justice Oliver Wendell Holmes in *United States* v. *Johnson* (221 U.S. 488 (1911)). In holding that the 1906 act did not give the Executive power to decide questions of therapeutic efficacy, Justice Holmes stated for the Supreme Court: Congress—

> was much more likely to regulate commerce in food and drug with reference to plain matter of fact * * * than to distort the uses of its constitutional power to establishing criteria in regions where opinions are far apart. (P. 498)

Again in 1916 with respect to the 1912 amendments to the Pure Food and Drug Act the Supreme Court stated, this time through Justice Charles Evans Hughes: "Congress deliberately excluded the field where there are honest differences of opinion between schools and practitioners (concerning therapeutic efficacy) * * *." *Seven Cases* v. *United States* (239 U.S. 510, 517 (1916)).

The great and extensive amendments of 1938 likewise reaffirmed this basic philosophy. As one court summed it up in 1944: "Plainly, therefore, the subject of regulation in the 1938 act, as in its predecessors, is matter of fact, not matter of opinion"—referring to the report of this very committee. *United States* v. *7 Jugs, etc., of Dr. Salsbury's Rakos* (53 F. Supp. 746, 758 (D.C.D. Minn. 1944)).

This basic philosophy will be changed if the provisions of H.R. 11581 concerning "efficacy," "substantial doubt," and "affirmative approval" are enacted. Although these provisions have an attractive and apparent simplicity, the pharmaceutical industry faces a rule of men, not our traditional rule of law, if these provisions are adopted without change. Each of them shares this fatal flaw: they give to FDA authority to decide for industry, for practicing physicians and, therefore, for the public itself, complicated questions of scientific opinion rather than of fact, concerning what drugs should be available, and without application of objective and clear criteria or other safeguards. These provisions, in their present form, will upset the system which has played such a responsible role in this country's unmatched progress in medicine, and will impede the development of

new products which are essential to that progress. Accordingly, we are opposed to these provisions of H.R. 11581 as they stand and, while we are in sympathy with the objectives sought by some of them, we believe that certain modifications are essential if they are to be adopted, as I shall now discuss in detail.

THERAPEUTIC EFFICACY

Let me first discuss section 102(b) of the bill, which would require new drugs to be cleared by FDA for efficacy, in addition to safety as at present. We fully endorse the principle that a drug should be effective—that it should have the effects which its manufacturer claims for it—and we are not opposed to having this principle properly reflected in the statutory provisions applicable to new drugs, although under section 502(a) of the act it was and is a crime to market a drug that is not effective as claimed. Obviously, drugs should be effective as well as safe. While the present new drug sections of the law deal only with safety, FDA nevertheless does consider effectiveness when passing on new drug applications. If FDA desires confirmation of its power to pass on the effectiveness of new drugs, we have no objection, so long as appropriate safeguards are included in recognition of the difficult problems involved in determining efficacy. I will discuss these problems first to show why safeguards are necessary, and then state what safeguards we believe should be added if the concept of efficacy is included to the law.

Efficacy has a deceptively simple and attractive sound, but it raises a host of problems which I feel need to be discussed in some detail so that this committee may have a full understanding of the matter. In the entire realm of medical science nothing is more difficult and more subject to honest differences of qualified opinion than the determination of the therapeutic effectiveness of drugs in human beings. The Supreme Court of the United States recognized this truth as early as 1902 in the famous *McAnnulty* case (187 U.S. 94 (1902)), and, as I pointed out earlier, our food and drug laws have been based upon this premise from their inception right up until today.

Despite advances in scientific techniques, therapeutic representations and claims remain essentially matters of opinion. Different schools of thought with respect to the proper treatment of various diseases are prevalent and sometimes completely contradictory. Not infrequently, it takes years and sometimes decades of widespread clinical experience to evaluate the true or relative merit of a drug in given conditions. From such long experience, a medical consensus generally emerges but even then some qualified physicians refuse to go along with their colleagues.

History teaches that authoritarian bodies have often been guardians of orthodoxy rather than champions of progress. Medical experts rejected Jenner's smallpox vaccine, Pasteur's anthrax vaccine, Lister's theory of antisepsis and Semmelweis' discovery of the cause of childbed fever. Cod liver oil was rejected as worthless by the Council on Pharmacy and Chemistry of the American Medical Association. When Prontosil, the first sulfa drug, was introduced in the United States, it was greeted as another quack remedy by the outstanding American authority on infectious diseases and chairman of the U.S.

Army's Commission on Infectious Diseases. In the early 1930's, the same authority, unfortunately, dismissed early English reports on penicillin as incredible and refused to employ for clinical testing a culture of penicillium that had been brought to him by one of his associates, and that culture was poured down the sink.

The Committee on Medical Research of OSRD, faced with the problem of allocating a short supply of penicillin to the treatment of the most serious diseases for which penicillin was then known to be effective, refused to release penicillin for the treatment of subacute bacterial endocarditis because the initial dosage used experimentally by physicians had not proved to be effective, although subsequently when material became more readily available and larger dosage was applied, this drug proved to be a cure for what was until then a 100 percent fatal disease.

I would like to interpolate that before the outbreak of World War II, our military rejected Atabrine as a safe and effective treatment for malaria.

They scrambled to build up a stockpile of quinine, even recalling the small dribbles that lay on the druggists' shelves.

Atabrine subsequently proved to be not only safe and effective, but actually superior to quinine.

Dr. Keefer discussed the differences of medical opinion with respect to the drugs employed for the treatment of rheumatoid arthritis. He also referred to epilepsy, and the curious fact that one drug will be effective on a small proportion of cases and not at all useful in other cases. He also referred to the fact that if such a drug, effective in 20 percent of the cases, was submitted to the Food and Drug Administration, how would the Food and Drug Administration react toward it?

At the present time, there are sharply opposed views among experts concerning the proper treatment of many common diseases. Rheumatoid arthritis is such a condition. There are highly qualified physicians who favor the use of corticosteroid drugs. There are others who feel that the employment of the corticosteroids does more harm than good and that the only meritorious drug is aspirin. Still others are proponents of, respectively, Butazolidin, gold salts and antimalarial drugs such as quinacrine, chloroquine and hydroxychloroquine. The use of pyramidon, or large doses of vitamin D, still has adherents, and particularly among clinicians in foreign countries. The reaction of experts to any new drug offered for the treatment of rheumatoid arthritis will inevitably be conditioned by the school of thought to which they happen to adhere. By whose advice is FDA to be guided in the evaluation of a new drug for this condition?

Epilepsy is an affliction for which a variety of drugs is available. For reasons not now understood, any one of these drugs may be effective in some cases of epilepsy and worthless in others. If a new drug were found to fail in 80 percent of the cases in which it was tested and successful in the remainder, would it be released by FDA as "efficacious," or would the clinical testing required be so extensive and costly that no manufacturer could afford to carry through such a program for the possibility of gaining only 20 percent of a limited and already highly competitive market? If this were to happen, it might deprive a number of unfortunate epileptics of a drug uniquely

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effective in their particular cases. Much the same situation prevails today with the antihistamines. There are now over 30 different substances with antihistamine activity on the market. While they all share a basic antihistamine activity, yet the fact is some work for some patients while others work only for other patients. If H.R. 11581 were the law, how many antihistamines would we have?

Mucous colitis is a disease, the cause of which is still unknown. For almost a century, it was considered to be due to intestinal infection from an organism as yet unidentified. In 1924, Bargen of the Mayo Clinic reported the isolation of a bacterium from cases of mucous colitis. This discovery was hailed as the revelation of the culprit responsible for the disease. It gave impetus to the use of antiseptic agents and later sulfa drugs and antibiotics in the treatment of the condition. Unfortunately, no drug was found to be uniformly successful and as a result other theories were advanced to explain the nature of the disease and to provide a rational basis for its treatment. Reputable surgeons, concluding that no drugs are effective, still remove large segments of the bowel. More recently, psychiatrists became convinced that the condition was due to emotional disturbances and represented nothing more than an extension of the well-known diarrhea of fear and fright. At the present time, these and other divergent schools of thought adhere to their theories. With all the various forms of treatment, some cases improve and others go on to death. Here again the attitude of medical officers of FDA, if given the authority to decide for all doctors the effectiveness of new therapies, will be conditioned by the theories which they happen to favor.

There is no known cure for the common cold. Many physicians are convinced that nose drops with vasoconstrictors, or antihistamines, or sulfa drugs, or antibiotics are helpful. Others believe that they do no good and may even be harmful. Some feel that a cold vaccine is effective in preventing a cold. Others consider such vaccines utterly useless. Who is to say which view is correct and impose his particular bias on the 180,000 practicing physicians who are sharply divided on the proper management of the common cold?

Spinal anesthesia with drugs of the procaine series is widely employed by anesthesiologists.

Here, again, we have a serious difference of opinion. One investigator reported the successful use of this form of anesthesia in over 50,000 cases. Numerous anesthesiologists have had similar and perhaps even more extensive favorable experience. However, some equally expert anesthesiologists have found that unexplained and serious side effects occasionally result, and they do. The majority of the investigators favor the use of these drugs because they believe their superior effectiveness offsets the risk of occasional serious side effects. Other investigators will not use them. They think the dangers outweigh the benefits. What will be the fate of a new drug application for a drug of this kind, if the medical officers of FDA happen to share the view of the latter school of thought?

The above specific illustrations are only a few of the many that can be cited to show that—

(*a*) The determination of the effectiveness of a drug is always difficult and sometimes cannot be achieved except by the test of time and widespread use.

(*b*) Therapeutic representations are essentially matters of opinion.

(*c*) Differing schools of thought frequently exist concerning therapeutic issues, and the school which favors one theory as to the nature and treatment of disease tends to be skeptical of the drugs advocated in opposing schools. Moreover, medical opinions as to effectiveness of a particular drug can differ widely among equally qualified physicians because of basic differences in opinion relating almost entirely to questions of diagnosis and preferred method of treatment, as well as differences as to the comparative efficacy of one member of a class of drugs in relation to others or the mode of action of a particular drug in the complex body mechanism.

I might also add that the present law recognizes specifically two systems of medicine: the homeopathic system and the allopathic system, and provides different textbook standards for each of those systems of medicine.

(*d*) Initial authoritative opinion concerning the effectiveness of new drugs has often proved to be wrong.

(*e*) Where a drug is useful for only a small number of patients, or where the incidence of a disease is small, the expense of extensive clinical trials to provide conclusive evidence of usefulness may deprive patients of such drugs.

The foregoing examples and considerations point up the difficulties and the danger inherent in giving FDA the authority to pass explicity on "efficacy." They serve to explain why it has been decided on previous occasions that FDA should not have such authority. As a former official of FDA who participated in the councils of FDA concerning the Federal Food, Drug, and Cosmetic Act in 1938—especially the new drug provisions—I can state that FDA at that time did not want to assume the awful power of deciding this complex question. FDA then felt that it was best and wisest for all concerned to leave these decisions to the physicians of the world who in the final analysis must be assured this freedom if they are to practice their profession in a rational and responsible manner. In this connection it must be kept clearly in mind that FDA then and now has full authority to rid the market of products whose claims are not supported by honest, reputable medical opinion. FDA has consistently and successfully invoked this power thereby protecting the public health and responsible manufacturers.

The question of including "efficacy" as a standard in the law was also considered by the Congress as late as in 1951 in connection with the Durham-Humphrey amendment to the Food, Drug, and Cosmetic Act and was rejected.

The majority report No. 700, issued by this committee, dated July 16, 1951, which accompanied H.R. 3298, included the following statement:

> The standard which the bill, as amended, would write into the law (subparagraph (B)(1) of the amendment) contains the words "efficacy" and "efficacious." The use of these words has given rise to some apprehension * * * that the Federal Security Administration—

which was then the parent organization—

> might have the power to determine which drugs are "efficacious" or "effective" and which are not. It may be stated unequivocally that this provision is not in-

tended to grant any such power to the Administrator, nor does it lend itself in any way to such an interpretation. (P. 11.)

On the floor of the House, when the bill was being discussed, a distinguished member of this committee, Mr. Roberts of Alabama, who, I am pleased to note, is still a member, stated as follows:

Mr. Chairman, when this bill was being considered in committee there was quite a difference of opinion as to the meaning of the word "efficacy" and the meaning of the word "efficacious." Webster's Dictionary defines efficacious to mean possessing the quality of being effective. Many of us feel perhaps that it is too broad, and in fact many of us voted to strike those words out in committee. I feel the bill will be just as good and will accomplish the same purpose and will answer some of the objections being made along the line that we are giving too much power to the Administrator.

Mr. Roberts' motion was passed on the floor and the efficacy provisions were stricken from the bill thus keying the standard of what drugs must be sold on prescription to those that are not safe for self-medication. This, I submit, after 24 years, has been a satisfactory and workable standard.

Now I come to the safeguards which we think are esential if FDA is given the power to pass on the efficacy of new drugs. In the light of the problems and considerations I have mentioned, we believe that the following should be reflected in any amendment on the subject:

(1) The terms "effective" and "effectiveness" should be used instead of "efficacy" and "efficacious". The latter terms tend to connote a curative result. The test should be whether the drugs will have the effects—the biological or pharmacological activities—claimed by their producer, which a physician may desire even though they may not find it possible to cure the patient.

(2) It should be clearly provided or understood that the test for effectiveness is whether a drug produces an effect in the body or is inert, not whether the effect is or is not desirable in the treatment of a given class of patients where medical opinion may differ according to basic differences in schools of medical opinion and thought.

(3) It should be clearly provided that a drug meets the test for effectiveness if there is substantial (but not necessarily preponderant) evidence that it has the effect claimed, and it should be understood that the authority to pass on effectiveness does not include the authority to consider the relative efficacy of one drug over another.

(4) There should be a specific provision that the new requirement of "effectiveness" shall not apply to old drugs already on the market or to new drugs which were cleared before the amendment, and such new drugs should be subject to withdrawal or suspension only on safety grounds.

In our view, the foregoing modifications are essential if we are to preserve the physician's freedom to prescribe as he sees fit and to encourage the development of new products. It would be perilous to rational medical practice and the public welfare to require that, before a drug can be marketed, its therapeutic effectiveness must be supported by all investigators or even by a preponderance of opinion. It should be enough if responsible and qualified clinicians have found that the new drug produces the claimed effect, although equally responsible and qualified clinicians have not yet found it to be effective or believe it to be ineffective. FDA should not be the arbiter of such conflicting views which necessarily involve large elements of subjective

opinion by qualified clinicians. Otherwise, we face the serious danger to medical progress inherent in a central authority where conflicting viewpoints in medicine will be indirectly resolved, as they are under a totalitarian system, and we run the very grave risk of recasting our system in a sterile, foreign mold and denying to physicians drugs which they may want to have for their patients.

What I am saying is equally relevant to the problem of research and development of new materials. It has been the experience of my company that the cost of development of a new drug for marketing is approximately $5 million. I might add that the cost of other major pharmaceutical houses is about the same as ours. If it is made more difficult and more costly to bring new drugs to market because of added redtape and restrictions—if a new drug can be barred because of conflicting views, honestly held—but involving subjective judgments on its effectiveness—research is seriously threatened and indeed may be effectively foreclosed in the case of drugs for serious diseases which are not highly prevalent. It is vitally important that development of new products of potential public health significance not be shut off for such reasons, for the result will be to hamper seriously progress in the conquest of disease and the prolongation of life.

So we urge that, if "effectiveness" is added to the law, the safeguards I have outlined should be written in.

DEFINITION OF NEW DRUG

I come now to section 102(a) of the bill which would amend the definition of new drug to include drugs which are not generally recognized as "efficacious". We are opposed to this amendment as confusing and unnecessary. For almost 25 years the touchstone of whether an article is a new drug has been whether it is generally recognized as safe. That has been a satisfactory and workable standard. Under it, industry and FDA have been able to conclude, with reasonable certainty, what is, and what is not, a new drug. The proposal to add "efficacy" to this standard would cause confusion without benefit and would substantially destroy the workability of the standard. The conflicting views, often involving subjective judgment, which are frequent on the matter of "efficacy," would make it virtually impossible to determine what drugs are generally recognized as efficacious, and for a manufacturer to know when a "new drug" became an old drug, and therefore was no longer subject to the new drug procedures. Many unquestionably safe "old rugs" would have to be processed by FDA as "new drugs" to determine their "efficacy," and would probably have to be withdrawn from the market until FDA had cleared them. This would be wasteful, and would needlessly deprive patients of some drugs which they have been using for years. Such a situation could be catastrophic to them as well as to the manufacturer. It would also, and this is important, bog down FDA and industry with needless new drug applications.

They are having difficulty enough in handling the applications under the present provisions of the law.

As the Senate Report No. 1744, on S. 1552, dated July 19, 1962, points out, this would be unsound. No question of safety would be involved, and FDA presently has ample power, including seizure,

to proceed against any old drugs of unquestioned safety for which unsupported claims of effectiveness are made.

It is also unnecessary to amend the definition of new drug in order to give FDA specific authority to consider the effectiveness of new drugs, which we have conceded they should have. By retaining the present definition FDA will be assured of having submitted to it for clearance under the new-drug procedures all genuinely new drugs, because as to them there will necessarily be a question as to safety. When the required new drug application is submitted—either for a new product or for a new use of an existing product which is not generally recognized as safe—FDA can pass on the question of the drug's effectiveness if that power is given to it. That is the power FDA seeks—the specific authority to consider effectiveness in passing on new drug applications—and that is all that should be given to FDA. It is accordingly unnecessary to amend the definition of new drug to include "effectiveness," and such amendment should not be made because it would only produce needless confusion as I have pointed out above. We agree with the Senate Report No. 1744, on S. 1552, dated July 19, 1962, which states at page 17—

> that there is no basis for the concern which has been expressed that if the definition of new drug is not amended to refer to effectiveness, a drug once cleared for the market under the new drug procedures as a tranquilizer, for example, could subsequently be marketed for some other use without going through the new drug procedures as to such use.

As that report points out, this is not true under existing law and would not be true under the law if it is amended to give FDA specific authority to consider effectiveness. Any such new use would have to be submitted under a supplemental new drug application and would have to be cleared for safety under existing law, and also for effectiveness if that power should be added to the law.

AFFIRMATIVE APPROVAL AND TIME LIMITS

Section 104(a) of H.R. 11581 would make two basic changes in existing law. It would require FDA to affirmatively approve new drug applications, instead of letting them become effective unless the FDA disapproves them. It would also extend the time limits for action.

We are opposed to requiring affirmative approval of NDA's. It shifts the responsibility for products from the manufacturer to FDA, it places a very heavy burden of decision on the personnel of FDA, and the inevitable result will be undue delay in the introduction of new drugs. The consequences of that are serious indeed. We have heard much about making sure that dangerous drugs do not get on the market inadvertently, a situation which in 24 years has not arisen in practice. Just as important, however, is the drug that wasn't there—the drug which has been delayed from coming on the market by misplaced caution and which, if it had been available, would have saved lives.

As an official of FDA at the same time the present law was adopted, I can say that the present procedure is what FDA itself wanted. It was then the considered opinion of FDA that it would be unwise for FDA to be placed in a position of having to affirmatively approve each application. FDA recognized then and for many years that this

was unwholesome prior censorship, that it placed an impossible burden of decision and responsibility on the individual employee involved, and that the result would be needless delay and misplaced caution. This conclusion was reinforced by the view that if FDA had affirmative approval power its exercise would be interpreted by the physicians and the public as Government endorsement of each new drug placed on the market.

FDA's position on the matter in 1938 sprug from its realization of his historic and intended role as an agency of Government which saw to it that manufacturers produced pure products, properly labeled, and adequately tested and not an agency which established or enforced "official" medical or scientific opinion. Moreover, FDA was mindful of its early experience under the Pure Food and Drug Act of 1906. That act required that a manufacturer make to the trade certain guarantees that his product complied with the act. Shortly after the act went into effect, a custom arose of manufacturers placing prominently on their package a statement to the effect that the product was "guaranteed under the Pure Food and Drug Act of 1906." When segments of the public took these statements to mean that the Government had approved the product when actually it had not, FDA issued a regulation forbidding such statements from appearing in labeling. This experience with the favorable reaction of the public to any product that seems to be approved by the Government convinced FDA personnel that if FDA actually had such authority the consequent responsibility and demands of the public would be unbearable burdens. I see no reason to suppose that the public would react any differently or expect any less today if FDA were granted the power of affirmative approval. Likewise, I fail to see why FDA should now have the power which all along since 1906 FDA believed was unwise for it to have when the new drug provisions were enacted in 1938.

The drug manufacturers do not want to hide behind the skirts of Government approval. We are prepared to continue to be responsible for our products. If every new drug has to be affirmatively cleared by the FDA, pharmacists, physicians and patients will inevitably tend to relax their vigilance, and rely more strongly on the FDA approval. At the same time, FDA will become increasingly cautious over extending approval, and there will be inevitable delays. In an area where the safety of a product is not, and never will be, susceptible to absolute conclusions, and will vary from time to time, depending upon new knowledge and new conditions, it seems quite evident that many new drugs of enormous potential will be withheld from use for increasingly long periods. I cannot repeat enough how serious this will be.

I might also add that when new facts are found that show that a drug once considered safe is no longer safe, it makes the FDA look very foolish, having positive, affirmative approval.

So far as time limits are concerned, we have no objection to the provisions of section 104(a) of the bill which would lengthen the time for initial consideration of NDA's to 90 days and allow a total of 180 days for the Secretary to act or give notice of hearing. Actually, the time limits of existing law have not operated to deprive FDA of whatever time it thinks necessary to consider an NDA. Such

limits have not been a problem because of FDA's practice of requiring more information when it is unsatisfied, and industry's record of cooperation. For example, preliminary results of an industry questionnaire indicate that in 1961 about 60 percent of the NDA's filed took more time to process than the 60-day initial period fixed by present law. So far as we know, there are no instances in which a new drug application has become effective before FDA has satisfied itself as to the drug's safety for the asserted uses.

And I might add that if our experience is any criterion, our notice at the end of 60 days has not always arrived at the end of that period, and nobody had any question about going on the market.

However, we do object to the failure of section 104(a) of the bill to specify a time for beginning the hearing which the Secretary is to give notice of at the end of the 180-day period if he believes the application should not become effective. We urge that provisions be included requiring the hearing to begin within a specified period after notice, say 30 days or such further time as the Secretary and the applicant may agree upon, and also requiring that the hearing be conducted on an expedited basis. FDA should not be permitted to temporize and delay action or hearing indefinitely.

Commissioner Larrick, with the concurrence of Secretary Ribicoff, has conceded our points that the law should not be changed to require affirmative approval and to allow indefinite time for action. At the previous session of these hearings on June 19, 1962, Mr. Springer asked a series of questions about the record of industry cooperation in making sure that new drugs did not go on the market until FDA was satisfied of their safety and why in the light of that record there was any need for requiring affirmative approval and for allowing an indefinite time for action. In response, Commissioner Larrick yielded, stating after conferring with the Secretary:

> If you were to add to the 180 days whatever length of time it takes to proceed with this hearing and to conclude it, then we probably would have enough relief. (Transcript, pp. 57–58)

That is the only relief which should be given—180 days for consideration of a new drug application, plus the time thereafter required for any hearing, which should be required to begin within a specified time and to be completed on an expedited basis. The law should not be changed to require affirmative approval.

WITHDRAWAL OF NDA

I turn now to the provisions covering the withdrawal of an effective new drug application by FDA. This is section 104(b) of the bill, which would amend section 505(e) of the Food, Drug, and Cosmetic Act. Of course, a withdrawal order when issued means that the drug in question must be recalled and may no longer be marketed under pain of criminal sanction. At present FDA may take such action only on the basis of new evidence showing the drug to be unsafe and after a hearing. H.R. 11581 would allow the extraordinary procedure of withdrawal if FDA has a "substantial doubt" as to the "safety or efficacy" of the drug on the basis of any evidence—even just the evidence in the NDA file alone. In other words, if FDA merely changes its mind, it may withdraw an NDA. Moreover, such

withdrawal could be accomplished in advance of a hearing if FDA finds that "an imminent hazard to public health" exists. In addition, withdrawal could be ordered because the applicant has failed to comply with any requirements as to records and reports; or because the facilities and controls used for the manufacture, processing, and packing of a new drug are then inadequate to assure and preserve its identity, strength, quality, purity, safety, and efficacy; or because any one of several technical conditions on which the application was approved has been violated.

We do not oppose the idea behind the proposed amendment—that the present standards for permitting FDA to suspend a new drug application may be too rigid and should be relaxed. However, we believe that the amendment goes much too far and that certain modifications are essential as a protection against hasty, ill-advised, and arbitrary administrative action which will be detrimental to the pharmaceutical industry and its ability to serve the public. Our concern centers on the provisions allowing suspension for "substantial doubt," for failure to keep records and so forth, and for immediate suspension without hearing.

1. "Substantial doubt" is a slippery phrase and when it is used in connection with such troublesome concepts as therapeutic "efficacy" and "safety," it becomes absolutely perilous, especially if action can be taken before any hearing. For the reasons given in my discussion of efficacy, and what I am about to say on safety, this power will allow complete censorship and justify essentially dictatorial action on the part of FDA. And we get no comfort from the efforts of Deputy Commissioner Harvey to give substance to the term "substantial doubt," in response to questions by Mr. Rogers at the hearing on last August 6 before the Health and Safety Subcommittee of this committee on H.R. 12437—I refer to pages 32–33 of the transcript of that day.

Since this provision of the bill would expand FDA power over consideration of the safety of new drugs, I would like to discuss therapeutic safety for a moment. As I have previously said, therapeutic "safety," like therapeutic "efficacy," is a relative term which involves opinion and judgment. Although therapeutic "safety" may involve less of the element of subjective opinion and be more demonstrable, it is not an absolute concept. Indeed, it is a rare drug that will not have some toxic effects on some people, and physicians have to take the element of risk, or lack of safety if you will, into account in deciding whether to use a particular drug for a particular patient. Because of this, physicians can and do differ in their opinions of whether a drug is safe for use—whether the situation presented justifies running the risks involved—just as they can and do differ in their opinions of a drug's effectiveness. Penicillin, for instance, is generally regarded as a safe drug, and yet in the 5 years period, 1953 to 1957, a nationwide survey reported 2,517 reactions to this drug and 82 fatalities. In another survey conducted by the World Health Organization of the United Nations, the incidence of reactions to penicillin was found to be 1.5 percent with fatalities occurring in 1 out of 95,000 patients treated. On the other hand, a drug would not generally be considered safe by physicians if it were used for some minor ailment, such as acne or headache, and caused a similar number of reactions and fatalities. In

other words, since the question of therapeutic safety may involve judgment, risk and other variables such as the patient's general health, it can be in many instances a complete matter of opinion on which honest differences can simultaneously exist.

That in most cases therapeutic safety is actually a relative matter and, therefore, a question of opinion is recognized by the agency to which this law will be assigned, FDA. Commissioner Larrick on May 18, 1962, made the following statement to the Antitrust and Monopoly Subcommittee of the House Judiciary Committee in testifying on H.R. 6245 which also seeks to amend the food and drug law:

> Mr. LARRICK. As I stated earlier, in response to a question, there is no drug, hardly, which is innocuous, so there is no drug which is safe in an absolute sense.
>
> * * * * * * *
>
> Mr. LARRICK. So, to determine whether or not the drug is safe within the statutory meaning, we always have to put on the scale on one side the good that the drug will do, the people that it will cure, the lives that it will save, and the suffering that it will prevent.
>
> We put on the other scale what we know about the harm it will do, and if the harm outweighs the good we deny the application—

subjective judgment—

> If the good outweighs the harm, we pass the application * * *

Mr. Larrick's concept of this matter is not personal to him. It is the official FDA position. For example, Dr. W. H. Kessenich, Medical Director of FDA, expressed the FDA's role and procedure this way in the January–February 1962 issue of Clinical Pharmacology and Therapeutics:

> Safety must be considered largely from a relative point of view. When the possible benefit is weighed against the possible harm of new drugs that have reached the market the scale will tip easily in favor of the beneficial effect they have—provided the balance on which they are measured is the sound professional judgment of a well-informed practitioner. (P. 54.)

Let me quote at this point from that part of the report of this committee approving the 1938 amendments to the Food, Drug, and Cosmetic Act which explains the "new drug" provisions:

> Section 505(a) requires new drugs to be adequately tested before they are commercialized. In order to insure that the tests made have been complete, the introduction of a new drug into interstate commerce is prohibited unless the manufacturer has submitted full information showing that the drug has been adequately tested and has not been found to be unsafe for use under the conditions prescribed in the labeling. This is not a license provision but is intended merely to prevent the premature marketing of new drugs not properly tested for safety * * *.
>
> This provision will not put the Federal Government into the business of developing new drugs, nor will it require the Government to duplicate laboratory and clinical tests made by responsible manufacturers. The provision merely sets up a method for the authoritative review of the manufacturer's tests and will not unreasonably delay the introduction of new drugs in the market. (P. 9.)

This language and the history of this act indicate to me that Congress did not intend FDA to be the final arbiter of medical opinion on matters of therapeutic safety—to decide for physicians what drugs they may use when honest differences of medical opinion exist. We must remember that under present law FDA has tremendous authority over labeling and may and should require full disclosure to the physicians, including disclosure of any differences of opinion that may exist as to risks, side effects, contraindications, and so forth. FDA

should see that physicians are fully informed, not that they may not form their own opinions as to whether it is safe to use a drug in a particular situation in the light of all the circumstances.

However, if Congress now gives to FDA authority to withdraw new drugs from the market because of substantial doubt as to their safety or efficacy, FDA will became the final arbiter of medical opinion on matters of safety and efficacy, the physicians will have their decisions made for them, and industry will be living under a continual threat. Given the fallibility of man, the conflicting opinions which can arise, and the pressures which can be generated, FDA will naturally feel compelled to exercise its sweeping withdrawal power every time its judgment in passing a new drug for the market is subsequently questioned in any degree. The resulting impact on drug manufacture and research and the practice of medicine is a grave thing to contemplate.

Complaints of many different side effects from even the most ordinary product such as a vitamin preparation come to us very frequently. It is very difficult to sift out these complaints and weigh their validity. This is done, however, and most of them turn out to be groundless. With the proposed authority of this bill and the legislative mandate that will follow from its adoption, however, FDA will be put in a position of withdrawing new drugs as soon as any question is raised. One or two incidents of this type with subsequent newspaper publicity can undermine the confidence of the medical profession and the public in good and safe medicine. Once shattered, this confidence is always difficult to reinstate and sometimes impossible. Thus the public will be deprived of good and lifesaving preparations without good cause. In these situations administrative officials will probably adopt the course of least resistance and the course least subject to criticism. That course will be to withdraw first and restore later if subsequent investigations show the error of the initial withdrawal—but by that time irreparable damage to the product and to the public confidence will have been done.

We accordingly urge that the power to suspend because of "substantial doubt" should not be given because it will adversely affect the public health by interfering with drug research and manufacture and the practice of medicine. Let me cite one example in which the power to remove a product from the market because of substantial doubt would probably have been exercised had FDA possessed it. You can judge the consequences. Dr. Harvey W. Wiley, as this committee knows, is generally considered the father of the pure food and drug law of 1906 (it is still popularly called the Wiley Act). He was its first administrator as Chief of the Bureau of Chemistry of the Department of Agriculture. Dr. Wiley himself has published this story and other authors have corroborated it. Dr. Wiley in 1908 conducted a series of tests from which he concluded that benzoate of soda—a common food preservative—and saccharin—as you all know, a universally used artificial sweetener—were injurious to the health of users and specifically requested President Theodore Roosevelt to ban their use in foods and drugs. Of course, no one has ever accused Dr. Wiley of improper motives or of rigged research. His integrity and good faith are beyond dispute. In fact, that is what sharpens the point of the incident. Apparently only because President Roosevelt's own physician had previously prescribed saccharin for him was the Ameri-

can public spared the enormous loss, inconvenience and wrong that would have followed the banning of these safe and highly useful ingredients. Dr. Wiley has stated that the President had decided to follow his advice on benzoate of soda and reversed it only on learning of Dr. Wiley's position on saccharin. According to Dr. Wiley, President Roosevelt characterized Dr. Wiley's position in these words: "Anybody who says saccharin is injurious to health is an idiot."

We fear that adoption of the "substantial doubt" provisions of H.R. 11581, without change, will make probable a repetition of incidents like this, but without the happy ending that this one had because under H.R. 11581 FDA will not have to ask the President or the Congress—indeed, it may create the unfortunate result without a hearing at all. So we urge that the nebulous concept of substantial doubt be rejected, and submit that the purpose for which it is intended will be fully served by amending the law to provide that a new drug can be taken off the market if new evidence shows that it no longer meets the test for going on the market—that is, if the drug is no longer shown to be safe. This will relieve FDA of the present burden, which it deems too onerous, of proving that a drug is unsafe, and at the same time will protect industry against all the uncertainties which are wrapped up in substantial doubt.

(2) We are also opposed to the provisions for suspension for failure to keep records, to make reports, or to maintain manufacturing standards. Those provisions require the Secretary to suspend if he finds such a failure. He is given no discretion, even though the failure may be minor or inadvertent in nature and have nothing to do with the safety of the new drug. If a matter of safety is involved, suspension can be invoked on that ground. If safety is not involved, other sanctions of the act, such as criminal penalties, seizures, and injunctions, are adequate to enforce the obligations to keep records, to make reports, and to maintain manufacturing standards. The drastic remedy of suspension should not be added.

(3) The power to suspend prior to hearing, as I have reiterated, is drastic indeed. It is contrary to our traditions of due process and it poses fearful consequences for our industry. Once a product is so withdrawn, with all the attendant publicity, it is finished for practical purposes, even if the withdrawal was an honest mistake in judgment which government as well as industry can make. We are accordingly strenuously oppose the grant of this sweeping power of sentence first and verdict after. We think it is unnecessary. The Secretary already has a broad range of sanctions available—criminal proceedings, seizures, injunctions, and public warnings—which are adequate to protect the public.

He also has one very important additional protection. He has the cooperation of our industry when any serious question arises.

Through 24 years we have demonstrated the willingness, the public sense of responsibility, of this industry, and we have cooperated.

The pharmaceutical manufacturers are as concerned as the Government to prevent the marketing of dangerous drugs and we believe that FDA will agree that we have met our responsibilities in that regard.

(4) Finally, the evidence supporting suspension should be new evidence, not available when the application became effective. FDA

should not be permitted merely to change its mind on the basis of unchanged evidence.

To sum up, the objections we have to the broad suspension provisions of section 104(b) of the bill would be met, and the public would be fully protected, if section 505(e) of the act were amended to allow FDA to take new drugs off the market if new evidence shows that such drugs no longer meet the standards for letting them go on the market. That would relieve FDA of the present burden, which it deems too onerous, of proving that a drug is unsafe in order to suspend it—instead, the drug could be suspended if it is no longer shown to be safe. At the same time, such an amendment would not pose the threat to continued progress in drugs and medicine which we see in the drastic provisions of section 104(b) and their possible abuse, however well intentioned any particular action thereunder may be. And, if effectiveness is added to the standard for new drug clearance with the modifications I have urged, suspension would likewise be allowed if there is no longer substantial evidence (not conclusive or preponderant evidence) of effectiveness. That would permit a drug whose effectiveness continues to be supported by substantial evidence to remain available for prescription in the judgment of physicians, even though other evidence may create substantial doubt as to its effectiveness. However, if effectiveness is added as a requirement for new drug clearance, there should also be a grandfather clause exempting previously cleared new drugs from suspension on "effectiveness" grounds. Otherwise, manufacturers who had in good faith introduced a drug on the market before FDA was authorized to consider effectiveness could be penalized by having their investments destroyed even though no question of safety is involved.

CONCLUSION

I close with these thoughts:

Disease, disability, and premature death are man's greatest enemies. They are in every home, rich and poor alike, and the seeds of their destruction lie within each one of us.

Whether you or I live, suffer, or die depends on our physicians and the weapons that are placed in their hands. The pharmaceutical industry is the principal arsenal of these weapons. In large measure, through the research, skill, and know-how that our scientists have patiently developed, we have made more gains in the last half century in the conquest of disease and the prolongation of life than has been achieved in the entire 999 centuries of man's previous existence on earth. And yet our work has just begun. Not a single disease has yet been completely eliminated, and so much remains to be done.

You have heard it expressed in different ways, but to me the basic issue in these hearings is this:

Any legislation in the field of drugs must strike a delicate balance between Government control and freedom to develop and use new products for the conquest of disease.

Whatever safeguards may be needed against substandard practices and manufacturers should be drawn so as not to hobble responsible members of this lifesaving industry with unnecessary redtape, delay, and governmental restrictions. The American people cannot afford

to take a chance on bureaucratic controls which will stifle progress in drug research and in the practice of medicine. That to me, gentlemen, is what these hearings are all about, and that is why I urge the changes in the bill I have discussed.

The CHAIRMAN. Dr. Klumpp, you have given a very detailed analysis of the provisions in this bill from your standpoint, which I am glad to have.

Mr. Dingell?

Mr. DINGELL. Yes, Mr. Chairman.

Briefly, sir, I ask you if you would tell us which sections of the bill you do favor without reservation?

Dr. KLUMPP. Well, Mr. Dingell, there is a great deal in this bill that we do favor with some qualifications and with some amendment. We favor the general purpose of this legislation. We are in accord with it.

The reasons, the arguments that I have given in my presentation as to why certain provisions should not be enacted in their form as they appear in this bill, speak for themselves.

I am not wholly prepared to go through this bill at the present time—I have not marked it up—and tell you which we favor and which we do not.

I hate to shove the burden on my counsel here, but he is in detail more familiar with language and the rest of it.

Mr. DINGELL. The reason I asked that:

Let me say I want to commend you for a very fine statement. I think you have done an excellent job, and your work here in the committee today shows that you have prepared carefully, and I think you have made a very fine statement.

Dr. KLUMPP. Thank you.

Mr. DINGELL. But in fairness I am sure you recognize the Administration has worked very hard to get to this committee a good bill.

Dr. KLUMPP. We recognize that.

Mr. DINGELL. Which, in its opinion, is a good bill.

For example, I note here that you say, speaking on behalf of the industry, that you do not like the idea of "efficacy." You want it changed to "effectiveness."

Then a little later you indicate to the committee that you do not favor "effectiveness," the test of effectiveness, to be applied to new drugs, and then later you say you want the "effectiveness" to be applied to old drugs.

Dr. KLUMPP. Oh, no, no.

We think that the test of effectiveness, Mr. Dingell, should be applied to new drugs. We support that when it is based on substantial evidence of effectiveness.

Mr. DINGELL. I see.

But you do not want it applied to old drugs, drugs which are already on the market?

Mr. CUTLER. Mr. Dingell, drugs already on the market can be taken off the market by action of FDA, if they are worthless drugs.

Mr. DINGELL. If they are worthless?

Mr. CUTLER. If FDA can prove——

Mr. DINGELL. But not according to the same criterion that you would have?

Mr. CUTLER. No, sir.

Mr. DINGELL. With regard to new drugs?

Mr. CUTLER. Yes, they can.

If FDA can prove to a court that a drug already on the market is not effective for the purposes claimed in the labeling, the court under this law is required to withdraw the drug from the market and FDA can start the proceeding by seizing the drug.

Mr. DINGELL. In other words, FDA, to all intents and purposes, must show by the preponderance of the evidence. The function of this bill is to shift the burden of proof. I am sure you agree with that?

Mr. CUTLER. That is very definitely the purpose of this bill with regard to effectiveness, which we oppose, Mr. Dingell.

Mr. DINGELL. So that you oppose the concept of a change of burden of proof with regard to effectiveness?

Mr. CUTLER. That is correct.

Mr. DINGELL. Especially so in the case of old drugs, drugs which are already on the market?

Mr. CUTLER. Both new and old drugs.

Mr. DINGELL. I see.

Now, I want to read something. I checked up on my quote here from the President's Consumer Report, where the following statement was made:

> For example, over 20 percent of the new drugs listed since 1956 in the publication of New and Non-Official Drugs were found, upon being tested, to be incapable of sustaining one or more of their sponsor's claims regarding their therapeutic effect.

Now, do you think that that is a good situation for the protection of the American public?

Dr. KLUMPP. Mr. Dingell, if there is a drug on the market which does not provide the effectiveness that it claims, the Food and Drug Administration now has the authority to take the drug off the market.

And if there were 20 percent of those drugs, I would be very surprised that the Food and Drug had not acted.

Mr. DINGELL. Just a minute. You are not understanding my question here at all, because I say:

> For example, over 20 percent of the new drugs listed since 1956 in the publication New and Non-Official Drugs were found, upon being tested, to be incapable of sustaining one or more of their sponsor's claims regarding their therapeutic effect.

I did not say these were worthless drugs.

Dr. KLUMPP. No, I did not either.

Mr. DINGELL. I just said that some of the claims made as to therapeutic effect were either false or incapable of proof.

Mr. CUTLER. Mr. Dingell, section 502(a) of this act says that:

> A drug or device shall be misbranded if its labeling is false or misleading in any particular.

If its claim as to effectiveness is false or misleading, if the Food and Drug Administration can show that it is wrong, the Food and Drug Administration can start out by seizing the drugs in what the lawyers call a libel.

Mr. DINGELL. I am aware of this.

Mr. CUTLER. And on the basis of that, bring an action in the court.

Mr. DINGELL. Why do you think that drugs should be permitted to enter the market, although, according to this very responsible source, where, in over 20 percent of the cases, some of the claims made in regard to these same drugs were found to be incapable of sustaining one or more of their sponsor's claims?

Do you think that a drug should be able to enter the market under these circumstances?

In other words, here is what we are faced with. These drugs come on the market. Then Food and Drug Administration can show these claims are false. Then they can libel, seize them, and so forth, but I am sure you are aware this is a very difficult legal process.

What I want to know is, Why should not a drug which is coming on the market be compelled to bear the same standards that it must bear once it is on the market?

In other words, should not these claims for efficacy or effectiveness be true when the drug comes on the market?

Dr. KLUMPP. Yes, Mr. Dingell.

We think that the standards should be the same for those drugs that are on the market as well as those that are proposed for introduction.

Now, I do not know where you got that quote or what its source was, where it came from.

Mr. DINGELL. I will give you the source right here. It comes from the drug industry antitrust hearings on Friday, May 18, in the Judiciary Committee of the House of Representatives, and the ultimate source is the President's Consumers Report that is quoted there.

Dr. KLUMPP. We agree.

The drugs should be considered for effectiveness before they are introduced on the market, Mr. Dingell, but the question is what the standards should be and how they are to be applied. I have tried to show that with respect to these elements we are in an exceedingly difficult realm.

You are not dealing with matters of exact science or the demonstration of absolutes.

You are dealing with relatives and with opinions.

Mr. DINGELL. I recognize this.

I am both a lawyer and previous to that time I had a degree in chemistry, so I have some familiarity, and, as a matter of fact, I worked on some of these food and drug cases that we are discussing, so I am aware of some of the scientific implications, although not as well aware as you.

But the simple question is: Does it occur to you that it is appropriate that we should say they can come on the market with just "substantial evidence"?

Dr. KLUMPP. I certainly do.

Mr. DINGELL. Whereas in any other situation we have to have a good deal more, in order to prevail in any other kind of legal proceedings you have to have a good deal more, and have to bear a good deal heavier burden of proof?

Mr. CUTLER. Mr. Dingell, may I as a lawyer speak now as a lawyer on this, sir?

Mr. DINGELL. Yes.

Mr. CUTLER. What we are saying in a capsule is that if there is a responsible difference of opinion among responsible clinicians, trained investigators, as to whether or not a drug is effective, the mere existence of a responsible difference of opinion, based on adequate and well-controlled tests, should be sufficient for the FDA to allow the drug on the market.

The FDA's role should be to decide: Is there a responsible difference of opinion; and, if there is, they should let it on the market, even though a numerical majority or a preponderance of evidence, or whatever else you might call it, might still be on the side that the drug is not effective or not proven effective.

That is what we are after.

Mr. DINGELL. Is this not a——

Mr. CUTLER. And that is what the Senate Judiciary Committee agreed on.

Mr. DINGELL. The Judiciary Committee where?

Mr. CUTLER. Of the Senate in S. 3352 and its report on that bill.

And I do not really believe we are in substantial difference with the administration on this point, sir.

Mr. DINGELL. I think there is a great difference between "preponderance of the evidence" and "substantial evidence," you will agree as to that?

Mr. CUTLER. Oh, certainly, but what I mean is that we believe that we and the FDA are close together on what the tests should be, and I think that may become apparent when they testify.

Mr. DINGELL. You also discussed here the matter on page 28 of your statement, you discuss here:

"There is no drug which is safe in an absolute sense."

I am sure you will agree that the statement of Mr. Larrick, which you quoted there, is substantially true; that no drug is absolutely safe, is this not correct?

Dr. KLUMPP. Yes.

Mr. DINGELL. And this being true, essentially Food and Drug, in permitting new drugs on the market, has to, for example, make such objective judgments.

In the case of penicillin, which you cited, penicillin is not absolutely safe, but it is safe enough for the conditions to justify the use, in other words, to justify the risk that must be taken in prescribing this drug, is that not true?

Dr. KLUMPP. It is true, but it is equally true that no two people will come to the same conclusion with respect to all drugs.

That is the problem.

Mr. DINGELL. I recognize this, the Food and Drug did allow penicillin on the market, did they not?

Dr. KLUMPP. Yes, of course, they did, and quite properly so.

Mr. DINGELL. And Food and Drug made the objective or subjective judgment, depending on how you choose to put it, with regard to this, and this was sufficient to admit penicillin, am I correct, to the marketplace?

Dr. KLUMPP. Yes.

Mr. DINGELL. All right.

Now, let us take a little different case.

Are you familiar with MER/29?

Dr. KLUMPP. In a general way, yes.

Mr. DINGELL. MER/29 was marketed principally as an anticholesterol substance, am I correct?

Dr. KLUMPP. Yes, sir.

Mr. DINGELL. And this substance marketed for its anticholesterol properties was suddenly determined to have other effects, am I correct?

It caused skin conditions; it caused hair problems including eyebrows and eyelashes to fall out and change colors; and, over and above this, in rather large quantities it was shown, with some degree of certainty, to have the effect of creating cataracts, am I correct?

Dr. KLUMPP. In some instances, yes.

Mr. DINGELL. Now, is it your view that this is a safe drug to be marketed?

Dr. KLUMPP. It seems to me that the fact that the company voluntarily withdrew MER/29 indicates the company's view that evidence developed subsequent to its marketing no longer allowed that drug to be considered safe.

Mr. DINGELL. I see.

Now, are you in concurrence with this?

Dr. KLUMPP. I do not know enough about the facts, Mr. Dingell.

Mr. DINGELL. All right.

Then let us put this in a different way.

If this drug had not been withdrawn, what would Food and Drug have been able to do to remove it from the market?

Dr. KLUMPP. They could have obtained an injunction, if they saw fit.

Mr. DINGELL. How long would it have taken to obtain an injunction?

Dr. KLUMPP. I am told about 2 days.

Mr. DINGELL. This is perhaps true, but to resolve a case of this sort through the courts involving the food and drug law might have taken 2 to 4 years, am I correct?

Dr. KLUMPP. Seizures, Mr. Dingell, which are another avenue of action and can be exceedingly effective, can be accomplished in a day.

Mr. DINGELL. In a day?

Dr. KLUMPP. In a day.

Mr. CUTLER. Dr. Klumpp's point, Mr. Dingell, is that, while a long litigation went on, if it did, all supplies of the drug can be seized under the present law and withheld from the market.

Furthermore, in your MER/29 case, if the manufacturer had refused under existing law, the Food and Drug Administration could have instituted a proceeding under section 505(e) to define the drug as unsafe and take it off the market.

Mr. DINGELL. You note on page 33 that you were opposed to the provisions for suspension for failure to keep records, to make reports and to maintain manfuacturing standards.

You say:

> These provisions require the Secretary to suspend if he finds such a failure.

If you were to have—if the requirement were eliminated and it were made permissive upon the Secretary, would this meet your objections to the bill?

Dr. KLUMPP. No, it would not, Mr. Dingell.

Mr. DINGELL. It would not?

Dr. KLUMPP. No.

Mr. DINGELL. In other words, you simply object to the fact that the Secretary can withdraw for failure to adhere to good manufacturing practices and so forth?

Dr. KLUMPP. Yes.

Mr. DINGELL. I find, in substance, that you have very little agreement with the bill, and, basically, you are in substantial disagreement with the bill.

I recognize that this is a perfectly proper and honorable difference of opinion, but I can only see two sections of the bill that you do not object to, one of which is the amphetamine and barbiturate section—the other section to which I note no objection is the section dealing with generic names, and assume that the objection to the generic-name section has been raised by other witnesses on behalf of the Pharmaceutical Association.

Am I correct?

Dr. KLUMPP. Yes, sir.

Mr. DINGELL. So for all intents and purposes here we have involved a situation where the Pharmaceutical Association is opposed, for all intents and purposes, to the whole bill?

Mr. CUTLER. Mr. Dingell, I really respectfully, sir, do not feel that is a fair way to put the matter.

This is a very complicated law, this food and drug law.

Mr. DINGELL. I recognize this.

Mr. CUTLER. There are a series of amendments proposed on some 12 or 14 subjects that take 33 pages.

Mr. DINGELL. I recognize that.

Mr. CUTLER. Mr. Beesley has testified that in principle we agree with a great number of the proposals. We have some changes in language to suggest in a great number of these proposals.

But it is hardly fair to say to us, because we have a few changes in language to suggest in a substantive proposal, that, therefore, we are against the proposal. We are not, sir.

Let us go down the table of contents on page 2 of the bill.

We are in favor of a requirement of adequate controls in manufacture.

Mr. DINGELL. I see, but with regard to that, now, you favor it, but you want this to be advisory?

Mr. CUTLER. No, sir.

Mr. DINGELL. Am I correct?

Mr. CUTLER. No, sir.

We favor a provision in this statute which would make a drug adulterated if it is manufactured in accordance with methods and controls that are not in conformity with good manufacturing practice.

Mr. DINGELL. You differ on this with Food and Drug and the administration. You have reservations on this section.

Mr. CUTLER. No, sir.

We differ with the Food and Drug Administration on whether the Food and Drug Administration should be empowered by regulation to be the final arbiter of what is good manufacturing practice or whether the manufacturer should have an opportunity to show in

court, if he is challenged, that his practice is good manufacturing practice.

That is our only difference.

On section 102 we agree.

We disagree as to the standard of proof. We say if there is a responsible difference of opinion as to the effectiveness of the drug, the FDA should allow the drug on the market and let each doctor decide this difference of medical opinion for himself.

And I could go on through the bill and in almost every case we agree with the principle. We have some changes to suggest in the procedures and standards and burdens of proof.

Mr. DINGELL. Some of your reservations, though, and changes that reflect them are so substantial, in some I am sure you will agree, as to constitute outright opposition to the proposal and substitution of a new proposal.

Mr. CUTLER. And somewhere we have said, frankly, that we do oppose the proposal, but in others I take it that the reason we are here is you are examining the language of this bill, and we are making suggestions about the language of this bill, and I do not think you should say to us that because we are making suggestions to change some words in the bill, we must be against the purpose of the bill.

Mr. DINGELL. I note only that you have endorsed only one section completely and that only by not opposing it.

Mr. CUTLER. I would be very surprised, sir, if this committee has accepted without change more than 25 percent, let us say, of the precise sections offered to it in administration bills.

Your function is to change a bill where you think it is appropriate.

Mr. DINGELL. I am sure this is true.

No further questions, Mr. Chairman.

Thank you very much.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Mr. Chairman, I was very much interested in Dr. Klumpp's testimony here, and I think he has covered the subject very well.

Where I disagree is a matter of record.

I do not see any reason that the industry should be concerned about keeping proper records.

You certainly have to keep proper records for Internal Revenue.

Dr. KLUMPP. We are very much in agreement with that, Mr. Schenck.

Mr. SCHENCK. It would appear to me that the human side of the picture is even more important.

Dr. KLUMPP. Yes.

Mr. SCHENCK. I have great respect for the pharmaceutical industry and for the very wonderful service and the distinguished service that our dedicated physicians are giving to all of the people of the United States.

I agree wholeheartedly that the health of our Nation and the advance in the manufacture of drugs is the most outstanding in the world.

At the same time, the industry cannot escape the responsibility of the salesmen it hires who visit the doctors, overburdened with heavy schedules of patients, salesmen who are neither pharmacists or scientists or doctors.

Dr. KLUMPP. Most of them are pharmacists.

Mr. SCHENCK. But who really do sell drugs?

Dr. KLUMPP. Most of them are trained pharmacists, Mr. Schenck.

Mr. SCHENCK. Sir?

Dr. KLUMPP. Most of them are trained pharmacists, sir.

Mr. SCHENCK. Well, I have known a number who were not, and that is going back to the salesman, because that has been my life's work, as a salesman.

I would say that you, Dr. Klumpp, are an excellent salesman for your point of view and your company.

Dr. KLUMPP. I could not sell nickels for 5 cents, Mr. Schenck.

Mr. SCHENCK. I would just make the observation that the industry does have a responsibility to hire salesmen who are very conscious of their own responsibilities and who are well informed in this whole field.

Dr. KLUMPP. We make the greatest effort to do that, to hire the very highest type people that we can, and we pay them very well.

May I also add that one of our detail men was the first witness here, Mr. Beesley, who started out as a detail man for our industry, and his company.

Mr. SCHENCK. Mr. Beesley has done a remarkable job.

Dr. KLUMPP. He represents the caliber of the people that we endeavor, and do everything we can, to obtain, and occasionally, and quite often, we succeed.

Mr. SCHENCK. I quite agree with you that your well-expressed confidence in Mr. Beesley is justified but, of course, there are relatively few such opportunities to become a president of a concern as large and as good as the Eli Lilly Co.

Dr. KLUMPP. I agree with that, too.

Mr. SCHENCK. So I would guess that the opportunity for salesmen who aspire to such a position would be quite limited.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. I want to thank you for the suggestions that you make in regard to this bill. We want to get out a good bill, and there is no one that I know of who has a corner of all this information, and certainly I for one appreciate the recommendations made by the pharmaceutical industry.

Dr. KLUMPP. Thank you very much, Mr. Younger.

We have a common objective there. We are eager to have a good bill and one which will provide the protection which our 182 million citizens are entitled to have.

Mr. SCHENCK. 186 million, almost 187 million now.

Dr. KLUMPP. You must have seen that clock more recently than I.

The CHAIRMAN. By the time we get this good legislation, maybe we will have 193.

Mr. YOUNGER. The extra ones will be in California.

Dr. KLUMPP. That is right, where my children are.

The CHAIRMAN. Mr. Moulder had to leave, but he did suggest this question, which I also had in mind.

On page 16 of your statement, according to Mr. Moulder, referring to the physician's freedom to prescribe as he sees fit to encourage the development of new products and so forth, he asked me to inquire for him what information or knowledge is given or reported to the

prescribing physician concerning conflicting opinions on the effectiveness or safety or efficacy of a new drug?

Dr. KLUMPP. Mr. Chairman, we go to great lengths to provide the practicing physicians with all the information available concerning the action and use of our products.

We have brochures which are distributed to every physician which tell the whole story, tell both sides of a story, the good as well as the bad.

We believe that every physician should have that, and that, it seems to me, is the most practical way of conveying the full story of the practicing physicians.

The CHAIRMAN. May I then assume from what you have said that the industry will make full disclosure to the physician?

Dr. KLUMPP. Yes, and FDA now passes on our booklets to satisfy itself that we are telling the whole story. That is under the present law.

The CHAIRMAN. I am not talking about FDA for the moment. I am talking about what you tell the doctors, particularly on tests of experimental drugs.

Dr. KLUMPP. Yes.

Mr. Chairman, one of the subsequent witnesses will furnish you and the committee with examples of the kind of information that goes to the practicing physicians.

The CHAIRMAN. Thank you very much, Dr. Klumpp, for your very forthright and fully explanatory statement of your views on this subject matter.

Dr. KLUMPP. Thank you.

I am sorry it was so long.

The CHAIRMAN. Mr. John T. Connor.

I might say for the information of those who are interested that after the presentation of Mr. Connor's statement, the committee will recess for a little while and give everyone an opportunity to relax a little bit and get a bite to eat and we will come back here at 7 to resume hearings.

The Chair is going to hear these witnesses, so that is the information for both the witnesses and everyone else.

Mr. Connor, you may proceed.

STATEMENT OF JOHN T. CONNOR, ON BEHALF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ACCOMPANIED BY LLOYD CUTLER, ESQ.

Mr. CONNOR. Thank you very much.

Mr. Chairman, my name is John T. Connor. I am president of Merck & Co., Inc., Rahway, N.J. I have made available a brief biographical statement which you may wish to incorporate in the record.

As you will see when reading that statement, I am another Federal Government alumnus now working in the pharmaceutical industry.

I shall present the views of the Pharmaceutical Manufacturers Association on these parts of H.R. 11581: Section 101: Requirement of Adequate Controls in Manufacture; Sections 201 and 202: Factory Inspection; and Section 105: Certification of All Antibiotics. In addition, I shall propose a new provision having to do with the registration of prescription drug manufacturers.

SECTION 101—REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

Section 101 of the bill provides that any drug—no matter how good it is intrinsically—will be outlawed from interstate commerce if it has been made in inadequate facilities, by improper methods, with inadequate controls, or by the use of unqualified personnel. The purpose of this amendment is to assure that all drug producers meet standards of good manufacturing practice.

Under the amendment, the Food and Drug Administration would issue regulations setting up ground rules for what constitutes a good manufacturing practice, and enforce those ground rules by its traditional procedures of injunction, seizure, and action for criminal penalties.

As background for my comment on this section, Mr. Chairman, let me point out that it takes many things to make drugs that meet the needs of modern medicine. It takes complex chemical factories, scrupulously correct materials and supplies, extremely delicate equipment and facilities, highly trained professional and technical employees, and intricate control systems to guard against error from raw material to finished package. It takes thousands of tests and samplings, and a lot of checking and rechecking. It requires good organization, good communication, and good morale. It requires character and stern discipline in rules, and character in individuals from bottom to top. It requires a good bit of courage, because we are making some of the most complicated compounds that exist, for one of the most intimate, delicate, and sensitive purposes there is. Failures or mistakes are dreadful things—and a respectful fear of them is built into our tradition if we have been doing our work properly for a long time.

Unlike most other products, the care and concern devoted to manufacture of drugs are not visible in our products. Drugs made under the best conditions look like their cheaper versions.

Mr. Chairman, I think I can say that despite public and competitive pressure to cheapen their products, the sound companies in this industry have continued to carry on with their good manufacturing standards, disciplines, control procedures, insistence on top-flight personnel, and other traditions of quality.

When the Commissioner of the Food and Drug Administration testified before the Senate Antitrust and Monopoly Subcommittee in June of 1960, he presented a 21-table summary of the agency's enforcement experience for the period 1950 to 1960. From these tables it can be seen that 28 major firms in that decade supplied 87 percent of the total volume of presciption drugs. An estimated 1,200 firms supplied the remainder. During this time, those major firms were subject to four Food and Drug legal actions based on drug composition. The others, supplying 13 percent of the drugs, were subject to 484 legal actions for the same cause.

Mr. Larrick testified as follows:

*** * * The facts are that those manufacturers, large and small, who have adequate scientific personnel and controls are producing pure and safe drugs while those that do not have such controls are likely to violate the Food, Drug, and Cosmetic Act. As a matter of fact, we occasionally encounter a violation by a manufacturer whose controls are beyond reproach, which simply emphasizes the fact that even with the best scientific controls human error will occur. But**

it occurs less frequently with those firms who rely on properly trained scientists and with much greater frequency in the case of those firms who rely on improperly trained and unqualified employees who have neither the understanding of modern drug manufacturing nor the appreciation of the serious responsibility that rests on those who offer drugs to sick people.

In view of the importance of scientific control to insure the composition of drugs, this logically raises the question whether we should not propose, to the committee of the Congress with legislative responsibility in this area, new provisions to require the adoption and use of appropriate manufacturing and control procedures by firms producing drugs now subject to the new drug provisions of the law ("Administered Prices," hearings before the Senate Subcommittee on Antitrust and Monopoly, p. 12115).

I would emphasize a point that Mr. Larrick made. Some of our very best and most responsible companies are the smaller ones. Size has nothing to do with the excellence of manufacturing and control standards. The problem for legislators and for officials of executive agencies, and indeed for all of us, is to find ways to set and enforce standards that will bring the performance of all manufacturers closer to the high level of excellence already being set by the better members of the industry.

In our efforts to make more uniform throughout the industry those practices which now characterize the best of the industry, we must have means of dealing with the fringe operators who purvey drugs to the American people. The flow of such drugs has, if anything, increased since Mr. Larrick testified 2 years ago.

A large drug counterfeiting plant, distributing nationally, was uncovered in my own State of New Jersey and prosecuted under State and Federal laws. The owners obtained bulk supplies of important new drugs and formulated and packaged them in containers with labels that simulated those of established, reputable drug firms. I am sure the committee can imagine the manufacturing standards, quality control, and basic sanitation—or lack of it—of such a company.

We are only now beginning to learn the extent to which drugs formulated in this country from raw materials of foreign origin have been placed into the American supply line by people operating in the shadow of the responsible industry, people who have in prior years given the Food and Drug Administration its largest number of enforcement headaches. Within the past year we have discovered that imported drugs are coming here from foreign producers who use technical and scientific data stolen from American firms who first invented the drugs. And unless broad and sound regulatory standards can be established and rigidly enforced, an increasing number of entrepreneurs will probably be attracted into the drug field to exploit the attractiveness of seeming drug bargains.

We thus support, as we publicly announced at the Senate subcommittee hearings last December, an amendment to the Food and Drug Act which gives the FDA the power to enforce proper standards of manufacturing performance across-the-board as to all drug manufacturers.

At the same time that we urge your adoption of this amendment, we wish to present several reservations about its precise language.

1. Our first reservation has to do with who in fact establishes good manufacturing practice. The Food and Drug Administration, which does not manufacture drugs, cannot create manufacturing practice. It can only impose on some manufacturers standards set and met by others. Thus FDA's detailed regulations, in our judgment, cannot

authoritatively state what good manufacturing practice should be, but can only reflect and interpret what good manufacturing practice is. Let me expand on this for a moment.

The standards cannot be extreme, cannot be so unrealistic or unreasonable that they can be met by no one. They cannot, for practical purposes, be so high as to be met by only a few of the best manufacturers. They must not, on the other hand, be so low as to fail to protect the public against weak or shoddy production and control practices. We agree that the standards should, as stated in the amendment, be "good" manufacturing practice. But it simply has to be "good" manufacturing practice as manufacturing experience has established it at the time. And it must also be good practice as manufacturing experience continues to establish it, Mr. Chairman.

Standards of practice are improved with experience. New procedures are discovered, shortcuts found, better ways developed to test and control batches of drugs. In the dozen or so years since Merck started producing cortisone, for example, the number of separate processing steps has been cut from 30 to about half that number, and our control systems are far superior to what they were.

To establish standards by Government fiat over something as dynamic and vital as drug production, testing, and control methodology would be to stifle manufacturing progress and important improvements in control and safety systems.

Thus we say that the Secretary should be empowered to issue regulations on good manufacturing practice that are interpretive of what good practice is, and not determinative of what it is.

We would not object to a provision that would spell out that such regulations will be considered prima facie evidence of what constitutes good manufacturing practice in any enforcement proceeding under that section of the statute. While this would put a defendant manufacturer in the position of carrying the burden of proof, it would still give him the opportunity to show—if true—that his practice is good manufacturing practice despite the agency's interpretation that it is not. Such flexibility will allow minimum standards to reflect the best judgment and practice prevailing in the industry, permit superior standards to be reflected in quality products, and permit all standards to be upgraded with experience.

2. Our second reservation on this section has to do with whether the Food and Drug Administration should have the power to establish and enforce standards of training, experience, and background for all personnel in the multifold operations of a drug manufacturing establishment.

Our feeling is that a Government agency cannot set up meaningful general standards for all those skills and disciplines without doing more harm than good.

It is perfectly true, as Mr. Larrick has said, that firms relying on properly trained and qualified employees are likely to have better compliance records than those which do not. But the selection and use of scientific and technical personnel is a delicate function, involving subjective judgment and long-term, close experience with people.

Should a good analytical chemist, for example, be dismissed from his job because he did not get a degree?

Every company surely has that topflight veteran production chief whose record may not look impressive on paper, but who never makes an operational error. It is rather frightening to contemplate the inevitable arbitrariness of personnel standards set by Government for industry, and the difficulty, hardship, and discrimination likely to attend their application.

We therefore urge that the standard-enforcing authority of the Food and Drug Administration be directed to those measurable things that men and women in our plpants make and do—to facilties, buildings, equipment, methods, systems, and procedures—and not to the professional and technical competence of our employees, what they have done, and who they are.

3. Our third reservation on this section has to do with a redundancy.

The purpose of subsection (i) is to establish minimum manufacturing standards to assure that a product's identity, strength, quality, and purity are what they purport to be. We think that is all that such standards can properly assure.

Subsections (ii) and (iii) of the amendment provide that standards of manufacturing practice must assure that a product will not be injurious to health and is properly labeled under the act. Since other sections of the statute deal with whether a product—being what it purports to be—is injurious to health when used in accordance with directions, or is properly labeled under the act, it seems to us that subsections (ii) and (iii) are redundant and create a double layer of enforcement. We urge that these two subsections be deleted.

4. Our fourth and final reservation on section 101 rests on a single word. We would like the word "assure" to be used instead of the word "insure." Our view is based simply on the desire to avoid the possibility of the section's being used to impose on manufacturers an insurer's liability without fault under the common law.

This concludes my comment on section 101. For the convenience of the committtee, I should note that S. 1552 as reported out by the Senate Judiciary Committee on July 19, 1962, contains language satisfactory to us for carrying out these recommendations.

SECTIONS 201 AND 202—FACTORY INSPECTION

May I turn your attention now to section 201. This section would amend the factory inspection authority of the Food and Drug Administration to include everything in a drug-producing or drug-storing establishment (including records, processes, controls, and facilities) having a bearing on violations or potential violations of the act.

We also support, and have publicly supported since last December, this broadening of inspection powers over drug manufacturers as an appropriate requisite to enforcement of the new section establishing minimum standards of manufacturing practice.

We have two reservations about the language proposed in section 201.

1. The first can best be stated as a question.

Should the Food and Drug Administration, through its inspectors, be authorized to go through all the records and files of a manufacturer whether or not they are relevant to enforcement of the act?

We believe the words of the amendment before us would permit him to do this if he insisted. The only restraint in the amendment

is that the records and files have a bearing on a violation or a potential violation of the act. An inspector could say of almost any record that it might have a bearing on a potential violation of the act. He could say, even about financial records, pricing records, personnel records, and fundamental research records, that he could not know whether or not they had a bearing on a potential violation until he had seen them.

This raises a constitutional question, Mr. Chairman.

The guarantee against unreasonable search and seizure has been held to mean that Government agencies should not invade and search a citizen's private premises without probable cause to believe that a crime has been or is being committed. We do not maintain that argument against the proper needs of the food and drug enforcement agency. But we do maintain that the power of inspection should not be so broadly worded as to authorize unlimited search into irrelevancies. Such unlimited search is unfair and detrimental to us as manufacturers, and from the public standpoint opens the amendment unnecessarily to constitutional attack in future enforcement situations.

We suggest that the language should clearly limit inspectors to matters that have a real and substantial bearing on enforcement of the Federal Food, Drug, and Cosmetic Act. We ask that the phrase "material bearing" be used, and that the catchall phrase "or potential violation" be deleted.

We further suggest that there be specific exclusion of types of confidential records that would not properly concern the Food and Drug Administration in its legitimate enforcement activities—records such as financial data, sales data (other than shipment data), pricing data, personnel data, and research data (other than clinical records of the type that must be furnished to the Food and Drug Administration under the new drug provisions of the act).

2. Our second reservation on section 201 has to do with the confidentiality of complaint files. The inspection powers will, of course, extend to complaint files. Such files normally contain a great deal of helpful correspondence from doctors and other professionally trained people, as well as the general public. It is essential, of course, that all such correspondence continue to flow freely without fear of the disclosure of professional confidences. And while we agree that the Food and Drug Administration should have access to reports from professional medical correspondents, we feel such reports should be made available only to physicians on the FDA's staff.

We thus request that provision be made for the Secretary to issue regulations that place this safeguard around the complaint file inspection. At the same time, we believe provision should be made to permit physicians in the affected company to examine similar information received from professional sources by the Food and Drug Administration itself.

Section 4(a) of S. 1552, as reported on July 19, 1962, contains language which is generally satisfactory from our point of view concerning these qualifications we have on section 201 of the instant bill, but some additional language would be needed which we will be glad to suggest.

We have one reservation on section 202 of the bill which relates to protecting the confidentiality of information learned during a fac-

tory inspection. These expanded factory inspection powers will put inspectors into the midst of the most confidential aspects of production, processing, and control operations, and will enable them to learn scientific and technical data that are invaluable competitive assets. While so far as we know it has never happened, any disclosure of such assets to competitors by inspectors should be very carefully guarded against. The beneficiaries of revealed data are always saved the cost and given the advantage of the innovator's scientific and technical work; and the manufacturer who has done the innovative work is forced to compete in the marketplace—at an obviously unfair disadvantage—against those who have capitalized on his own research and technical development.

We therefore support section 202, but ask that it be further strengthened by permitting disclosures only when "required" by law, not when "authorized" by law.

SECTION 105—CERTIFICATION OF ALL ANTIBIOTICS

We have supported the principles of sections 101, 201, and 202 of this bill, Mr. Chairman, but must strongly oppose section 105, which extends to all antibiotics the batch-by-batch certification which now applies only to five specified antibiotics.

In order to understand our position on this matter, it is necessary to go back to the original 1945 amendment that placed this special control on penicillin.

Penicillin was developed during World War II. It was a wholly new kind of drug material produced by a micro-organism grown in fermentation media. Under critical conditions of material supply, the American drug industry hurriedly developed and put into operation factory fermentation processes for penicillin—one of its outstanding contributions during the war. But even while these facilities were being rushed, penicillin was desperately needed for both military and civilian populations. The decision was made to get it into use despite the absence of uniform manufacturing methods, tests, and controls.

To ensure uniformity, it was decided that there should be a central agency to test each batch of every manufacturer's product. The War Production Board first had the responsibility for this function. When WPB went out of existence, the Congress transferred the responsibility to the Food and Drug Administration by an amendment to the Federal Food, Drug and Cosmetic Act. The words of the amendment made clear that the function was intended to be temporary.

Streptomycin came along 2 years later, and the statute was amended to include it. The statute was further amended in 1949 to include three new antibiotics—aureomycin, chloramphenicol, and bacitracin. Mr. Oscar Ewing, then Federal Security Administrator, supported this amendment before the Congress, and added:

> It is probable that as improved techniques in manufacture and better methods of testing are developed, the need for pretesting and certification of aureomycin, chloramphenicol, and bacitracin may no longer exist. That probability with respect to penicillin and streptomycin was recognized in section 507(c), which directs the Administrator to promulgate regulations exempting the drug from certification requirements when that procedure is not necessary to insure safety and efficacy of use. This provision would apply equally to aureomycin, chloramphenicol, and bacitracin if the recommended amendment is adopted.

The situation is quite different today. Antibiotics can be produced and controlled with as high an assurance of uniformity and quality as other commercially produced and much more complex drugs. We are no longer dealing with pioneer techniques of production and control. Consistently reliable methods have been developed for testing purity and potency. There are more than 20 other antibiotics now on the market which have gone through the regular new drug procedure and are not batch certified. They have an excellent record of safety and usefulness, and the Food and Drug Administration's own record of drug recalls during the last 4 years shows that they have presented no serious difficulty in manufacture or control.

In the 13 years since Mr. Ewing explained to the Congress the temporary character of the batch-testing controls and predicted administrative end to them at the appropriate time, the Antibiotic Division of the Food and Drug Administration has grown larger and larger. It has not substantially relinquished control as to any of the five antibiotics, in the sense intended by the original amendment. It has instead expanded the original control. The agency has extended batch control to other antibiotics when they are combined with batch-tested antibiotics. It has superimposed the controls onto other products containing antibiotics, even when these products are controlled by other sections of the statute.

As you know, Mr. Chairman, Mr. Roberts and other members of the Health and Safety Subcommittee of this committee have wrestled in recent weeks with the complex problem posed by multiple controls over animal feedstuffs. As they know, an animal feed may have to be cleared under three different sections of the act—food additives, new drugs, and antibiotics batch testing. The sections, administered by three different regulatory branches of FDA have different yardsticks for approval. An animal feedstuff may get through one branch, but not another. This complex and confusing triplification of regulation has raised difficult problems for the Food and Drug Administration, the drug and animal feed industries, and the livestock producers. To resolve these problems our association and the Animal Health Institute have proposed new legislation to deal separately with drugs for animal use.

The problems and the proposed legislative solution are fully discussed in the statements filed for our association and the Animal Health Institute on August 7 in the hearings of the subcommittee on H.R. 12437, and I simply want to state at this time that extension of batch certification to all antibiotics will further complicate an already difficult problem.

Now, what is the end result of this outmoded Government double-checking on the individual batch production of five well-established antibiotics?

In the fiscal year 1960—according to the Controller General's report to Congress dated September 1961—the FDA rejected one-eighth of 1 percent of all batches submitted to it by the manufacturers for testing. In some cases, rejections are based on failure to meet standards that have nothing to do with safety or potency. Some manufacturers speed certification by submitting batches before they have the final results of their own tests. It is certain that a number of FDA-rejected lots would have been rejected by the manufacturers anyway, on

the basis of their own tests. And it is a good guess that the remaining deficient batches would have been stopped by the tighter application of the manufacturer's own controls, which he would have exercised had he not had the crutch of a Government doublecheck.

This steadily growing branch of the agency used up about 150 man-years of technical talent in the batch certification of antibiotics last year. By almost everyone's admission, Mr. Chairman, the FDA badly needs, and we feel should have and properly use, additional scientific and technical manpower. That manpower is scarce enough as it is—everywhere. Placing 20 additional antibiotics under the certification system will simply make an obsolete function bigger and will use up additional talent that could be put to work on the enforcement of a statute that will be significantly stronger after this bill is passed.

Good judgment, in our opinion, dictates that the agency should use its manpower where it will do the most good—to carry out proper factory inspections, to enforce other essential provisions of the law, and to achieve adequate manufacturing and control standards among all producers of all drugs.

In summary, Mr. Chairman, we oppose section 105 on the grounds that batch certification is no longer needed; that it is wasteful of time and energy and scarce manpower; that batch certification of antibiotics, either some of them or all of them, weakens the development of strong, self-reliant manufacturer control systems, and that responsibility for safety and quality of antibiotics can be well safeguarded by the FDA, without duplicate testing, under existing authority and through the additional authority that would be provided under other provisions of H.R. 11581.

REGISTRATION OF DRUG MANUFACTURERS (NEW PROVISION)

Now that I have covered three provisions of this bill that we feel will strengthen the act, and one that we oppose, let me advance a new provision that we think should be in the bill. A proposal that would require every drug manufacturer in this country, whether he operates in interstate or intrastate commerce, to register with the Food and Drug Administration every one of his establishments that produce or process drugs. Under our proposal, failure to register would be, in itself, a violation of the act.

A provision such as this would bring into the open every individual or organization that embarks on the serious and responsible task of making drugs for the people of this country. Knowing who they are and where they are, the Food and Drug Administration could inspect and take any appropriate action needed to clean up or close down illegal operations by criminal action, injunction, or product seizure.

To assure no oversight, we think it should be mandatory that every registered establishment be inspected by the Food and Drug Administration at least once every 2 years.

Foreign producers who send their raw materials or finished products into this country should be subjected to no less stringent controls than domestic manufacturers, and we believe they, too, should be required to register.

For the assistance of the committee I submit, with the request it be inserted in the record, a draft of an appropriate amendment to carry

out these registration proposals. Similarly, I submit a draft of an amendment to carry out Mr. Beesley's recommendation that the counterfeiting provisions of the act be tightened. This is a necessary corollary of our registration proposal and our support for the principles of strengthened inspection and manufacturing controls. The drug counterfeiter is a menace to all and the law should contain provisions for dealing severely with him.

CONCLUSION

No law, Mr. Chairman, can guarantee infallibility or assure against mishap or deliberate violation. The best protection will always be the manufacturer's integrity and driving concern for his reputation and survival.

And no legislation can supply the incentive to build quality into a product. It must remain the desire for good reputation, the need to be trusted by physicians and patients, and the competitive urge to excel, that supply the fuel for outstanding performance.

The laws should serve to encourage the best of these motivations, to build discipline and a sense of responsibility, to foster self-reliance and initiative. The laws should place a floor under industry performance for the public safety; they should not permit industry standards to be lowered for the sake of marginal performers.

We believe that the sections of H.R. 11581 I have here supported will do these things.

We believe they will greatly strengthen the act where it should be strengthened, and will set the stage for the type of performance and the constant improvement of performance that the American public is entitled to from those who manufacture prescription drugs, and we urge your enactment of them with the changes I have discussed.

(The amendments referred to follow:)

FORM OF AMENDMENT TO STRENGTHEN THE COUNTERFEITING PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, PROPOSED BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

SEC. —. Section 301 of the Federal Food, Drug, and Cosmetic Act is hereby amended to add a new paragraph (o) as follows:

"(o) (1) Placing or causing to be placed upon any drug or upon the container of any drug transported, received, or held for transportation in interstate commerce, with intent to defraud, the trademark, trade name, or other identifying mark, imprint, or device of another of any likeness of any of the foregoing; or (2) selling, dispensing, disposing of or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug or any container of any drug transported, received, or held for transportation in interstate commerce, with knowledge that the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subparagraph (1) hereof; or (3) making, selling, disposing of or causing to be made, sold, or disposed of or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container thereof, transported, received, or held for transportation in interstate commerce."

FORM OF AMENDMENT TO PROVIDE FOR REGISTRATION OF DRUG MANUFACTURERS, PROPOSED BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Section 3 of S. 1552 as reported to the Senate on July 19, 1962, contains generally acceptable provisions for registration of domestic drug manufacturers. To provide for registration of foreign manufacturers and to make necessary clarifying changes, such section 3 should be further changed as follows (all page and line references are to S. 1552 as reported on July 19, 1962):

On page 24, at line 19, insert after the words "owns or operates" the words "in any State."

On page 24, at line 22, after the words "in accordance with" insert the words "the foregoing subsections of."

On page 24, at line 24, after the words "owns or operates" insert the words "in any State."

On page 25, at line 9, strike the word "This" and insert in lieu thereof "The foregoing subsections of this."

On page 26, following line 14, add the following:

"(i) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations shall include provisions for registration of any such establishment upon condition that:

"(1) adequate and effective means are available to enable the Secretary to determine from time to time whether the methods, facilities, and controls used in such establishment fulfill the requirements of section 501 (a) (2) (B);

"(2) the registrant permits the inspection of such establishment from time to time in accordance with section 704 of the Act;

"(3) the registrant pays such fees as are determined by the Secretary to be necessary to provide and maintain adequate inspection of such establishment;

"(4) the registrant files with the Secretary a designation in writing of the name and post office address in the District of Columbia of a person residing or having a place of business in the District of Columbia upon whom process issued by or under the authority of any court having jurisdiction of the subject matter may be served in any proceeding at law or equity brought against such registrant, and upon whom service of all notices and process and all orders, decisions, and requirements of the Secretary may be made for and on behalf of said registrant."

The CHAIRMAN. Mr. Connor, thank you very much for your statement.

Mr. CONNOR. Thank you, Mr. Chairman.

The CHAIRMAN. We are glad to have your suggestions and recommendations which deserve careful consideration. Obviously the committee will consider the merits of the proposals.

Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman.

I commend you for a very excellent statement, sir.

Mr. CONNOR. Thank you, Mr. Dingell.

Mr. DINGELL. I note here in red ink a statement made not too long back by Mr. Goodrich, who is Assistant General Counsel of the Food and Drug Administration, wherein he says as follows about factory inspection:

All too often inspectors are treated to a guided tour through the establishment. They are refused access to formula files, complaint files, shipping records, and a great deal more information that is absolutely essential for them to see, in order to determine whether products are being produced in compliance with the law. Every working day food, drug, or cosmetic manufacturers refuse to give our inspectors access to information needed to safeguard the public. These refusals are not restricted to the fly-by-night operator, but extend to some of the very largest manufacturers in the country.

He goes on and he says:

The list of refusals is indeed a long one. It covers all types of business. It covers all kinds of requested information, and it all arises from the uncertain conditions that prevail under existing law.

Then he goes on to say as follows:

We found some firms with a fixed policy against inspection were applying for effective new drug applications, certification of antibiotics, insulin, and coal-tar colors, exemption from certification food additive regulations and hazardous substance labeling exemptions. They were presenting data to us to support these requests asking us to rely on it, but at the same time denying our inspectors the right to inspect to determine the accuracy of the data.

You have endorsed strengthened factory inspections. You have of course suggested some modifications in it. Specifically, you suggest, as I note, that the language should clearly limit inspectors to matters that have a real and substantial bearing of importance to the Federal Food, Drug, and Cosmetics Act. You ask that the phrase "material bearing" be used. That is on page 10.

First of all, I am sure your counsel, seated next to you, can tell us—have you ever heard that word used in connection with statute before, "material bearing"?

That is not a work of art.

Mr. CUTLER. The word "material" appears in this statute, I believe, several times.

Mr. DINGELL. I said "material bearing." Have you ever heard that as a work of art?

Mr. CUTLER. Mr. Dingell, I have never seen the phrase "having a bearing" before in a statute. I agree with that.

Mr. CONNOR. We are just suggesting that if the word "bearing" is used as it is in this bill that it be modified by the word "material."

Mr. DINGELL. I see. Now, your principal concern is protection of trade secrets in this regard; am I correct? Protection also of the doctor-patient relationship and the relationship that your company has with doctors and with patients who are subject to clinical investigations; am I correct?

Mr. CONNOR. Mr. Dingell, you have three or four questions all rolled up in one. May I first take the question having to do with trade secrets?

With respect to new drugs that are subject to the new drug application procedure, I think it is safe to say that we have no trade secrets from the Food and Drug Administration, because we are now required and do in fact submit to the FDA as part of our new drug application detailed information about our production and control procedures. So with respect to all the drugs subject to the new drug procedure, they have that information.

Now, with respect to trade secrets for the production of old drugs, we are agreeing with the Food and Drug Administration suggestion that their inspectors be given broader authority than they now have. I think it is quite clear that if the Congress decides to give this broader authority, the FDA will have access to what we would call trade secrets with respect even to old drugs.

We are not objecting to that, but we think there are some of our records that would be subject to the language of the bill before this committee that do not properly come under the scrutiny of the Food and Drug inspector. Those financial records having to do with

production costs and profits in many cases become available to the Bureau of Internal Revenue in connection with the audit of our income tax returns, and this is proper. But we do not see that those matters having to do with that highly important competitive information necessarily have to be made available to the Food and Drug Administration for the exercise of their jurisdiction. So we are opposed to that.

The third part of your question had to do with the confidentiality of case clinical reports submitted to us by clinicians who are experimenting with our drugs or who are actually using the drugs after they have received an effective new-drug application.

We think that the material submitted by physicians to our physicians concerning the specific effect of the drugs on their patients does contain confidential information subject to the doctor-patient relationship.

We are agreeing with the proposal in this bill that information of that kind should be made available to the Food and Drug Administration, but we are suggesting that it should not go to everyone in the FDA. In order to maintain the confidential nature of the reports and to encourage clinicians to continue sending in reports, they should go just to medical personnel where they will be handled in accordance with the traditional requirements of the medical profession.

Mr. DINGELL. I wonder if this is really necessary when we have a situation where Food and Drug—if we require Food and Drug to maintain the confidentiality of this information, I wonder if we have to limit it to physicians.

Mr. CONNOR. We think it is important and we would refer you to some representatives of medical associations who might have some views to express on this.

Mr. DINGELL. Is there anything in the canons of medical ethics that requires that this information be preserved to physicians only?

Mr. CONNOR. Oh, absolutely. You heard Dr. Scheele and Dr. Klumpp testify on the importance of this.

Mr. DINGELL. What I am concerned about is, let's say that Food and Drug has a man who is a pharmacologist, not a doctor of medicine or a particularly qualified specialist, in another field. He is the only man who can do this work. How can we say, then, that he is not qualified to look at this or should not look at this if he looks at it under adequate safeguards to preserve the confidentiality of the information?

Mr. CONNOR. In a situation such as you describe, there perhaps is good reason for him to see it, and in accordance with medical traditions he probably would be able to see it.

What we are doing here is raising a point which we think needs to be covered.

Certainly all employees of the FDA should not have access to this kind of information and we think, therefore, that there should be some kind of safeguarding words used in the statute.

Mr. DINGELL. What if it were just limited then to qualified investigators in the Food and Drug who had clearance to maintain the confidentiality, and so forth?

Mr. CONNOR. Perhaps that is the best way of explaining it, but I think this is something that should be given some more thought and worked out with counsel.

Mr. DINGELL. I am sympathetic, but I think this is a better way than the rather inflexible way that you have.

Now, the next question I wanted to ask you, on page 9 you raised a constitutional question here with regard to unreasonable search and seizure.

Counsel perhaps remembers this a good deal better than I do, but I do not think you want this to stand in the record as you have it, and the reason is this: You are familiar with fire inspections, health inspections, and things of that sort that have gone on in the field of public health and safety for generations. These have never been challenged on a constitutional ground, am I correct?

Mr. CUTLER. No, sir. They have been challenged and the most recent decisions of the Supreme Court were 5 to 4 on this issue. It is a very close and hotly contested issue.

Mr. DINGELL. Excepting, though, that these are generally held by students of the law not to be instances where the protection against unreasonable search and seizure apply, at least insofar as access to the premises.

Mr. CUTLER. I am afraid I cannot agree with that, Mr. Dingell. Of the eight present members of the Supreme Court who sat on the *Frank* case, and there was another case after *Frank*, they split 4 to 4 on this precise issue.

Mr. DINGELL. What was the holding in the case?

Mr. CUTLER. The holding of the case was that an ordinance of the city of Baltimore which permitted the commissioner of health to enter any home when he had cause to suspect that a nuisance existed in the house was a constitutional statute, 5 to 4.

Mr. DINGELL. What did the lower court hold?

Mr. CUTLER. In that case?

Mr. DINGELL. Did the lower court hold that it was constitutional?

Mr. CUTLER. I believe the lower court did hold it constitutional, yes.

Mr. DINGELL. And the Supreme Court upheld it?

Mr. CUTLER. By a vote of 5 to 4, and of eight present members who sat in that case, they split 4 to 4.

Mr. DINGELL. You as an attorney are aware of stare decisis?

Mr. CUTLER. Not in the Supreme Court, Mr. Dingell.

May I point out that the statute in this case was a probable cause statute? It started out:

> Whenever the commissioner of health shall have cause to suspect that a nuisance exists.

This statute has nothing like that. The inspector may have no cause to suspect any violation whatsoever, but under this statute he is allowed to come in to see if he can find one.

We do not even object to that as long as there are some reasonable limitations on the scope of the search.

Mr. DINGELL. On the scope of the search. I have no objection to reasonable limitations on the scope of the search, but I do not want you to have us have constitutional questions raised in the record where really I do not think they properly belong.

Now, you have not shown me that this section is unconstitutional by this language. As a matter of fact, you have shown me that the most recent decision is that again the Supreme Court has upheld the traditional constitutional interpretation of statutes of this kind.

Mr. CUTLER. Where the statute stated that if the commissioner had probable cause to suspect a violation of law, this statute does not so state.

It says in effect whether or not he has any cause to suspect, he may go in and search, to see if he can find anything.

Mr. DINGELL. This is true. This is also true of many of the local statutes involving wiring of houses or construction statutes; building inspectors, for example, enter premises regularly without having to have probable cause at all. They just enter the premises.

Mr. CUTLER. Mr. Dingell, I really do not see the point in debating this when such strong-minded liberal lawyers as Chief Justice Warren, Justice Douglas, Justice Black, and Justice Brennan firmly believe that it is unconstitutional. It is at least a substantial question.

Mr. DINGELL. The Supreme Court has upheld the constitutionality of this for years.

The CHAIRMAN. The Chair thinks we cannot settle the constitutionality question.

Mr. DINGELL. I just want to have the record correct, Mr. Chairman. I realize the hour is late.

The CHAIRMAN. Any witness has the right to give his opinions and express whatever legal opinions he may have and I might say that the Constitution gives any person the right to express his beliefs.

Mr. DINGELL. I wholeheartedly believe in that, Mr. Chairman, but I wanted the record to be correct.

I have no further questions, Mr. Chairman.

The CHAIRMAN. Thank you very much, Mr. Connor.

The committee will recess until 7 o'clock.

(Whereupon, at 5:50 p.m., the committee recessed, to reconvene at 7 p. m., the same day.)

EVENING SESSION

The CHAIRMAN. Mr. George R. Cain. Mr. Cain is president of the Abbott Laboratories of North Chicago, Ill.

Mr. Cain, we are very glad to have you with us and we will be glad to have your presentation.

STATEMENT OF GEORGE R. CAIN, CHAIRMAN OF THE BOARD AND PRESIDENT OF ABBOTT LABORATORIES, ON BEHALF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ACCOMPANIED BY LLOYD CUTLER, ESQ.

Mr. CAIN. Thank you, Mr. Chairman. My name is George R. Cain. I am chairman of the board and president of Abbott Laboratories, of North Chicago, Ill. My career with Abbott started in 1940. I have been president since 1958 and became board chairman and president in April of this year.

I am a member of the board of directors of the Pharmaceutical Manufacturers Association and have served other organizations in the health field.

Today I am speaking on behalf of the Pharmaceutical Manufacturers Association, of which Abbott Laboratories is a member. I shall deal with two subjects covered by H.R. 11581.

The first is the requirement set forth in section 131 of the bill that certain information appear in all prescription drug advertisements. We are strongly opposed to this provision.

The second topic I will discuss is contained in sections 121–126, relating to the illicit distribution of barbiturate and stimulant drugs. With some qualifications, we favor this proposed legislation.

PRESCRIPTION DRUG ADVERTISEMENTS

Section 131 of H.R. 11581 would amend section 15 of the Federal Trade Commission Act. It would deem any prescription drug advertisement to be misleading, and thus in violation of law, unless it contains a conspicuous, full, and accurate statement of the efficacy of the drug, as well as a conspicuous and truthful disclosure of the drug's formula, side effects, and contraindications.

The PMA supports, unreservedly, the principle that no drug should be marketed without full disclosure of its actions and limitations. This principle was formally approved in May of 1958 by the PMA in the form of a statement of principles of ethical drug promotion. This is attached to my statement for insertion in the record of these proceedings.

Nevertheless, despite our support of the objectives of full disclosure, we are strongly opposed to section 131. It is wrong in principle to require, as this section purports to do, that every advertisement contain full disclosure of the drug's actions and limitations. Furthermore, it would be a practical impossibility for industry to comply with this provision.

Section 131 is based upon a fundamental misconception of the function of medical journal advertising. This misconception is that physicians commonly prescribe drugs on the basis of journal advertising alone, thus necessitating full disclosure with each ad. This simply is not the fact. Physicians do not prescribe drugs on such a basis.

The function of medical journal advertising is to attract the attention of the physician and to remind him of particular products. It seeks to remind or impress, to arouse curiosity, and to encourage further investigation. It seeks to alert him to established as well as new areas of use and benefit.

But journal advertising is not the basis on which a physician prescribes drugs for his patients. The physician is a learned, competent and licensed professional. He is an informed man. He is exposed, in addition to his years of training and professional experience, to a wealth of informational and educational material on each drug. This includes brochures of the manufacturer, giving complete information as to indications, effects, dosage, routes, methods, frequency and duration of administration, and all relevant hazards, contraindications, side effects and precautions.

In addition to the extensive efforts of the drug industry, he is informed by medical literature, by impartial reports of the medical profession, by colleagues, by numerous reference works, by hospital and medical society meetings, and by special postgraduate education.

For further elaboration of the many sources of information available to the physician, I refer the committee to a statement by Dr. Theodore G. Klumpp. It was filed on behalf of the PMA in September of 1961 in connection with another bill that is pending before this

committee, H.R. 6471. This bill is quite similar in purpose and language to section 131 of H.R. 11581. The objections raised by Dr. Klumpp apply equally to section 131 of the present bill. Accordingly, I am submitting Dr. Klumpp's statement and request that it be included in the record of these hearings.

The efforts of the American Medical Association especially warrant attention here. Dr. Blasingame, executive vice president of the AMA, described these efforts in a letter on H.R. 6471, dated August 10, 1961. This was directed to the Subcommittee on Health and Safety of this committee. This improved and extensive program for providing information to physicians in the field of drug therapy was described in exhibits to Dr. Blasingame's statement. Under this program the AMA will keep before all physicians complete and continuing data about new drugs and drug modifications.

The physician understands clearly the distinction between reminder advertising and the wide range of informational and educational materials which are available to him.

This distinction is also well understood by the Food and Drug Administration. As the members of this committee know, Congress has charged the FDA, through supervision of drug labeling, with seeing that adequate information is available to the medical profession. Thus, Congress has properly distinguished "advertising," which is subject to the jurisdiction of the Federal Trade Commission, from "labeling," which is regulated by the FDA. This distinction between advertising and labeling was soundly conceived and should be maintained.

In the FDA regulations on the labeling of prescription drugs, full disclosure is not required in so-called "reminder piece labeling." Furthermore, the FDA regulations do not require full disclosure in the package insert when drug directions, hazards, warnings, and use are commonly known to licensed medical practitioners. I mention these "labeling" regulations in order to point out that the concept of reminding the physician, which is recognized in these regulations, shoulld be even clearer in advertising than in labeling.

To explain the essential difference between typical reminder advertising and informational material, I should like to show this committee examples of both journal advertisements and informational brochures.

I have examples of recent Abbott medical journal ads. Obviously, they make no attempt to tell everything about the product. If I may, Mr. Chairman, I call your attention particularly to the nembutal ad. You can see what I mean by our definition of purely reminder advertising. These types of ads alert, remind, call attention to some but not all aspects of the drug. But I might say that these ads, like our printed material, were subjected to medical scrutiny. The responsibility for approval of all ads is vested in our chief medical officer who is a vice president of our company and a member of its board of directors.

I also have a display of Abbott booklets which contain some 800 pages of meticulously prepared reference material. These documents, and not the advertisements, contain the full information for prescribing our drugs.

I remember this afternoon, Mr. Chairman, that you asked the question as to what drug companies do to supply the practicing physi-

cian with contraindications, dangers, warnings and so forth. These are the types of full disclosure brochures that are made generally available through the industry by all companies to physicians, and you will note if you glance through them that they contain reference to contraindications, side effects, warnings, so forth and so on.

I would like to emphasize, too, that some of these booklets go far beyond giving facts solely about our products and supply basic information about specific areas of medicine. A few of these are "Use of Blood, Fluids and Electrolytes"; "Parenteral Administration"; "The Vitamins"; and "Symptoms and Treatment of Overdosage with Selected Abbott Products." An unusual one is "Symptoms and Treatment of Overdosage with Selected Abbott Products." This is used in teaching institutions. Booklets such as these are widely used in teaching programs at medical schools and hospitals. They are furnished freely, without charge, incidentally.

These examples were selected from those sent out by Abbott Laboratories. Of course, materials comparable to these are prepared by other drug manufacturers for their own products and areas of special interest.

Such materials illustrate the pains to which we go to make sure that the practitioner has all of the information he needs. They show the concern of the manufacturer who wants above all to make certain that his product is used correctly. He wants to be certain that maximum benefit is obtained from the drug. In this way he best assures his own success.

To further show the basic distinction between the journal advertisement and the total library of information available to the physician, I refer the committee to a letter which Abbott Laboratories submitted on H.R. 6471 on November 14, 1961. As I have said, section 131 of H.R. 11581 is quite similar to that bill and the comments in our letter are pertinent here. In our letter we referred to a statement that the Federal Trade Commission filed with this committee in September 1961. In that statement a reminder advertisement for one of our prescription drugs, Oretic, was listed as an example of the failure to give space to a discussion of side effects and contraindications. The FTC asserted that " * * * only the pharmacist ordinarily would have the opportunity of seeing the manufacturers' printed warning of side effects and contraindications for his products that appear on the package inserts."

The FTC statement apparently rests on the erroneous assumption that the advertisement was the only information which the physician saw. Actually, Abbott had already supplied to the medical profession exhaustive information about Oretic, including complete detail on dosages, precautions and side effects.

The advertisement cited appeared in the October 22, 1960, issue of the Journal of the American Medical Association 14 months after the product was introduced. The advertisement called attention to this drug for use in edema and hypertension. With this reminder, the physician could and would refer to detailed data which he had in hand.

What was the scope of this information? At the time we first marketed Oretic in 1959, we began distributing a 16-page physician's reference booklet containing complete information about the drug.

Abbott distributed more than 120,000 copies of this booklet. Our first medical journal presentation of Oretic, also in the Journal of the American Medical Association was an eight-page insert containing complete statements on precautions and side effects. Later, this eight-page insert was also mailed directly to 106,000 physicians.

In these and other ways, the marketing of Oretic was fully consistent with the principle of full disclosure. Furthermore, information about this drug was available to the medical profession from a variety of sources other than Abbott Laboratories, as also shown in our letter to this committee, which is attached to this statement.

It should be obvious that physicians do not, are not, and should not be expected to prescribe on the basis of reminder advertising.

To require medical journal ads to carry the information called for by section 131 would not add to the information physicians receive about drugs. Instead section 131 would eliminate reminder-type advertising, which serves a useful and legitimate function for the medical profession and for the drug industry.

Section 131 would also present extremely troublesome practical problems for drug manufacturers. It is mechanically, as well as medically, impossible to include in single-page or smaller advertising space complete data bearing on efficacy, contraindications and side effects. So-called full disclosure under section 131 gives only the appearance of completeness. Actually, it isn't complete within the meaning of medical practice.

Our medical schools insist that prescribing be done on the basis of facts—all the known facts. As professionals, physicians expect to be thoroughly familiar with the drugs they are prescribing. They expect to know more—much more—than could possibly be included in a journal ad, even if it contained the data required in section 131.

If we abbreviate basic facts in journal advertisements, it might well encourage physicians to prescribe without going to the complete literature. This would lessen their professional knowledge about drugs rather than increase it.

Few medical journal advertisements could contain a full or accurate statement covering every possible reaction or effect, especially with complex drugs constantly undergoing evaluation. If some selection is to be made, who is to judge what portions of the full library available to the physician should be included? How could one satisfy the varying needs of the practicing physician? One warning in an ad might be of no concern to one practitioner, yet vital to another.

In addition, there is always a variety of scientific opinion about the effectiveness of any drug. In many cases it is necessary to set forth the findings and conclusions of a great many researchers so that individual practitioners may draw their own conclusions. So we come down to the fact that the use of a drug depends on the judgment of the physician and the medical history of the patient. Each patient is separate and unique, to be treated according to medical judgment.

The ultimate question, then, is this: Would section 131 help the physician in treating patients? We believe it would hinder rather than aid the further progress we all seek in the field of health care. For journal advertising was never intended to provide, and as a practical matter cannot provide, the total data which the physician should have available as a basis for prescribing for his patients.

The plain fact is that this data is now readily available to the physician, and he makes good use of it.

It should be noted that the proposed requirements could have a most harmful effect on medical journals. They depend on pharmaceutical advertising as their principal source of income. Medical journals serve as a useful educational aid for both the specialist and the general practitioner. Most likely, many worthwhile journals would be forced to curtail medical articles and even to cease publication. Thus a valuable source of medical knowledge would be lost to the profession.

In concluding my comments on section 131, I should like to refer the committee once again to Dr. Klumpp's statement on H.R. 6471. As suggested there, if it is believed that some additional safeguard is necessary, the PMA proposes that all advertisements of prescription drugs bear the following statement:

Before prescribing, be sure to consult the manufacturer's literature for information about possible side effects and contraindications.

BARBITURATES AND STIMULANTS

Sections 121 through 126 of H.R. 11581 provide for special controls intended to reduce the illicit distribution of barbiturate and stimulant drugs.

These drugs are highly beneficial and have many important uses. When prescribed under medical supervision, they are effective and safe. They have long been drugs of choice for a variety of medical indications. At present they can be dispensed only on prescription of a licensed practitioner.

According to the testimony of former HEW Secretary Ribicoff, abusive, nonmedical use of certain of these drugs presents serious public health problems, for this illicit use in quantities far exceeding the usual dose may lead to abnormal and antisocial behavior.

The PMA therefore supports amendments strengthening Federal power to prevent such illicit distribution. But, because of the extraordinary nature of the proposed legislation, the PMA believes that any action should be carefully limited to proven needs. Unneeded authority should not be granted, nor should unwarranted burdens be imposed.

We favor provisions that would (1) require manufacturers of barbiturates and stimulates such as the amphetamines to register with FDA; (2) require manufacturers to keep adequate records; and (3) limit and specify the classes of persons who may deal in these drugs. We also agree with the position taken by the administration that the Federal Government, if it is to control this illegal traffic, must have the power to reach intrastate as well as interstate commerce.

We are commenting on these provisions because they are included in H.R. 11581. It should be pointed out, however, that the control of amphetamines and barbiturates has been extensively studied in the House. Also, in the Senate, Senators Dodd and Wiley have cosponsored S. 1939, dealing with the control of illicit traffic in these drugs. It might therefore be desirable for this area to be treated in a separate bill.

We have a number of suggestions to offer. In order to conserve the time of this committee, I am attaching to my statement a memorandum setting forth our recommendations. I will only refer to two of them at this time.

First, the severe criminal sanctions should be applied only to illicit peddlers of these drugs, and not to the people they are victimizing.

The supporters of this legislation—both in Government and in industry—agree that this illicit trade can be stopped only by eliminating the peddler. FDA has publicly taken the position that it wishes to prosecute only the peddlers, and not their customers as well. As it stated in its answers to questions put by this committee—

> * * * it may well be that possession for personal use and not for disposition to others could be eliminated as an offense without greatly impairing the effectiveness of the law in actual practice.

We believe the illegal possession clause presently contained in the bill is needlessly severe and of marginal, if any, value in controlling improper use of these drugs. It might encourage physicians to prescribe other, perhaps less effective, drugs even when a barbiturate or amphetamine would otherwise be the drug of choice. For these reasons, we are opposed to any measure that would go so far as to subject otherwise innocent individuals to Federal criminal law.

Second, this legislation, which grants extraordinary powers to the FDA, should be clearly limited to those drugs for which there is evidence of significant misuse and abuse; namely, barbituates, amphetamines, and certain derivitives of phenethylamine. The definitions in H.R. 11581 should make the limitation to these drugs clear.

In conclusion, I wish to reemphasize that the PMA is in favor of measures to combat illicit peddling and use of barbiturates and amphetamines. Any such measures, however, must not interfere with the important place these drugs have in many areas of medicine.

The CHAIRMAN. I believe, Mr. Cain, you said you were filing or would file with the committee a memorandum setting forth recommendations.

Mr. CAIN. Yes, sir.

The CHAIRMAN. Do you have that memorandum?

Mr. CAIN. I think it should be attached to the file that was submitted to you, sir. It is dated August 20, 1962. It is on the bottom of the file I think.

The CHAIRMAN. Yes, here it is. I observe that you have a good many attachments to your statement. Of course the one with reference to yourself will be included at the appropriate place. Now, as to the statement of principles of ethical drug promotion, which you referred to in your statement, you would want that included in the record would you not?

Mr. CAIN. Please, sir.

(The information mentioned follows:)

MEMORANDUM ATTACHMENT TO STATEMENT OF GEORGE R. CAIN

AMENDMENTS TO SECTIONS 121–126 OF H.R. 11581, RELATING TO BARBITURATES AND STIMULANT DRUGS, RECOMMENDED BY THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

I

In order to implement our recommendations that the innocent victims of the illicit traffic in barbiturates and stimulant drugs not be caught up in the pervasive criminal provisions of the bill, the words "sell, or possess for sale," should be added after "process" in section 509(f), on page 22, line 15. Consistent with this, subsections (c) and (d) of section 509, on pages 24 and 25, should be deleted, and the succeeding subsections properly renumbered. In addition, section 123, on page 27, lines 19–23, should be amended so as to read, "(o)(1) The manufacture, compounding, processing, sale, or possession for sale of a drug in violation of section 509(b); (2)(A) the failure to prepare or obtain, or the * * *."

II

This legislation, which grants extraordinary powers to FDA, should be clearly limited to those drugs for which there is evidence of significant misuse or abuse. The evidence of misuse, and thus of need for greater public protection, relates only to barbituates, amphetamines, and certain derivatives of phenethylamine. We believe that the extension of this legislation beyond these drugs is wholly unwarranted, and that the definitions in H.R. 11581 should make this limitation clear and unambiguous.

The definitions, as presently drafted, would permit the Secretary to bring within the proposed legislation any substance which the Secretary finds to be habit forming because of its stimulant effect on the central nervous system. The use of the term "habit forming" is inappropriate. The purpose of these extraordinary controls is to eliminate the misuse of certain drugs which because of their stimulating effect on the central nervous system, rather than any habituating properties, pose a threat to public health and safety. There has been no showing that any other possibly habituating drugs pose a similar threat of antisocial behavior due to their abusive nonmedical use. Therefore, there is no need for all such drugs being placed within the confining conditions of this bill.

The Food and Drug Administration itself, in its answers to questions posed by Congressman Williams, recognized that the problem of antisocial behavior was presently limited to barbiturates and stimulant drugs such as amphetamine. If in the future, other drugs are shown to present social dangers, the PMA would, of course, support legislation strictly controlling their distribution. Until such time, however, we do not believe these controls should be extended beyond the area of proven need.

For this reason, we recommend that the committee adopt the definitions set forth below in place of those presently contained in proposed section 509(a)(1) and (2), pages 21–22 of the bill. We further recommend that each definition exempt products which contain other drugs in combination with such minor quantities of amphetamines or barbiturates that the product does not raise the possibility of illicit traffic. This concept, covering some over-the-counter products, is already well recognized by the FDA. The language we recommend is:

"(1) The term 'barbiturate' means any drug which contains any quantity of (A) barbituric acid or any of the salts of barbituric acid; or (B) any derivative of barbituric acid, which derivative has been designated by the Secretary under section 502(d) as habit forming; provided that such terms shall not include drugs containing in addition to any such barbiturate, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate to cause a hypnotic or somnifacient effect; and shall not include any drug permitted to be sold over the counter without prescription;

"(2) The term 'amphetamine' means (A) amphetamine or any of its optical isomers; or (B) any salt of amphetamine, or any salt of an optical isomer of amphetamine; provided that such terms shall not include drugs containing, in addition to any such amphetamine, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of amphetamine to cause a stimulating effect on the central nervous system; and shall not include any drug permitted to be sold over the counter without prescription;

"(3) The term 'stimulant drug' means any derivative of phenethylamine which the Secretary, after investigation, has found to have become a threat to the public health and safety when used illicitly, because of its stimulant effect on the central nervous system, and by regulation has designated as a 'stimulant drug'; provided that any such regulation shall exempt from the provisions of this section any drug containing, in addition to such stimulant drug, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of such stimulant drug to cause a stimulating effect on the central nervous system."

III

As we have pointed out, the term "habit forming" is inappropriately used in this bill to refer to stimulant drugs. "Habit forming" is often taken to mean that the failure to use the drugs leads to physically debilitating symptoms—withdrawal symptoms or the so-called abstinence syndrome—and a craving is developed for the drug. This condition (properly characterized as "addiction") does not result from the use of stimulant drugs, according to Dr. Chauncey Leake, in his book, "The Amphetamines."

Moreover, the danger presented by these drugs, as detailed in testimony before the Senate and this committee, is not that they may be "habituating" (a term characterizing drugs taken regularly which do not produce cravings or withdrawal symptoms), but that taking them may so stimulate the central nervous system as to lead to antisocial behavior. Thus their habituating qualities are irrelevant to the threat they present, for withdrawal of the drug will remove the threat without presenting the danger of antisocial action due to cravings or withdrawal symptoms associated with addiction.

Therefore, line 23 on page 21 should be amended to read: "Barbiturates and Stimulant Drugs." Similar amendments should be made on line 25, page 20; line 15, page 22; line 25, page 23; lines 3–4, page 24; lines 9, 15, and 21, page 25; lines 7 and 17, page 26; line 10, page 27; and line 9, page 28.

IV

The PMA also recommends that the power to designate drugs should be qualified by the hearing and review provisions of the Federal Food, Drug and Cosmetic Act. This safeguard is consonant with the extraordinary controls placed on those who manufacture the drugs which these provisions would regulate. Therefore, a new section should be added to this portion of H.R. 11581, amending section 701(e) of the Food, Drug and Cosmetic Act by adding section 509 as one of the sections subject to the provisions of section 701(e).

V

While the PMA agrees that recordkeeping requirements must be complete and effective, we also believe that they should not be needlessly burdensome. For example, we see no reason for requiring each local druggist to record the address of the person to whom a drug controlled by section 509 is dispensed so long as the prescription presented shows the name and address of a licensed practitioner. We therefore recommend that line 3, page 26 (section 509(e)(1)) be amended to read:

disposed of, and the date of such transaction: *Provided*, That no record need be made of the address of any person to whom such drug is sold, delivered or otherwise disposed of if such sale, delivery or other disposition shall have been pursuant to a prescription showing the name and address of a practitioner licensed by law to prescribe barbiturates and stimulant drugs: *And provided further*, That there shall be no set form or forms for the foregoing records so long as they contain the required information.

VI

Finally, we suggest the deletion of section 125 of H.R. 11581, page 28, lines 16–21. This section permits the continued effectiveness of State laws.

This legislation, to halt effectively the illicit traffic in these drugs, must extend to all commerce, intrastate as well as interstate. The congressional findings properly call for such coverage. Section 125 might, however, encourage State legislation which will only increase the complexity of regulation without providing any additional significant public benefit. The PMA believes, moreover, that the field of barturate-amphetamine-phenethylamine regulation is one primarily and predominently of Federal concern.

Therefore, we recommend the deletion of section 125 so that the courts may, as specialized Federal controls evolve in practice, make appropriate determinations on issues involving conflicts between Federal and State law.

GEORGE R. CAIN

George R. Cain has been associated with Abbott Laboratories since 1940 and has been a director since 1947. He was elected president in 1958 and became board chairman and president in April 1962.

Mr. Cain was born September 9, 1910, in Noblesville, Ind. He attended Williams College from which he received his A.B. degree in 1933.

After graduation he joined the Equitable Life Assurance Society of the United States as a group department representative. In 1937 he became a general insurance broker with W. A. Alexander & Co.

Mr. Cain joined the Abbott sales department in 1940 as a member of the hospital division. In 1947 he was elected to the board of directors and was named secretary of the executive committee and administrative assistant to the president. He became a member of the executive committee in 1949, executive vice president and chairman of the executive committee in 1950, president in 1958 and chairman of the board and president in 1962. Mr. Cain is also a director of Abbott Universal, Ltd., and Abbott Laboratories, Ltd. (Canada).

He is a director of Evanston Hospital, a trustee of Northwestern University, a director of the Pharmaceutical Manufacturers Association, a director of International Harvester Co., and past chairman of the board of the Health Information Foundation.

Mr. Cain and his wife, Jane, reside at 115 Meadow Lane, Winnetka, Ill.

The CHAIRMAN. Do you intend for Dr. Klumpp's statement to be inserted in the record here too?

Mr. CAIN. I think it is already in the record, sir, since he filed it with your committee under the date of September 21, 1961, in which he commented on H.R. 6471, but for convenience——

The CHAIRMAN. You said we had it in that record?

Mr. CAIN. Yes, sir.

The CHAIRMAN. We could make it part of this record by reference.

Mr. CAIN. Yes, sir. It might be convenient only as a reference.

(See p. 325 for Dr. Klumpp's statement on H.R. 6471.)

The CHAIRMAN. Yes. And then you have a letter referred to of November 14, 1961, on the same subject. That is in the record and may be referred to by reference here.

Mr. CAIN. Yes, sir.

(See p. 331 for the letter dated Nov. 14, 1961.)

The CHAIRMAN. You had this exhibit A, "Physician's Reference on Oretic." I think we will receive that along with these other booklets that you presented for the record.

Mr. CAIN. Thank you very much, sir.

(The document referred to follows:)

EXHIBIT A

PHYSICIAN'S REFERENCE

ORETIC™

(HYDROCHLOROTHIAZIDE, ABBOTT)



YOUR MOST POTENT MEANS
WHEN THE END IS DIURESIS

ABBOTT LABORATORIES • NORTH CHICAGO, ILL.

RADIO-PHARMACEUTICAL LABORATORIES
OAK RIDGE, TENN.



ORETIC the most potent
and effective oral
diuretic-antihypertensive
yet discovered.

ORETIC high therapeutic ratio
and low toxicity
—effective doses
only 1/10 to 1/15 those needed
with chlorothiazide.

ORETIC for renal, cardiac,
steroid edema and edema
and toxemia of pregnancy.

ORETIC alone, effective
in mild hypertension;
with other agents,
effective in moderate to
severe cases.

ORETIC useful in
management of
obesity and
premenstrual tension.

ORETIC | YOUR MOST
POTENT MEANS
WHEN THE END
IS DIURESIS.

ORETIC | CONTENTS

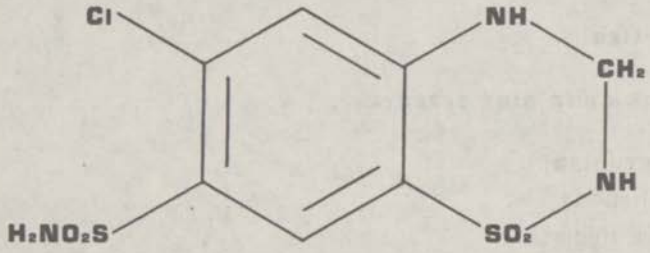
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ORETIC

is the Abbott trademark for hydrochlorothiazide, a synthetic heterocyclic compound possessing diuretic properties. This agent enhances the excretion of sodium and chloride by a direct action on the renal tubules similar to that of the mercurial diuretics. It also inhibits the action of carbonic anhydrase. It is as effective as chlorothiazide, but at considerably reduced dosage (from one-seventh to one-twentieth of the dose of the parent compound).

ORETIC is a white, crystalline solid, which is slightly soluble in cold water or alcohol, and more readily soluble in alkaline solutions. Chemically, it is 6-chloro-3,4-dihydro-7-sulfamyl-2H-1,2,4-benzothiadiazine 1,1-dioxide, and has the following structural formula:



ORETIC—TRADEMARK FOR HYDROCHLOROTHIAZIDE, ABBOTT

ORETIC | METABOLIC EFFECTS

The primary action of ORETIC appears to be on the renal tubules, where the reabsorption of both sodium and chloride are blocked to approximately the same degree. This results in a profound increase in the excretion of these electrolytes. There is also a much smaller increase in the excretion of potassium and bicarbonate.

Particularly when fluid has been retained in the body, the excretion of these electrolytes causes a secondary excretion of water. The action resembles that of parenterally administered mercurial diuretics.

Although the action of oral and mercurial diuretics on the renal tubules has been the subject of a number of studies, a full explanation of the mechanism has not yet been offered. However, current studies show that renal blood flow and glomerular filtration rate remain essentially unchanged.

The action of ORETIC in lowering elevated blood pressure is also not fully understood. After working with the heterocyclic diuretics (chlorothiazide and hydrochlorothiazide), a number of investigators have offered theories regarding their mode of action.

Freis, et al.,[1,2] and Tapia, et al.,[3] have drawn attention to the alteration in plasma volume which may be observed for long periods of time in patients receiving maintenance therapy with chlorothiazide. They suggest that this may alter the fundamental reactivity of the arterioles to other drugs, and they have shown that the fluid changes approximate those seen in patients receiving the rice diet, or on very restricted sodium intake. It is also well known that patients on rigid sodium restriction respond better to the usual antihypertensive drugs.

Wilkins and his associates[4,5] believe that the redistribution of fluid and electrolytes are important factors in the antihypertensive effect of oral diuretics of this class. However, these authors also suggest that agents of this type may have an antihypertensive action not specifically related to the diuretic effect.

There are two primary indications for use of ORETIC—elimination of excess fluid (edema from any cause) and treatment of hypertension. ORETIC may be used alone in mild cases of hypertension or in combination with other antihypertensive agents in management of more severe cases.

RENAL EDEMA ORETIC is of value in the management of nephrotic edema caused by various forms of renal disease. Its employment may reduce the necessity for very rigid sodium restriction usually required when ACTH or steroids are administered. However, severe renal impairment may render kidneys unresponsive to any form of diuretic therapy. If a response is not obtained, and if clinical and laboratory studies indicate progressive renal failure, therapy with ORETIC should be discontinued.

CARDIAC EDEMA In congestive heart failure, ORETIC produces a copious diuresis comparable to that produced by parenterally administered mercurials. The potency, long-term effectiveness and safety of ORETIC make it an agent of choice for maintenance therapy in cases of cardiac failure. Symptoms such as dyspnea, orthopnea and chronic cough may be dramatically improved. ORETIC may reduce the necessity for salt restriction, and is thus particularly useful in patients who find it difficult to follow a salt-free diet.

If desired, ORETIC may be used together with mercurial diuretics, though this is seldom necessary. It should be remembered that successful employment of diuretic agents does not eliminate routine measures in the treatment of heart disease such as rest, digitalization and careful attention to the diet.

TOXEMIA OF PREGNANCY ORETIC is especially useful when salt and fluid retention present a problem. It should be used as an adjunct to the usual measures and, if necessary, may be combined with the use of more potent antihypertensive drugs. The dosage of these is generally reduced when

ORETIC is employed and the danger of toxic side effects is thereby minimized.

PREMENSTRUAL TENSION, EDEMA IN PREGNANCY Small doses of ORETIC are often useful in overcoming the antidiuretic effect which may be seen, in some patients, in the above conditions.

STEROID EDEMA The administration of adrenal and pituitary hormones (ACTH, cortisone, hydrocortisone, etc.) may be accompanied by salt or water retention leading to clinical edema. ORETIC may be successfully employed for the treatment of these secondary effects and may eliminate the need for cessation of steroid therapy.

HYPERTENSION ORETIC is indicated in the management of the majority of cases of hypertension. In mild cases, it can be used alone and will often eliminate the necessity for a rigidly controlled salt-free diet. In more severe cases, it may be employed in conjunction with any of the standard antihypertensive drugs including Harmonyl®, and other rauwolfia derivatives, hydralazine, veratrum alkaloids and ganglionic blocking agents. It may also be of value, and produce improved control of blood pressure, in patients who have received a surgical sympathectomy.

ORETIC | DOSAGE AND ADMINISTRATION

The adult dosage of ORETIC is in the range of 25 to 200 mg. daily. Usually 75 to 100 mg. will produce the desired effect.

This may be given as a single dose in the morning, or if desired (particularly with larger doses) the tablets may be administered two or three times each day. Laboratory and clinical evidence indicates that ORETIC is as effective as chlorothiazide, but that the equivalent dosage is only one-seventh to one-twentieth of the amount required with the latter agent.

CONTROL OF EDEMA ORETIC is the most potent and most effective oral diuretic agent available. It will usually eliminate the necessity for paren-

teral administration of mercurials and will often permit a reduction in rigid sodium restriction. It may be given alone or in combination with other agents for the elimination of retained fluid.

Dosage should be adjusted in accordance with the patient's response. At the start of treatment, 50 to 100 mg. may be administered after breakfast. If necessary, this dosage may be repeated later in the day, and be administered twice daily for several days until the patient's weight approaches its non-edematous value.

When control of edema has been established, it may be maintained by daily or intermittent therapy with small doses. In some patients, a daily dose as low as 25 mg. may be effective; in others, as much as 150 mg. may be required.

When regular therapy is employed, it is important to keep a careful and constant watch on electrolyte balance. Particular care should be taken to guard against potassium depletion. Patients on regular maintenance therapy should be instructed to take approximately 8 ounces of tomato, orange or citrus fruit juice two to four times *each day*. If this is not possible, potassium chloride may be administered by mouth at a dosage of 1 gram two to four times daily.

In many patients, intermittent therapy is all that is necessary to maintain control of edema. Thus, administration of ORETIC may be reduced to every second day or to three or four consecutive days in each week. The optimum dosage and time interval between administrations can only be determined by individual trial in each patient. Intermittent therapy is recommended (when adequate), since this will reduce the possibility of producing electrolyte imbalance.

It is important to realize that the elimination of edema fluid does not necessarily cure the underlying disease or condition which initially caused the retention of the fluid. An appropriate treatment which takes into consideration the underlying cause of the edema should not be neglected.

MANAGEMENT OF HYPERTENSION At the start of treatment it is best to administer ORETIC early in the day. For the first few days, some diuretic action may be apparent, and it is more convenient for the patient if this occurs during the waking hours. When fluid balance has adjusted, the diuretic action is not usually noticeable. Therefore, at the start of treatment it is recommended that the total daily dose should be given after breakfast. For maintenance therapy, the daily dose can be divided and given two or three times a day. Dosage must always be individualized, but the following suggestions should provide guidance in establishing optimum benefit.

(a) **ORETIC** *used alone*

In mild cases of hypertension, a satisfactory response may be obtained without the use of potent antihypertensive agents. For initiating therapy, the average daily dose in the adult is 75 mg. After a few days, the dosage should be adjusted upwards or downwards, according to the response.

In general, the maintenance dosage should be the minimum which will produce the desired effect on blood pressure. A maximum dose for maintenance is generally considered to be about 150 mg. daily (which may be divided and administered as 50 mg. t.i.d.).

If the blood pressure does not respond to ORETIC alone, therapy may be continued while other more potent agents are added to the regimen.

(b) **ORETIC** *with Harmonyl or other rauwolfia derivatives.*

ORETIC may be administered to patients receiving rauwolfia alkaloids without an initial alteration in the dosage of these compounds. After a few weeks, the dosage of both agents may be reduced slowly, until the minimum amount necessary to produce the desired benefit is established.

Adjustments in dosage should not be made too quickly, since the

action of rauwolfia derivatives is prolonged. Thus, the effect of a reduction in dosage may not become apparent for some weeks.

If the desired benefit has not been obtained, Harmonyl may be added to the regimen of the patient receiving ORETIC alone. Therapy with Harmonyl may be started at a daily dosage of 0.25 to 0.5 mg. (one or two tablets). The dosage may be revised according to the individual response. The combination of ORETIC with Harmonyl will often prove effective in lowering the blood pressure in patients who do not respond satisfactorily to either agent used alone.

(c) **ORETIC** *with other antihypertensive drugs*

It must be remembered that regular administration of ORETIC tends to make the patient more sensitive to the action of other antihypertensive agents. Therefore, if drugs such as hydralazine or ganglionic blocking agents are employed, the initial dosage of these agents should be relatively small (approximately one-half of the recommended dosage when these agents are used alone). A satisfactory maintenance dose of the two agents can be established only by individual trial. Generally speaking, the maintenance dose of the additional agent will be less when it is employed with ORETIC than when given alone.

MANAGEMENT OF OBESITY In some obese patients, fluid retention is a complicating factor. In these cases, ORETIC may be helpful in promoting early weight loss. An average dosage is 25 mg. once or twice daily during the first few weeks of treatment.

The administration of a diuretic agent is *not* a substitute for dietary restriction, and the usual measures to limit the intake of total calories must be observed.

ORETIC | HOW SUPPLIED

ORETIC tablets are supplied in bottles of 100 and 1,000 in dosage sizes of 25 mg. (List No. 6978) and 50 mg. (List No. 6985).

ORETIC | PRECAUTIONS AND SIDE EFFECTS

Since ORETIC is the most potent and effective oral diuretic available, it is to be expected that small doses will markedly increase the excretion of fluid and electrolytes. Therefore, the dosage and frequency of administration must be carefully adjusted to the needs of each patient. All patients should be observed closely for early signs of fluid or electrolyte imbalance. Precautions against potassium depletion are described on page 6.

Early indications of electrolyte imbalance may include symptoms such as thirst, dryness of the mouth, lethargy, weakness and drowsiness. If these symptoms are ignored, muscular fatigue, muscle pains, gastric upset, oliguria, and hypotension may result. Finally, convulsions, coma, or a condition resembling "shock" may develop. The latter symptoms will never occur if the warning offered by earlier ones is not ignored.

With intensive or prolonged therapy, it is particularly important to guard against alkalosis (due to chloride depletion) and hypokalemia. In cardiac patients receiving digitalis, potassium depletion can be particularly hazardous. The sensitivity to digitalis is increased in the presence of depleted serum potassium, and heart block or other manifestations of digitalis intoxication may result. These conditions may result from excessive administration of ORETIC, and may be precipitated by dehydration (e.g., from vomiting) or severe salt restriction.

While therapy with ORETIC will often allow some relaxation of severe sodium restriction, it is also true that sodium restriction reduces the need for diuretic therapy. Thus, dosage of ORETIC and sodium intake must be considered together and mutually adjusted for maximum benefit.

The "low salt syndrome" has not been reported as occurring during ORETIC therapy. Yet the possibility should be kept in mind, especially if heavy dosage is employed together with severe sodium restriction in a very edematous patient. When frequent massive doses of ORETIC are employed, it is recommended that serum sodium levels should be followed by means of laboratory studies. If facilities are not available, the

patient should be allowed a moderate amount of sodium (one gram or more) in the daily diet. It is of interest that the administration of some salt in a patient in whom serum sodium levels are low, may actually help to initiate diuresis.

An occasional hypertensive patient who receives ORETIC may show some evidence of nitrogen retention. This can be expected to occur only in patients whose blood pressure is markedly reduced. It seems probable that the causative factor is the lowering of the blood pressure, which in turn produces reduced blood flow through impaired kidneys. Under these conditions, the kidneys are no longer able to eliminate the excess nitrogen, but are often able to do so if the reduced blood pressure is allowed to rise toward the previous levels.

In patients with cirrhosis and ascites, chlorothiazide has been observed to produce symptoms of impending hepatic coma (confusion, drowsiness and tremor).[6] In this study it was suggested that impending hepatic coma could be prevented by the simultaneous administration of broad-spectrum antibiotics. Similar effects could be anticipated following the administration of ORETIC to patients with impaired liver function. If laboratory tests reveal the presence of ammonia intoxication, it should be treated by the usual methods.

If the possibility of hepatic coma, hypokalemia and alkalosis are kept in mind, cautious administration of ORETIC may produce benefit in some patients with cirrhosis and ascites. However, in these cases, potassium chloride administration should be considered on a routine basis, and a careful watch must be kept on the patient's general condition and laboratory findings.

Specific side effects following the administration of ORETIC have been infrequent. They have included occasional reports of nausea, skin rash, anorexia, headache, restlessness, fatigue and constipation. Side effects of this type can often be overcome by lowering the dose or administering the drug following a meal.

ORETIC | CLINICAL STUDIES

Results following the administration of ORETIC have been uniformly favorable. Effectiveness and tolerance have been carefully assessed in patients with edema who had a variety of diagnoses including congestive heart failure, nephritis, nephrosis, diabetes, Raynaud's disease, premenstrual tension, glaucoma, obesity and hypertension of various types. Laboratory studies, in addition to clinical indications, have confirmed the safety of this type of therapy.

In general, side effects (even from large doses) have been few. Elimination of edema fluid has been prompt and usually complete. Control of hypertension has been facilitated, both in mild cases in which ORETIC has been effective when used alone, and in more severe cases when it has enhanced the action of other hypertensive agents. In some instances, the dosage of ganglionic blocking agents has been lowered by as much as 50 percent when their use has been combined with administration of ORETIC. Some patients refractory to mercurial diuretics and chlorothiazide have shown a good response after administration of ORETIC.

Laboratory studies have indicated that comparatively small doses of ORETIC have markedly increased the excretion of water sodium chloride. Excretion of potassium and bicarbonate has also been increased, but to a much lesser degree. In many cases potassium levels have remained relatively unaffected.

PUBLISHED REPORTS The clinical effectiveness of heterocyclic oral diuretics has been well documented.[7-11] These agents have properties similar to both carbonic anhydrase inhibitors and the mercurial diuretics.

Pitts and his associates[12] have pointed out that the molecule in this type of compound contains a free sulfonamyl group, and consequently "it inhibits carbonic anhydrase *in vitro* and in large doses *in vivo*, alkalinizes the urine, and increases the urinary excretion of potassium. In addition it causes naturesis and chloruresis, actions similar to those of

mercurial diuretics." There is also evidence of an additive action when ORETIC is administered together with mercurial diuretics.

Herrmann[13] presented the results of a study with hydrochlorothiazide at the Texas Academy of Internal Medicine in December, 1958. He and his associates studied 21 patients suffering from edema. In 20 patients the cause was congestive heart failure; in 1 patient it was undetermined.

Detailed laboratory and clinical studies were carried out on all patients. The authors found hydrochlorothiazide "to be a clinically effective oral diuretic which is well tolerated."

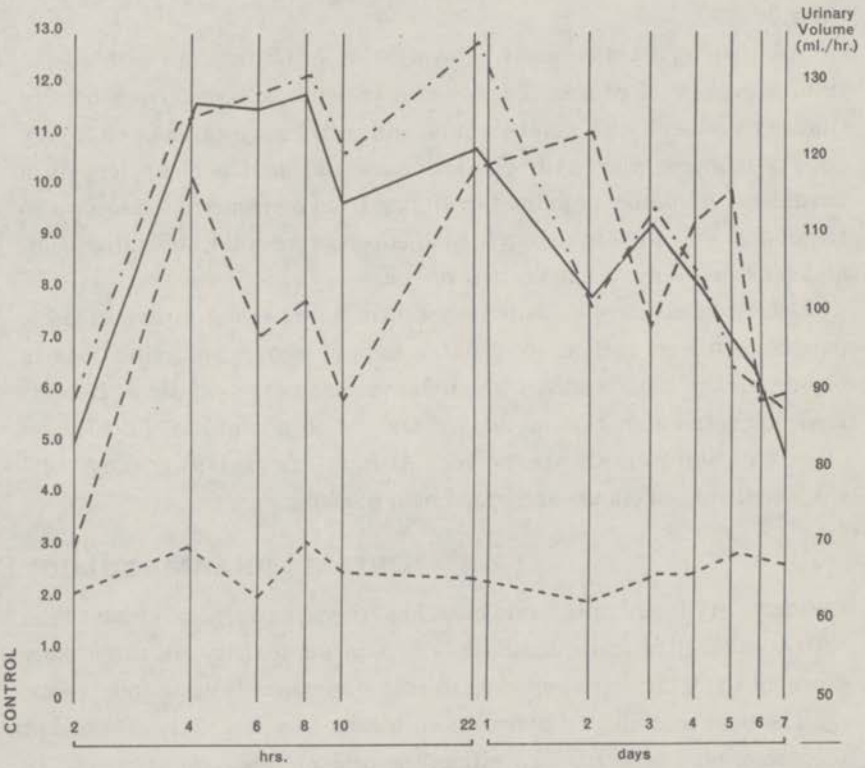
Other conclusions from this study were as follows:

- "The diuretic effect appears to be similar to that of the mercurials, in that urinary volume is augmented, with predominantly an excretion of sodium and chloride to about three times the control levels. Potassium excretion was increased slightly, to a maximum increase of 30 percent in these short-term studies."
- "The dosage necessary was one-fourth to one-eighth that of chlorothiazide, and so milligram for milligram (hydrochlorothiazide) is the most effective diuretic that we have used."
- "A single dose of 200 mg. produces a diuresis which begins about two hours after one ingestion, and is maintained for more than 24 hours. Effective diuresis can also be achieved by 50 mg. doses administered twice daily."
- "On the basis of a limited number of cases, the anti-hypertensive action of (hydrochlorothiazide) appears promising. However, the matter of nitrogen retention calls for care in long-term therapy in hypertensive patients, especially those with renal disease, just as is the case with chlorothiazide."

Average values for the excretion of urine and electrolytes following the administration of hydrochlorothiazide to 14 patients included in this study are shown in the accompanying graph.

OUTPUT OF URINARY VOLUME AND ELECTROLYTES

AVERAGE VALUES FROM 14 HOSPITALIZED PATIENTS RECEIVING HYDROCHLOROTHIAZIDE



(Adapted from Herrmann, et al.[13])

UNPUBLISHED REPORTS A number of investigators have evaluated various aspects of therapy with ORETIC. In one study, patients under treatment with mercurials or chlorothiazide were transferred to hydrochlorothiazide in order to determine relative potency. The 50 patients selected were suffering from congestive heart failure and response was evaluated on the basis of serum potassium levels, weight and serial electrocardiograms. Eighty percent showed marked improvement with an average weight loss of 9 pounds on being transferred to therapy with hydrochlorothiazide. An equivalent dosage relationship appeared to be approximately 150 mg. of hydrochlorothiazide, as against 1000 mg. of chlorothiazide.

Another report was based on evaluation of 60 patients with edema from a variety of causes. Twenty-two patients suffering from obesity (under treatment with amphetamine and restricted diet) showed a very good weight loss when hydrochlorothiazide was used as a supplement in treatment. A number of patients suffering from premenstrual tension also responded well to this therapy. Side effects were mild and infrequent, and consisted only of nausea in a few cases.

Other reports have indicated a good clinical response in hypertensive patients with or without congestive failure. Significant reductions in blood pressure have occurred when ORETIC has been used alone. Reports have indicated a marked ability of ORETIC to potentiate the effect of other anti-hypertensive agents, such as rauwolfia derivatives, hydralazine, veratrum alkaloids and ganglionic blocking agents.

ORETIC | PHARMACOLOGY

TOXICITY Hydrochlorothiazide has a high therapeutic ratio (greater than 1:1000 in the dog and rat) and has a very low toxicity. In dogs, daily doses up to 60 mg./Kg. were well tolerated for periods up to four weeks.

The poor solubility of hydrochlorothiazide in water makes it difficult to determine a true LD_{50} by either the oral or intravenous routes. In

rats, a 10 percent solution in 80 percent N,N-dimethylacetamide was injected intravenously. The LD_{50} for this mixture was greater than 350 mg./Kg. but the specific effect of the hydrochlorothiazide could not be determined because of the toxicity of the N,N-dimethylacetamide. However, no symptoms developed which could be directly attributed to the hydrochlorothiazide *per se*.

The oral LD_{50} of hydrochlorothiazide in the rat was greater than 2.7 grams/Kg. The amount which could be administered was limited by the poor solubility of the drug in water and by the amount which could be ingested at one time.

Dogs have tolerated hydrochlorothiazide at a dosage of 100 mg./Kg. by the intravenous route (as a 10 percent in N,N-dimethylacetamide) and at a dosage of 1 gram/Kg. orally. The intravenous administration produced transient ataxia and vomiting. There were no toxic symptoms following the oral administration.

In all species of laboratory animals hydrochlorothiazide was well absorbed following oral administration. Diuretic activity started promptly, was maximal within approximately three hours, and persisted for four to six hours or longer.

Studies indicated that the drug was eliminated by the kidney although glomerular filtration rate and renal plasma flow were not significantly altered. In animals with normal blood pressure, there was no change, but in hypertensive animals some effect on blood pressure was noted. Chronic toxicity studies employing 750 mg./Kg./day in rats and 250 mg./Kg./day in dogs have been carried for many months without the development of toxic symptoms.

PHARMACOLOGIC EFFECTS Comparative experiments in dogs have indicated that hydrochlorothiazide possesses a longer duration of action than chlorothiazide. A similar relationship can be demonstrated in rats.

Hydrochlorothiazide appears to have no effect on carbohydrate metabolism, but does show an inhibitory effect on carbonic anhydrase at

relatively low concentrations.

In normal anesthetized and unanesthetized dogs, hydrochlorothiazide did not show any effect on blood pressure, heart rate, or pulse pressure. In the anesthetized dog, it did appear to potentiate the action of hydralazine in producing a reversal of the epinephrine effect.

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16 **ORETIC** | YOUR MOST POTENT MEANS WHEN THE END IS DIURESIS

The CHAIRMAN. Now, you have an exhibit B on Oretic. Would you want that in the record?

Mr. CAIN. It would be pertinent, Mr. Chairman, because it substantiates the statement regarding the ad that appeared, the eight-page ad.

The CHAIRMAN. That will be received in the record.

(The document referred to is as follows:)

88589 O—62——20

EXHIBIT B

PRESENTING A SPECIAL NEW-PRODUCT REFERENCE ON

ORETIC™

(HYDROCHLOROTHIAZIDE, ABBOTT)



YOUR MOST POTENT MEANS
WHEN THE END IS SALURESIS*



doctor: if you have low-salt patients you can

put some real pleasure (and some real salt) back on their table ... often take rigid diet plans (and all their bother) out of your treatment ... new product for edema and hypertension

ORETIC™

(HYDROCHLOROTHIAZIDE, ABBOTT)

YOUR MOST POTENT MEANS WHEN THE END IS SALURESIS*



*In many clinical problems the elimination of salt (saluresis) is just as important as diuresis. And ORETIC provides your most potent means to these ends.

ORETIC | INTRODUCTION

Doctor: In simplest terms, prescribing new ORETIC is like packaging a low-salt regimen in a single tablet . . . because ORETIC steps up excretion of sodium and chloride, and thereby often cuts down the need for an extremely rigid low-sodium or salt-free diet.

It follows that the more potent the diuretic-antihypertensive, the greater the chances that sodium restrictions can be relaxed.

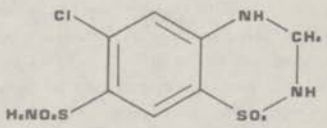
And new ORETIC is the most potent oral diuretic-antihypertensive yet discovered. It has a high therapeutic ratio, low toxicity. It works successfully with dosages only 1/10—1/12 those of chlorothiazide.

The following pages of product information . . . indications, dosage, precautions and clinical reports . . . are presented here to give you useful facts about the application of new ORETIC—not only to low-salt therapy but to all other conditions in which this potent drug could conceivably be your agent of choice.

ORETIC | WHAT IT IS

ORETIC is the Abbott trademark for hydrochlorothiazide, a synthetic heterocyclic compound possessing diuretic properties. This agent enhances the excretion of sodium and chloride by a direct action on the renal tubules. It also inhibits the action of carbonic anhydrase. It is as effective as chlorothiazide, but at considerably reduced dosage—from 1/10—1/12 of the dose of the parent compound.

ORETIC is a white, crystalline solid, which is slightly soluble in cold water or alcohol, and more readily soluble in alkaline solutions. Chemically, it is 6-chloro-3,4-dihydro-7-sulfamyl-2H-1,2,4-benzothiadiazine 1,1-dioxide, and has the following structural formula:



ORETIC | INDICATIONS

There are two primary indications for the use of ORETIC . . . the elimination of excess fluid (edema from any cause) and the treatment of hypertension. ORETIC may be used alone in mild cases of hypertension or in combination with other antihypertensive agents such as Harmonyl®.

ORETIC | EDEMA

RENAL EDEMA ORETIC is of value in the management of nephrotic edema caused by various forms of renal disease. *Its employment may reduce the necessity for very rigid sodium restriction usually required when ACTH or steroids are administered.* However, severe renal impairment may render kidneys unresponsive to any form of diuretic therapy. If response is not ob-

®Harmonyl—Deserpidine, Abbott

tained, and if clinical and laboratory studies indicate progressive renal failure, therapy with ORETIC should be discontinued.

CARDIAC EDEMA In congestive heart failure ORETIC produces a copious diuresis comparable to that produced by parenterally administered mercurials. The potency, long-term effectiveness and safety of ORETIC make it an agent of choice for maintenance therapy in cases of cardiac failure. Symptoms such as dyspnea, orthopnea and chronic cough may be dramatically improved. ORETIC *may reduce the necessity for salt restriction, and is thus particularly useful in patients who find it difficult to follow a salt-free diet.* If desired, ORETIC may be used together with mercurial diuretics, though this is seldom necessary. It should be remembered that successful employment of diuretic agents does not eliminate routine measures in the treatment of heart disease such as rest, digitalization and careful attention to the diet.

TOXEMIA OF PREGNANCY ORETIC is especially useful when salt and fluid retention present a problem. It should be used as an adjunct to the usual measures and, if necessary, may be combined with more potent antihypertensive drugs. The dosage of these is generally reduced when ORETIC is employed, and danger of toxic side effects is thereby minimized.

PREMENSTRUAL EDEMA, EDEMA IN PREGNANCY Small doses of ORETIC are often useful in overcoming the antidiuretic effect which may be seen, in some patients, in the above conditions.

STEROID EDEMA The administration of adrenal and pituitary hormones (ACTH, cortisone, hydrocortisone, etc.) may be accompanied by salt or water retention leading to clinical edema. ORETIC may be successfully employed for the treatment of these secondary effects and may eliminate the need for cessation of steroid therapy.

ORETIC | HYPERTENSION

ORETIC is indicated in the management of many cases of hypertension. *In mild cases, it can be used alone and will often eliminate the necessity for a rigidly-controlled salt-free diet.* In more severe cases it may be employed in conjunction with any of the standard antihypertensive drugs, including Harmonyl® and other rauwolfia derivatives, hydralazine, veratrum alkaloids and ganglionic blocking agents. It may also be of value, and produce improved control of blood pressure, in patients who have received a surgical sympathectomy.

ORETIC | DOSAGE AND ADMINISTRATION

The adult dosage of ORETIC is in the range of 25 to 200 mg. daily. Usually, 75 to 100 mg. will produce the desired effect.

This may be given as a single dose in the morning, or if desired (particularly with larger doses) the tablets may be administered two or three times each day. Laboratory and clinical evidence indicates that ORETIC is as effective as chlorothiazide, but that the equivalent dosage is only 1/10—1/12 of the amount required with the latter agent.

ORETIC | CONTROL OF EDEMA

ORETIC will frequently eliminate the necessity for parenteral administration of mercurials *and will often permit a reduction in rigid sodium restriction.* It may be given alone, or it may be used in combination with other agents for effective elimination of retained fluid.

Dosage should be adjusted in accordance with the patient's response. At the start of treatment 50 to 100 mg. may be administered after breakfast. If necessary this dosage may be repeated later in the day, and be administered twice daily for several days until the patient approaches dry weight.

When control of edema has been established, it may be maintained by daily or intermittent therapy with small doses. In some patients a daily dose as low as 25 mg. may be effective. In others, as much as 150 mg. may be required.

When regular therapy is employed, it is important to keep a careful and constant watch on electrolyte balance. Particular care should be taken to guard against potassium depletion. Patients on regular maintenance therapy should be instructed to take about 8 ounces of tomato, orange or citrus fruit juice two to four times daily. If this is impossible, potassium chloride may be administered by mouth at a dosage of 1 gram two to four times daily.

In many patients intermittent therapy is all that is necessary to maintain control of edema.

Thus, administration of ORETIC may be reduced to every second day, or to three to four consecutive days in each week. The optimum dosage as well as the time interval between administrations can only be determined by an individual trial in each patient. Intermittent therapy is generally recommended (when adequate) since this will reduce the possibility of producing electrolyte imbalance.

It is important to realize that the elimination of edema fluid does not necessarily cure the underlying disease or condition which caused the fluid retention. Appropriate treatment for the underlying cause of the edema should not be neglected.

ORETIC | MANAGEMENT OF HYPERTENSION

At the start of treatment it is best to administer ORETIC early in the day. For the first few days some diuretic action may be apparent, and it is more convenient for the patient if this occurs during the waking hours. When fluid balance has adjusted, the diuretic action is not usually noticeable. Therefore, at the start of treatment, it is recommended that the total daily dose should be given after breakfast. For maintenance therapy, the daily dose can be divided and given two or three times a day. Dosage must always be individualized, but the following suggestions should provide guidance in establishing optimum benefit.

ORETIC | USED ALONE

In mild cases of hypertension a satisfactory response may be obtained without the use of other antihypertensive agents. For initiating therapy, the average daily dose in the adult is 75 mg. After a few days the dosage should be adjusted upwards or downwards according to the response.

In general the maintenance dosage should be the minimum which will produce the desired effect on blood pressure. A maximum dose for maintenance is generally considered to be about 150 mg. daily. This may be divided and administered as 50 mg. t.i.d.

If blood pressure does not respond to ORETIC alone, therapy may be continued while other agents are added to the regimen.

ORETIC | WITH HARMONYL® OR OTHER RAUWOLFIA DERIVATIVES

ORETIC may be administered to patients receiving rauwolfia alkaloids without an initial alteration in the dosage of these compounds. After a few weeks the dosage of both agents may be reduced slowly until the minimum amount necessary to produce the desired benefit is established.

Adjustments in dosage should not be made too quickly since the action of rauwolfia derivatives is prolonged. Thus, the effect of a reduction in dosage may not become apparent for some weeks.

If the desired benefit has not been obtained, Harmonyl may be added to the regimen of the patient receiving ORETIC alone. Therapy with Harmonyl may be started at a daily dosage of 0.25 to 0.5 mg. (one or two tablets). The dosage may be revised according to the individual response. The combination of ORETIC with Harmonyl will often prove effective in lowering the blood pressure in patients who do not respond satisfactorily to either agent used alone.

ORETIC | WITH OTHER ANTIHYPERTENSIVE DRUGS

It must be remembered that regular administration of ORETIC tends to make the patient more sensitive to the action of other antihypertensive agents. Therefore, if drugs such as hydralazine or ganglionic blocking agents are employed, initial dosage of these agents should be relatively small (approximately one-half of the recommended dosage when these agents are used alone). A satisfactory maintenance dose of the two agents can be established only by individual trial. Generally, the maintenance dose of the additional agent will be less when it is employed with ORETIC than when given alone.

ORETIC | SUPPLIED

ORETIC tablets come in 25-mg. (List No. 6978) and 50-mg. (List No. 6985) strengths, each in bottles of 100 and 1000.

ORETIC | PRECAUTIONS AND SIDE EFFECTS

Since ORETIC is the most potent oral diuretic-antihypertensive available, it is to be expected that small doses will markedly increase the excretion of fluid and electrolytes. Therefore dosage and frequency of administration must be carefully adjusted to fit each patient. All patients should be observed closely for early signs of fluid or electrolyte imbalance. Precautions against potassium depletion were noted in the *Indications* section.

Early indications of electrolyte imbalance may include symptoms such as thirst, dryness of mouth, lethargy, weakness and drowsiness. If these are ignored, muscular fatigue, muscle pains, gastric upset, oliguria and hypotension may result. Finally, convulsions, coma, or a condition resembling "shock" may develop. The latter symptoms will never occur if the warning offered by earlier ones is not ignored.

With intensive or prolonged therapy, it is particularly important to guard against alkalosis (due to chloride depletion) and hypokalemia. In cardiac patients receiving digitalis, potassium depletion can be particularly hazardous. The sensitivity to digitalis is increased in the presence of depleted serum potassium; and heart block or other manifestations of digitalis intoxication may result. These conditions may result from excessive administration of ORETIC, and may be precipitated by dehydration from vomiting or severe salt restriction, for example.

While therapy with ORETIC *will often allow some relaxation of severe sodium restriction, it is also true that sodium restriction reduces the need for diuretic therapy. Thus dosage of* ORETIC *and sodium intake must be considered together and mutually adjusted for maximum benefit.*

The "low-salt syndrome" has not been reported as occurring during ORETIC therapy. Yet the possibility should be kept in mind, especially if heavy dosage is employed together with severe sodium restriction in a very edematous patient. When frequent massive doses of ORETIC are employed, it is recommended that serum sodium levels should be followed by means of laboratory studies. If facilities are not available, the patient should be allowed a moderate amount of sodium (one gram or more) in the daily diet. It is of interest that the administration of some salt in a patient in whom serum sodium levels are low, may actually help to initiate diuresis.

An occasional hypertensive patient who receives ORETIC may show some evidence of nitrogen retention. This can be expected to occur only in patients whose blood pressure is markedly reduced. It seems probable that the causative factor is the lowering of the blood pressure, which in turn produces reduced blood flow through impaired kidneys. Under these conditions the kidneys are no longer able to eliminate the excess nitrogen, but are often able to do so if the reduced blood pressure is allowed to rise toward the previous levels.

In patients with cirrhosis and ascites, chlorothiazide has been observed to produce symptoms of impending hepatic coma (confusion, drowsiness and tremor).[1] In this study it was suggested that impending hepatic coma could be prevented by the simultaneous administration of broad-spectrum antibiotics. Similar effects could be anticipated following the administration of ORETIC to patients with impaired liver function. If laboratory tests reveal the presence of ammonia intoxication, it should be treated by the usual methods.

If the possibility of hepatic coma, hypokalemia and alkalosis are kept in mind, cautious administration of ORETIC may benefit some patients with cirrhosis and ascites. But in these cases, potassium chloride administration should be routinely considered, and careful watch kept on the patient's general condition and laboratory findings.

Specific side effects following the administration of ORETIC have been infrequent. They have included occasional reports of nausea, skin rash, anorexia, headache, restlessness, fatigue and constipation. Side effects of this type can often be overcome by lowering the dose or administering the drug following a meal.

ORETIC | CLINICAL STUDIES

Results following the administration of ORETIC have been highly favorable. Effectiveness and tolerance have been carefully assessed in patients with edema who had a variety of diagnoses including congestive heart failure, nephritis, nephrosis, diabetes, Raynaud's disease, premenstrual tension, glaucoma, obesity and hypertension of various types. Laboratory studies

as well as clinical indications have confirmed the relative safety of this type of therapy.

In general, side effects, even from large doses, have been few. Elimination of edema fluid has been prompt and usually complete. Control of hypertension has been facilitated both in mild cases in which ORETIC has been effective when used alone, and in more severe cases when it has enhanced the action of other hypertensive agents. In some instances the dosage of ganglionic blocking agents has been lowered by as much as 50 per cent when their use has been combined with administration of ORETIC. Some patients refractory to mercurial diuretics and chlorothiazide have shown a good response after administration of ORETIC.

Laboratory studies have indicated that comparatively small doses of ORETIC have markedly increased the excretion of water sodium chloride. Excretion of potassium and bicarbonate has also been increased, but to a much lesser degree. In many cases potassium levels have remained relatively unaffected.

The clinical effectiveness of the heterocyclic oral diuretics has been well documented.[3-6] These agents have properties similar to both carbonic anhydrase inhibitors and the mercurial diuretics.

Pitts and his associates[7] have pointed out that the molecule in this type of compound contains a free sulfonamyl group and consequently "it inhibits carbonic anhydrase *in vitro* and in large doses *in vivo*, alkalinizes the urine and increases the urinary excretion of potassium. In addition it causes naturesis and chloruresis, actions similar to those of mercurial diuretics." There is also evidence of an additive action when ORETIC is administered together with mercurial diuretics.

Hermann[8] presented the results of a study with hydrochlorothiazide at the Texas Academy of Internal Medicine in December, 1958. He and his associates studied 21 patients suffering from edema. In 20 patients the cause was congestive heart failure; in 1 patient it was undetermined.

Detailed laboratory and clinical studies were carried out on all patients. The authors found hydrochlorothiazide "to be a clinically effective oral diuretic which is well tolerated."

Other conclusions from this study were as follows:

"The diuretic effect appears to be similar to that of the mercurials, in that urinary volume is augmented, with predominantly an excretion of sodium and chloride to about three times the control levels. Potassium excretion was increased slightly, to a maximum increase of 30 per cent in these short-term studies."

"The dosage necessary was (considerably less than) that of chlorothiazide, and so milligram for milligram (hydrochlorothiazide) is the most (potent) diuretic that we have used."

"A single dose of 200 mg. produces a diuresis which begins about two hours after one ingestion, and is maintained for more than 24 hours. Effective diuresis can also be achieved by 50 mg. doses administered twice daily."

"On the basis of a limited number of cases the anti-hypertensive action of (hydrochlorothiazide) appears promising. However, the matter of nitrogen retention calls for care in long-term therapy in hypertensive patients, especially those with renal disease, just as is the case with chlorothiazide."

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A SPECIAL NEW-PRODUCT REFERENCE

ORETIC™
(HYDROCHLOROTHIAZIDE, ABBOTT)



YOUR MOST POTENT MEANS
WHEN THE END IS DIURESIS

The CHAIRMAN. It may be that the print referred to on the last page, we may have some difficulty in getting that in the record, I am not sure that we can, but we will see about it.

Mr. CAIN. If it is possible, for the purpose of completeness only, Mr. Chairman, it brings out the point of completeness of the information furnished to the physician which I think at least partly answers the question you raised earlier in the afternoon.

The CHAIRMAN. Yes, but I merely caution that I am not sure that this last page can be printed. I doubt it. Now you have exhibit C.

Mr. CAIN. We can supply an original of that, Mr. Chairman, which will be more clear.

The CHAIRMAN. We will receive it and if it can be included in the record we will try to do it, but otherwise you will understand why.

Mr. CAIN. Yes, sir.

(The document referred to is as follows:)

EXHIBIT C
(J.A.M.A., October 22, 1960)

OLD SALT

(or, How to chart a course to brighter diets in edema and hypertension)



Man, food and salt: a satisfying triumvirate. Yet the edema or heart patient may be denied this pleasant union every day. He eats, but without the bright touch salt brings. Small loss? Certainly. Still, small losses often loom large in the patient's mind. A good diuretic like Oretic can help out here. Oretic will successfully treat edema, and work well in mild to moderate hypertension. It produces a generous elimination of water and sodium. And this latter saluretic effect often opens the door to a more liberal low-sodium regime. Not every time, naturally. Each patient—each diet—is different. But an adjusted diet should be possible often enough to make the plan worth considering. Consider what it will mean to the patient to have the real pleasure of some real salt back on the table. You'll know how much it means, when he thanks you.

ORETIC® a potent means when the end is saluresis. Tablets, 25- and 50-mg.

(Hydrochlorothiazide, Abbott)

ABBOTT

The CHAIRMAN. And then exhibit D, that may be all right for some people. I am not sure that the Congress will get much benefit out of that.

Mr. CAIN. No, sir, but it shows the completeness, Mr. Chairman. That is the point we are trying to bring out.

The CHAIRMAN. Let it be received, exhibit D. I think we will have a little difficulty in reading a few pages in this, but it does refer to a good many articles that may be of interest.

Mr. CAIN. Thank you, sir.

(The document referred to is as follows:)

EXHIBIT D (Part I)

LIBRARY
ABBOTT LABORATORIES, NORTH CHICAGO, ILLINOIS
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SCOPE OF SEARCH

Sources	Subjects
Per. Cat.	Hydrochlorothiazide - Clinical Hydrochlorothiazide - Pharmacology
Abbott Abstracts-IBM Search	Hydrochlorothiazide - Clinical (and chlorothiazide)

Oct. 10, 1961
JDM/jrf

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EXHIBIT D (Part II)

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SCOPE OF SEARCH

Source	Time	Subjects
CIML	July 1958 - Dec. 1959	Congestive heart failure Edema Heart diseases Hypertension Hypertension, postural
Library Bib. file Abbott Abstracts-IBM search	1957 - Dec. 1958	Chlorothiazide Chlorothiazide, Clinical (and Hydrochlorothiazide)

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The CHAIRMAN. And then the memorandum attached which has already been received for the record.

I made a notation on page 12 of your statement with reference to additional safeguards, and the suggestion that this particular statement be included in the advertisement. Do you think that would do any good at all?

Mr. CAIN. Well, I think, Mr. Chairman, that there is a feeling on the part of some people that perhaps some such reference might be included. I think personally that if you take in toto all of the available sources of information that are available to the physician, and keep in mind always that the physician does not prescribe drugs for use of his patients until he has made himself familiar with the drug, its background and all about it, then I think this is superfluous.

The CHAIRMAN. You say before prescribing. I assume that means by the doctor, doesn't it?

Mr. CAIN. Yes, sir.

The CHAIRMAN. It seems to me that the medical profession might take that as sort of an insult.

Mr. CAIN. We think that the medical profession could well take it as an insult, Mr. Chairman.

The CHAIRMAN. In other words, you are deliberately trying to insult them?

Mr. CAIN. Perhaps we are bowing to a little pressure from other sources.

The CHAIRMAN. Mr. Schenck, any questions?

Mr. SCHENCK. Thank you, Mr. Chairman. I am very much interested in Mr. Cain's statement. Now on page 5 I was wondering if this was an error. In the last paragraph in line 4 you say: "Furthermore, the FDA regulations do not require full disclosure in the package insert." Is this a correct statement?

Mr. CAIN. In certain instances, yes, sir.

Mr. SCHENCK. I thought FDA did require full disclosure in the package inserts.

Mr. CAIN. Well, if you go on, Mr. Congressman, it says "when drug directions, hazards, and warning uses are commonly known to licensed medical practitioners."

In other words if you take a well, old established drug, there are certain exceptions as I recall now that do not require these regulations. In other words, he knows so much about it that there is little if anything that can be added.

Mr. SCHENCK. That is quite all right. I wondered if it was an error in your statement.

Mr. CAIN. No, sir. I am glad you brought it up but it is accurate.

Mr. SCHENCK. Now, Mr. Cain, there seems to be a growing tendency by certain pharmacists to advertise prescription drugs in the local press of the community. These drugs can be purchased only through a prescription of the physician and not in the quantities advertised in the local advertisements, which I have in a number of cities. Do you care to make any statement on that?

Mr. CAIN. The only comment I can make on that is that I am accurate in this, that some outlets will advertise in local media: "Bring your prescriptions here." The purport of the advertisement: "We will fill them more cheaply than normally would be available to you from your normal source."

That, I suppose, is a form of competition at that level that exists, and I presume that that would be the choice of the individual proprietor or owner of that particular outlet. I don't think that that necessarily means that there is anything wrong with it, nor that there perhaps would be inferior drug supplies.

But maybe that particular man's overhead is lower; I don't know. That form of competition does exist and that is about the only comment I can make on it.

Mr. SCHENCK. I am thinking of such a drug as amphetamines here which you mentioned in your statement.

Mr. CAIN. Yes.

Mr. SCHENCK. Now that is a drug which I understand can be purchased only as a result of a physician's prescription.

Mr. CAIN. Yes, sir.

Mr. SCHENCK. Yet if a local store advertises that at so much per hundred, perhaps the physician limits it to 25, I just wondered if the pharmaceutical society has a position on that.

Mr. CAIN. The patient would still have to present the written prescription of his physician to be filled by this type of an outlet that you are talking about.

Mr. SCHENCK. Yes.

Mr. CAIN. If the prescription read "for only 25," that would be all that that prescription could authorize. He could not obtain a bottle of 100 legally.

Mr. SCHENCK. I knew that of course, but I was wondering what would be the advantage in advertising such prescription drugs on this basis.

Mr. CAIN. Cutrate drugs. I mean they advertise that in the papers on Sunday morning.

The CHAIRMAN. Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. Cain, I would like to welcome you before the committee. You are well vouched for by my good friend Mr. Harrold B. Jones, who speaks very highly of you.

Mr. CAIN. Thank you, Mr. Dingell.

Mr. DINGELL. I hope you won't think it is unkind of me if I ask you a few questions, since you made a few comments on portions of this bill of which I happen to be the principal sponsor. I notice that you have inserted into medical periodicals the number of ads which you submitted to this committee, the first of which is a full page in one on "fast acting Nembutal."

Mr. CAIN. Yes, sir.

Mr. DINGELL. Now in this ad you take up a full page. It comes from the "Current Medical Digest and Annals of Surgery," February 1961. You also list some others in approximately an 8 by 10 or 8 by 12 size page, and on this appears these words "fast-acting Nembutal (Pentobarbital, Abbott), Nembutal rapidly produces cerebral depression of any desired degree, depending upon the dose." And then way down the bottom in small letters appear the numbers "102194."

Now, you used a whole page to tell the reader just those things. Why couldn't you put on there contraindications and side effects too without any undue hardship on Abbott, which is a very fine corporation.

Mr. CAIN. I think that we go back, Mr. Dingell, to the principle that this is simply and only intended to be reminder advertising.

Mr. DINGELL. I see. Now in another one you put down here in a full page in Resident Physician, Medical Economics, and New Physician, you put a two-page ad and on one side of the page the only thing you show is you are talking about Compocilin V–K (Potassium Penicillin V) Granules for Oral Solution. This is one one side. On the other side you have a picture of a box of cherries, a spoon and these words "Now in a pleasing cherry oral solution, the high blood levels of Potassium Penicillin V."

Now why couldn't you on that page put down the side effects and contraindications?

Mr. CAIN. Because we chose again to use this medium as reminder advertising. We keep getting back to that point.

Mr. DINGELL. Another one here, a two-page ad, on one side you talk about Oreticyl. One one side you have Oreticyl——

Mr. CAIN. Yes, sir.

Mr. DINGELL. "Just one prescription for new Oreticyl," and you have a picture of a man unloading a truck that takes up three-quarters of the page.

Now, certainly, it would not be any hardship for you to apprise the physician who is going to look at this of the side effects on this, especially since in the one on Oreticyl you came out and you said:

> This is because * * * it lowers blood pressure without producing excess side effects.

Then you say:

> When Harmonyl, Abbott's unique rawolfia alkaloid is combined with the potent diuretic antihypertensive Oretic, the result is convenient, efficient, one-tablet treatment especially suited to hypertensives who must remain alert and active during the day.

Then you go on and you say that it "produces elimination of water and sodium," so that in many cases it is helpful to low salt diets, and you go on.

Now, I do not want to burden you unduly with this piece of legislation, but it does seem to me that when you put out an ad this big with this little copy in it and you tell the good things about it, it seems like maybe in the interests of protecting the doctor and making life just a little easier for him you might give him a little bit of information as to the contraindications and side effects.

Mr. CAIN. Mr. Dingell, as I say and have said and will continue to say, we are merely using this form of medium as a form of reminder advertising to the doctor.

Now, he has full, complete data on this drug in various other mediums, example of which you have before you, plus medical journals, plus medical meetings, plus scientific exhibits.

He is well informed. He does not prescribe on the basis of reminder advertising.

Mr. DINGELL. If he reads all that you tell us about, when does he see his patients? That is the question. He is a busy man, you will concede?

Mr. CAIN. Of course, he is a busy man. He is also a learned and talented man, who is well educated and well grounded in his profession.

Mr. DINGELL. I recognize that, but the fact of the matter is it would not be an undue burden on him to have a quick rundown of the contraindications and side effects put into these remainder advertisements.

Mr. CAIN. Mr. Dingell, that is a point of view.

Mr. DINGELL. I see. Now, I note here that a substance by the name of Norlutin was advertised for 3 months in a Journal of the American Medical Association, 3 months after it was found that it had caused difficulties to children born of mothers who used it.

Mr. CAIN. We are getting into a medical area with which I am not competent to comment on. That is a drug of another house.

Mr. DINGELL. I know that, I am aware of that, and that is one of the reasons why I chose it rather than some of the others, because I did not want anything to reflect on anyone who was testifying here today.

Mr. CAIN. Well, I am not competent to judge on the merits of the drug or its use.

Mr. DINGELL. Here we have a situation where 3 months after this situation is found, the same advertisement continues, directed to the medical profession, without mention of this particular effect.

Now, do you not think that calls for some corrective action or for some redress or perhaps some reappraisal of the comments you have made to the committee today?

Mr. CAIN. Not in the slightest, because I am not familiar with the history of this, and I have to take your word for it.

Mr. DINGELL. Well, the interesting thing is this is in testimony on the hearings of another committee.

Now, let us go a little bit further, if we may, here. Are you familiar with the practice of using detail men in the industry?

Mr. CAIN. Am I?

Mr. DINGELL. Yes.

Mr. CAIN. I certainly am.

Mr. DINGELL. Do you know how many detail men there are?

Mr. CAIN. I do not know in total, but I think somewhere in the neighborhood, I would guess—I think this came out in earlier testimony—somewhere in the neighborhood of 15,000.

Mr. DINGELL. I have seen that figure used rather widely, and there are approximately 150,000 practicing physicians in the country; am I correct?

Mr. CAIN. I think closer to 160,000.

Mr. DINGELL. This is roughly a ratio of 1 detail man for every 10 physicians; am I correct?

Mr. CAIN. Yes.

Mr. DINGELL. Now, what controls does the industry impose on the detail men and what do you do with regard to representations that are made by them orally to physicians?

Mr. CAIN. I can only cite, Mr. Dingell, the experience in our own company.

I have forgotten who it was on the committee that asked the question earlier.

I think it was Mr. Schenck who asked about the quality of the detail men.

We try to obtain men with backgrounds in pharmacy or premedicine or chemistry. Those men, before they are ever put into the field, are brought into the home office and given a period of intensive train-

ing by our medical staff, by our research people, by our pharmacologists, on the different drugs that they will be detailing. They are then sent out under supervision of trained supervisors in the field. They receive weekly bulletins on information of a scientific nature on drugs, new developments, literature, so forth and so on. They are held strictly accountable for what they represent regarding our products, as well as competing products, and, quite obviously, based on your experience as well as mine, you quickly learn the people you can depend upon for accurate and thorough and reliable information.

Mr. DINGELL. Now, let me ask you this question——

Mr. CAIN. Pardon me, may I finish?

Mr. DINGELL. Certainly.

Mr. CAIN. They are also brought back for a period of periodic review, training, and instruction at frequent intervals of not less than every 2 years, and we have sales meetings at least once a year, mostly devoted to reinstructing these men as to what is happening, and they are brought up to date as to recent developments in medicine.

Mr. DINGELL. Now, in the field of securities, the sale of securities, I am sure you know that we license security dealers, and I am sure you are familiar with the fact that the Securities and Exchange Commission very closely supervises security salesmen?

Mr. CAIN. I understand that, but I am not familiar with it.

Mr. DINGELL. But there is no one other than the company which employs these men who supervised their qualifications, for example, whether they are registered pharmacists?

Mr. CAIN. We select the best men we can get and train them accordingly. It is our responsibility.

Mr. DINGELL. I am aware that your company does, but I am sure you are also aware that there are other companies that are not so ideally situated insofar as having means to secure competent people or some perhaps might not even have the inclination to secure——

Mr. CAIN. Mr. Dingell, I cannot sit and pass judgment on that statement.

Mr. DINGELL. I make the statement, but the simple fact of the matter is when a man wants to buy $100 worth of stock, he has to get it from a licensed broker-dealer, and if he wants to buy a $2 prescription, it may have come through a detail man who has no licensing supervision over him whatsoever; am I correct?

Mr. CAIN. The drug comes through the route, Mr. Dingell, of the pharmacist on prescription of the doctor, not through the detail men.

Mr. DINGELL. But what I am trying to find out is what scrutiny is given to what the detail man says when he visits the doctor behind closed doors?

Mr. CAIN. I have already told you that.

Mr. DINGELL. What supervision do we have over the claims that he might make on behalf of the drug?

Mr. CAIN. I have already answered that question, Mr. Dingell.

Mr. DINGELL. The best efforts that your company can make, I am sure, and I am sure that most other companies try to do the same thing, but what happens if he makes exaggerated claims and is not caught, or what happens if you receive no complaint on a matter of this sort, or what happens if, through some fluke, he gets in without proper supervision?

The problem is very real, is it not?

Mr. CAIN. Mr. Dingell, the doctor is an informed, intelligent, learned, practicing physician.

Now, if the man makes one mistake, the doctor is the first one that is not going to let him back in.

Incidentally, your problems in the security field are such that lately I notice in the paper we had a loss of $280,000 worth of securities.

Mr. DINGELL. Now, the other question I wanted to ask was:

Do you know what is spent on drug advertising in this country in total?

Mr. CAIN. Mr. Dingell, very fortunately, I was in the room this morning when you asked the question about Mr. Beesley's company.

Unfortunately, Mr. Beesley did not have the answer for his company, but I took the trouble to have one of our men who is down here with me to call North Chicago, and, for your information and only because I am here as a witness before the committee would I divulge this rather, what we would call, trade secret.

Last year our budget——

Mr. DINGELL. I did not ask for your company particularly, but I wanted the industry generally.

Mr. CAIN. I am glad to tell you. I do not have the industry information generally.

Last year our budget for journal advertising was $2,275,000, and, to complete that statement, our research expenditure was close to $11 million.

Mr. DINGELL. I am delighted to hear that.

Mr. CAIN. Thank you.

Mr. DINGELL. The reason is that the Senate Antitrust Committee came up with a figure that 24 cents on the sale's dollar was spent on advertising by the drug industry and 6.3 cents of the budget was spent for research.

Mr. CAIN. Mr. Dingell, there were some statements made in the statistical testimony of the Senate committee that I cannot quite agree with.

Mr. DINGELL. I am happy to hear that you set the record straight on your excellent company.

I appreciate your kindness in being before the committee today.

By the way, I noticed that when my bill, to which you referred in your testimony, was before this committee previously, that neither you nor any member of the Pharmaceutical Manufacturers Association appeared in opposition or submitted any testimony in opposition.

Mr. CAIN. We filed a letter, Mr. Dingell.

Mr. DINGELL. Oh, you filed a letter?

Mr. CAIN. Yes, sir.

Mr. DINGELL. But did not appear in opposition to the bill?

Mr. CUTLER. We filed the letter of Dr. Klumpp that is attached to Mr. Cain's statement.

Mr. DINGELL. I see.

I have a copy of the transcript, and it does not indicate that you were in opposition.

Mr. CUTLER. It would not show up in the transcript, sir, but it was filed on September 21, and I believe it will appear in your record when it is printed.

Mr. DINGELL. Thank you very much.

The CHAIRMAN. That presents another problem. You say it is not in the record of hearings of 1961?

Mr. CUTLER. I believe all that Congressman Dingell has is the typewritten transcript. We filed the letter on September 21.

The CHAIRMAN. Mr. Clerk, were those hearings printed?

Mr. WILLIAMSON. No, sir.

Mr. DINGELL. I believe the hearings were not concluded, Mr. Chairman.

I asked the same question.

The CHAIRMAN. If the letter referred to has not been included and it is not printed in this record, it should be printed in this record.

Mr. CUTLER. It would be most convenient to have it printed in this record, Mr. Chairman, because it relates so closely to this issue.

The CHAIRMAN. The two exhibits referred to a while ago that would become a part of this record by reference to those hearings will be included in this record.

I thought they were printed.

I did not see any need to print them twice.

If they have not been printed in the other record, let them be included in this one.

(The documents referred to are as follows:)

STATEMENT OF THEODORE G. KLUMPP, PRESIDENT OF WINTHROP LABORATORIES, ON BEHALF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION ON H.R. 6471

My name is Theodore G. Klumpp. I am president of Winthrop Laboratories and a member of the board of directors of the Pharmaceutical Manufacturers Association. I was graduated from the medical school of Harvard University in 1928 and practiced at various hospitals in Boston, Cleveland, and New Haven, where I was on the faculty of the Yale University Medical School. In 1938 I became Chief of the Drug Division of the Food and Drug Administration and served in this capacity until 1941. I was vice president of the United States Pharmacopeia from 1950 to 1960 and was reelected to a second term running from 1960 to 1970. I also served as Chairman of the Medical Service Task Force of the Hoover Commission and am presently a member of the Medical Advisory Committee of the Department of Health, Education, and Welfare's Office of Vocational Rehabilitation. In addition, I was Chairman of the Office of Defense Mobilization's Task Force on Employment of the Handicapped.

The Pharmaceutical Manufacturers Association is a nonprofit membership association. Its membership includes approximately 140 companies engaged in the manufacture of ethical pharmaceutical and prescription drug products. These companies account for more than 95 percent of the Nation's total production of such items. No one company accounts for more than 10 percent of the total national output. My own company, Winthrop Laboratories, a division of Sterling Drug Inc., accounts for less than 3 percent of the total national output.

As we stated in our letter to this committee dated August 4, the Pharmaceutical Manufacturers Association supports the objective of full disclosure to physicians. On May 24, 1958, the association adopted a statement of principles of ethical drug promotion, by which our members pledged themselves to a policy of full disclosure to the medical profession with respect to our products. This statement of principles formalized as an industry policy what had long been the practice of the reputable manufacturers. We believe very strongly in this policy because we realize that a physician needs this information in order to fulfill his professional obligation properly when prescribing our products. We endeavor to disseminate this information through all appropriate channels. A copy of these principles is attached to my statement today.

The purpose of H.R. 6471 is to promote such disclosure. This purpose is entirely consistent with the established policy of the Pharmaceutical Manufacturers Association. Although we believe that the bill in its present form is extreme

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and would be unworkable, we also feel that with certain modifications H.R. 6471 can be made to achieve its intended purpose.

Section 15 of the Federal Trade Commission Act now provides that if an advertisement of a drug to the medical profession sets forth the formula of the drug quantitatively it shall not violate the act unless the advertisement contains a false representation of a material fact. This section expressly provides that "labeling" of a drug is not advertising and, therefore, not subject to the jurisdiction of the Federal Trade Commission. These provisions of section 15 spring from congressional recognition that physicians constitute a special audience because they are all highly trained professional people. Moreover, these provisions reflect congressional awareness and appreciation of the unique role that the Food and Drug Administration plays for physicians by seeing that all relevant information concerning drug products is readily available to physicians in drug labeling. Thus, Congress, on the one hand, has charged the Federal Trade Commission because of its knowledge and expertise in advertising to see that advertisements to the medical profession contain no false statements. On the other hand, Congress has charged the Food and Drug Administration because of its knowledge and expertise in drugs to see, through the labeling of these products, that the medical profession is promptly, fully, and properly informed concerning them. This clear and express dichotomy of jurisdiction and function between the Federal Trade Commission (advertising) and the Food and Drug Administration (labeling) is based upon the realization of the precise role and purpose of the respective Federal agencies and reflects an abiding congressional wisdom.

H.R. 6471 would delete the foregoing provision of section 15 of the Federal Trade Commission Act dealing with advertisements of drugs that are disseminated only to the medical profession. It would also require that all advertisements of prescription drugs would be "misleading in a material respect" and, therefore, subject to suit by the Federal Trade Commission if they did not list the side effects and contraindications of the drug. In addition, H.R. 6471 directs the Commission to prescribe "such rules and regulations as may be necessary" to administer these provisions. Even though the side effects and contraindications of drugs are and have traditionally been reported in drug labeling in the amount of detail and often in the precise language required by the Food and Drug Administration, H.R. 6471 would make each advertisement of a prescription drug cover these same subjects in such detail and in such language as the Federal Trade Commission may deem necessary.

It is plain that H.R. 6471 seeks to make a radical change in congressional policy and this committee will, of course, give it the serious consideration that such a proposed change warrants. From the preceding analysis of the existing law and the provisions and effect of H.R. 6471 it would seem that the proponents of H.R. 6471 feel either that (a) the congressional recognition of the medical profession as constituting a special audience insofar as drug advertising is concerned is no longer warranted or (b) physicians are prescribing prescription drugs merely on the basis of advertisements about them and without consulting either their professional experience or available literature. We believe that neither of these assumptions is in fact valid.

No one needs to describe at length the very high and ever increasing standards of education and training that prevail in our medical schools and among our medical licensing boards and commissions. Likewise, the ever increasing and ever successful efforts of the Food and Drug Administration as well as nongovernmental groups such as the American Medical Association and the United States Pharmacopoeia to achieve full, prompt, and uniform disclosure, and dissemination to physicians, of all relevant information concerning drugs, their activities and effects certainly does not need to be described in detail to this committee. In addition, we note that, concerning physician's prescribing practices, the American Medical Association—the Nation's largest and leading association of physicians—has objected to this committee concerning H.R. 6471 that the physicians of America deem the allegation or implication that they are prescribing drugs without having sufficient information about them to be completely without foundation.

We shall now consider the particular provisions of H.R. 6471. After serious and full consideration of these provisions we feel that as presently written they fail to recognize the function of medical advertising and do not give sufficient weight and consideration to the other ways in which a physician gets his information about prescription drugs.

In various stages of my own career I have been a physician reading medical journal advertising and other information about drugs; I have been in charge of the Food and Drug Administration's Drug Division regulating what pharmaceutical companies must say and must not say to the physician in labeling their products; and I have been an officer of one of the companies being regulated. I hope that with this experience and with my experience as an officer of the United States Pharmacopoeia I can give you a balanced view of the problem of journal advertising and the effects that H.R. 6471 would have on this advertising and on the established lines of communication between manufacturer and physician.

The most important point is that medical journal advertising is only one of the physician's many sources of information about drugs. He is trained as a medical student and as an interne in the properties and utility of all the principal drugs then existing. In active practice, physicians supplement this training by regular reading of the medical journals, which publish disinterested evaluations of the newest drugs, written by toxicologists, clinical investigators, and others who write according to rigid standards of accuracy and objectivity.

In addition, the physician receives a wide range of information directly and indirectly from the pharmaceutical companies. With respect to new drugs these companies give physicians a full statement in brochure form of all available information concerning the product in question. Before releasing this brochure the company must submit it to the Food and Drug Administration. The final version reflects the views and modifications of the Food and Drug Administration and is disseminated as specified by the agency. In effect, this brochure is an approved documentary report of all aspects of the drug including indications, dosages, methods of use, clinical and other experience, side effects and contraindications. The size and content of these brochures will vary with each product. These brochures, of course, must be kept up to date. The procedure concerning the content and dissemination of revisions is precisely the same as the procedure outlined above for the initial brochure.

It is pertinent here to mention the recently announced plan of the American Medical Association and the United States Pharmacopoeia to put these brochures in uniform style, size, and format and to distribute them through their own facilities to physicians and pharmacists. This will go even further to assure that the physician has before him a handy and usable form all the information about side effects, contraindications and other matters that the Food and Drug Administration deems to be desirable.

This plan should be in effect next year and will undoubtedly increase the already great impact and authority of these brochures in the minds of physicians. In addition to brochures the companies send the physicians letters, samples and other detailed information concerning their products. They also have so-called detail men make professional visits in which they can answer the doctor's questions face to face, and provide him with any additional information he may desire.

The great majority of pharmaceutical companies are extremely careful in the information they transmit to doctors. They know that their most priceless asset is the confidence of the doctors in their integrity, a confidence built up by years of professional experience with the company's products and with the accuracy, objectivity and completeness of the information the companies supply to him. As a doctor and as a former Government official, I can affirm that the standard of integrity of the pharmaceutical companies matches the high standard of the medical profession and of the Government service.

Thus, entirely apart from what the physician reads in a medical journal advertisement, he has at his command from the manufacturer a vast quantity of detailed information about each drug whether it be a new drug or an old drug. In judging the accuracy and completeness of this information he may rely not only on the knowledge of the integrity of the particular manufacturer, but also on the close control exercised by the Food and Drug Administration.

I have brought with me these posters on which we have mounted all the information Winthrop Laboratories has furnished to doctors about two of its principal drugs, Hypaque, and Levophed. (At this point appropriate comments will be made describing each piece of material, including references to side effects, dosage, contraindications, etc.) [1] As can be seen from this exhibit it is virtually impossible, even if it were desirable, to include in an advertisement all

[1] When the witness appears before the committee he will introduce certain exhibits and describe them to the committee.

the information concerning the indications, actions, warnings, side effects, contraindications, etc. Thus, any suggestion or implication in the advertisement to the effect that it does tell the whole story would in most cases be misleading to the detriment of the physician and his patient. A substantial portion of drugs cannot be properly and safely administered without accurate knowledge on the part of the physician of extensive directions for use, contraindications and possible untoward effects. Full information concerning these points can be presented not infrequently only in several pages of written matter. Who is to judge what excepted portion of this information is enough to satisfy the varying needs of practicing physicians? For one patient of a physician, one direction or warning may be vital, for another, some other portion of the whole story may be critically important. Anything less than the whole story may only succeed in conferring a false sense of security and because of this a simple reminder advertisement may be transformed into something that can be misleading. I need not remind this committee that a little knowledge is a dangerous thing and that anything less than the whole truth may do more harm than good. Yet, in its day-to-day practical applications, H.R. 6471 would require that "the partial story" be presented as if it were, in fact, "the whole story." Moreover, these requirements of H.R. 6471 would tend to undermine the traditional and highly effective means of communicating such information to physicians thereby impeding the current and planned efforts of the Food and Drug Administration and others to make the traditional system even more effective and reliable.

With this background, I hope the members of the committee will be able to appreciate the role of medical journal advertising in its proper relationship to the other information which the physician receives from the manufacturer and other sources. The medical journal advertisement is primarily intended as a reminder. It calls the physician's attention to a drug about which he already possesses detailed written information. As the American Medical Association has pointed out in its letter concerning H.R. 6471, no physician does or should prescribe a drug solely on the basis of what he reads in a medical journal advertisement. By the same token, no physician relies on a medical journal advertisement to include all the pertinent information about a drug that he requires in order to prescribe it. Thus such advertisements cannot and should not be judged by the standards of an SEC prospectus, as if it were the only or even the principal source of the doctor's information about a drug. Those who urge that medical advertisements should be judged by the standards of an SEC prospectus are impliedly attacking the physicians' professional reliability and integrity.

Once the proper role of medical journal advertising is understood, it becomes readily apparent that there are important practical limitations upon what the pharmaceutical manufacturer should be required to include in the advertisement:

(*a*) First and foremost, the advertisement obviously cannot include all the pertinent information about a drug that is relevant to a doctor's decision on whether to prescribe it. A medical journal advertisement is usually a half page or a full page in size. Smaller companies may only be able to afford a quarter page or less. From the poster I have shown you it is obvious that all of the pertinent information which the company supplies to the physician—and which the Food and Drug Administration properly requires him to supply—cannot possibly be printed on a quarter page, a half page or a full page, except in type so small that it cannot or will not be read. The problem is very much like trying to print the Declaration of Independence on the head of a pin.

(*b*) Apart from the physical limitations on the amount of information that can be squeezed into a medical journal advertisement, there is the problem of readability. There is no law requiring pharmaceutical companies to buy advertisements in medical journals. They are bought only because they perform a commercial function—the function of calling attention to a drug about which the doctor has already been informed through other means of communication. They will perform this function only if they attract the doctor's eye and if the copy can be readily perused. If the copy is too long, he will not read it any more than you or I would read the details of an insurance policy or of an SEC prospectus if they were crammed into an advertisement. The advertiser soon learns whether or not his advertisements are read. When they are not, he discontinues such advertising. Like most practicing physicians, I have a limited amount of time for medical reading. The general custom is to glance through the advertisements and devote most of the available reading time to the scientific articles. If the advertisements are clogged with detailed reading matter, like my colleagues, I won't bother to read them at all.

(c) In this connection, it should be noted that pharmaceutical advertising is the principal source of income of the medical journals. The scientific articles appearing in these jounrals are one of the most important sources of current education for the medical specialist and general practitioner. In my opinion, the proposed requirements placed on medical journal advertising will serve to destroy the commercial function of such advertising. This means inevitably that many of the medical journals will be forced out of business. If this happens, a valuable source of medical knowledge would be lost to the profession. As an example, I have attached a copy of an article in the New York Times of August 18, 1961, announcing the demise of Medical News, a weekly newspaper of the medical profession, because of advertising cutbacks by manufacturers.

In addition, a decrease in the number of medical journals without question will result in a serious delay in bringing important scientific communications to the attention of the medical profession. A personal experience may be cited to illustrate the point. In 1927 when the number of medical journals were fewer, I reported the discovery of the successful treatment of sprue, a fatal disease. Because of the backlog of papers awaiting publication, it took 9 months for the article to appear in print. No one can say for certain but it is likely that some patients with sprue died because of this delay. If the number of journals is seriously reduced, it can also be forecast that many scientific communications will never be printed because the existing journals will be forced to reject scientific papers to hold their own pages to manageable proportions. Thus, medical journal advertising serves a valuable function in bringing scientific reports promptly to the attention of physicians. Your committee will want carefully to weigh these serious adverse effects on medical communication which passage of this bill would most certainly bring about.

(d) Since it is impractical to place all information in the advertisement, some information must necessarily be omitted. For example, some drugs may be useful in treating a variety of diseases but the manufacturer may wish to call the physician's attention to the use of the drug in a single disease. We see no reason why he should not be permitted to do so. Similarly, most drugs have side effects or various types on various classes of patients, some of them extremely important and some of much less importance. They cannot all be listed in the advertisement in such a way as to convey their relative importance and significance to the medical reader except by a detailed discussion, similar to that included in the package insert or brochure, which would take up too much space in the advertisement. H.R. 6471 makes no provision for this problem.

(e) Lastly, there is the problem of overlapping jurisdiction. The Food and Drug Administration already has full jurisdiction over the content of all information referred to in H.R. 6471 and sees that it is transmitted to physicians in appropriate forms. In view of the matters outlined in this statement no useful purpose would be served by also giving the Federal Trade Commission power to require that the same subjects be covered to its satisfaction in medical journal advertisements.

As I stated at the outset there is no disagreement between the Pharmaceutical Manufacturers Association and the proponents of H.R. 6471 concerning the importance of full disclosure to physicians. We do disagree, however, on the means by which advertisements should properly be required to achieve this purpose. I have attempted to set forth the Pharmaceutical Manufacturers Association's position in this statement. To resolve the problem and at the same time to assure that medical journal advertising refers the physician to the appropriate literature about side effects and contraindications we would suggest that the following amendment be made instead of the amendment set forth in H.R. 6471:

"*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled*, That subsection (a) of section 15 of the Federal Trade Commission Act is amended (1) by striking out the period at the end of the last sentence of paragraph (1), and (2) by inserting in place thereof the following: "and, if it is an advertisement of a prescription drug, contains the following statement: 'Before prescribing be sure to consult the manufacturer's literature for information about possible side effects and contraindications'. For the purposes of this paragraph a prescription drug is one intended for use of man that Federal law requires to be dispensed only upon the prescription of a practitioner licensed by law to administer such drug".

We submit that the above amendment to the present section 15 would (a) adequately remind the physician that the advertisement of a prescription drug does not necessarily tell the full story of the product and refer him to the

appropriate source of such story, (b) preserve the accepted character of prescription drug advertisements as essentially reminder pieces that present only salient facts, (c) allow the medical journals to continue their important role of providing the physicians with current scientific reports, (d) draw increased attention to and thereby further the full disclosure program of Food and Drug Administration and other groups, (e) preserve intact the traditional roles and functions of the Federal Trade Commission and the Food and Drug Administration, and (f) allow manufacturers and editors to make their advertising judgments with certainty as to the law's requirements.

[From the New York Times, Aug. 18, 1961]

ADVERTISING: DRUGS IN A CUTBACK

(By Peter Bart)

The drug industry has been going through some trying times in recent months. Senator Estes Kefauver, Democrat, of Tennessee, and other political figures have kept up a barrage of criticism directed against the pharmaceutical companies. And a bewildering variety of new rules and regulations have been adopted in an effort to correct alleged abuses by drugmakers.

Meanwhile, many drug producers have complained about a squeeze on their profits arising out of increased operating costs. And only yesterday antitrust charges were filed against three major companies Chas. Pfizer & Co., Inc., American Cyanamid Co. and Bristol-Myers Co.

As a result of all this, a number of leading drug producers have quietly been cutting back on advertising. The reductions have not been dramatic—but they have been heavy enough to hurt the vast medical press.

It was learned yesterday, for example, that Medical News, a weekly newspaper of the medical profession, had been forced to suspend publication mainly because of the drug companies' cut in advertising. Its staff of 21 persons was told yesterday of their dismissal.

STARTED IN 1955

Medical News started publication in 1955 under the sponsorship of a big drug producer, Ciba Pharmaceutical Products, Inc. Last year Ciba cut the publication loose and it has operated as an independent journal since then. Scope, another well-known medical magazine published by a leading drug company (Upjohn Co.) also was cut loose last year, and ceased publication.

An official of Medical News said yesterday: "We had sufficient capital to make a go of it. But the ads just weren't there." The newspaper, which was sent free to 150,000 practicing physicians, depended on advertisements for all of its revenue.

Several other leading publications aimed at doctors also are feeling the advertising pinch. A spokesman for Medical Tribune, the rival to Medical News in the weekly field, acknowledged that advertising was down in the first half of 1961.

An official of the Journal of the American Medical Association said his publication had carried significantly fewer advertisements so far this year than it had last year. The publisher of another medical publication, who keeps a tabulation of advertising linage in his field, said advertisements were down from 10 to 30 percent in medical magazines during the first half of 1961.

DIFFICULTIES ENCOUNTERED

One key reason for the reduction in advertising by major pharmaceutical companies stems from their increased difficulties in introducing new products. The Government has imposed a number of new rules providing for increased testing of new drugs both by the producers and by the Government. All this has slowed the flow of new drugs into the market.

Because drug companies have not been able to introduce as many new drugs as before, they therefore have not had to advertise them in medical publications.

At the same time, drug houses have had to divert some advertising funds into revising their overall promotion effort to meet new Government rules. The Merck, Sharpe & Dohme Division of Merck & Co., for example, is spending $250,000 to revise its promotional literature. These revisions were required by

Government regulations providing that all circulars sent to doctors contain so-called contraindications—hazards, side effects and precautions.

Drug companies in recent months have been buffeted by criticism of their high promotion expenditures—criticisms mainly generated by Senator Kefauver's investigation. Thus, by cutting back on advertising, the pharmaceutical companies not only save money but also can contend that they are doing so in the hope of bolstering their industry's public image.

MULTIMILLION MERCHANTS

Top radio advertising officials will receive an education in retailing next month at a series of management conferences sponsored by the Radio Advertising Bureau, Inc. The bureau has completed a study of the Nation's "multimillion-dollar merchants" and plans to detail its findings at the meetings. Officials who attend the conferences will be told of the basic business views held by top retailers. They also will hear about the basic problems faced by the merchants. Eight management conferences will be held between September 7 and October 13 in various cities.

STATEMENT OF PRINCIPLES OF ETHICAL DRUG PROMOTION (PASSED BY PHARMACEUTICAL MANUFACTURERS ASSOCIATION BOARD OF DIRECTORS ON MAY 24, 1958)

We, members of the Pharmaceutical Manufacturers Association, recognizing our responsibilities and obligations to promote the public welfare and to maintain honorable, fair, and friendly relations with the medical profession, with associated sciences, and with the public, do pledge ourselves to the following statement of principles:

(1) Prompt, complete, conservative and accurate information concerning therapeutic agents shall be made available to the medical profession.

(2) Any statement involved in product promotional communications must be supported by adequate and acceptable scientific evidence. Claims must not be stronger than such evidence warrants. Every effort must be made to avoid ambiguity and implied endorsements. Whenever market, statistical or background information or references to unpublished literature or observations are used in promotional literature, the source must be available to the physician upon request.

(3) Quotations from the medical literature or from the personal communications of clinical investigators in promotional communications must not change or distort the true meaning of the author.

(4) If it is necessary to include comparisons of drugs in promotional communications, such comparisons must be used only when they are constructive to the physician and made on a sound professional and factual basis. Trademarks are private property that can be used legally only by or with the consent of owners of trademarks.

(5) The release to the lay public of information on the clinical use of a new drug or to a new use of an established drug prior to adequate clinical acceptance and presentation to the medical profession is not in the best interests of the medical profession or the layman.

(6) All medical claims and assertions contained in promotional communications should have medical review prior to their release.

(7) Any violation of these principles brought to the attention of the president of the Pharmaceutical Manufacturers Association shall be referred by him to the board of directors.

ABBOTT LABORATORIES,
North Chicago, Ill., November 14, 1961.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: On behalf of Abbott Laboratories, I would like to present our position on H.R. 6471, 87th Congress, and to correct the record in certain respects.

First, Abbott Laboratories, as a member of the Pharmaceutical Manufacturers Association, fully subscribes to the statement submitted on September 21, 1961, by Theodore G. Klumpp on behalf of this association. For the reasons stated by Dr. Klumpp, we oppose H.R. 6471 in its present form as adverse to the public

interest. Since no purpose would be served in doing so, I will not repeat these reasons in this statement.

Second, of special interest to Abbott Laboratories, I would like to express our concern about certain misleading implications which appear in the record of the proceedings of this committee on H.R. 6471, particularly as they apply to us.

Specifically, we feel impelled to correct the record concerning the promotion and advertising of our diuretic drug Oretic, the generic name of which is hydrochlorothiazide. As the record stands now, the public might be misled into thinking that doctors have not had the opportunity of seeing our printed precautions on this drug. Such a conclusion would be totally false.

In his letter to the Honorable Oren Harris, chairman of the Committee on Interstate and Foreign Commerce, dated September 1, 1961, the Honorable Paul Rand Dixon, Chairman of the Federal Trade Commission, listed an advertisement for Oretic appearing in the October 22, 1960, issue of the Journal of the American Medical Association as an example of an advertisement of one full page not devoting any space to a discussion of side effects and contraindications, although the drug may produce side effects and there are certain contraindications to its use. The overall category within which Commissioner Dixon listed this drug was entitled as follows: "(A) Copies of Advertisements Which Illustrate the Failure To Deal Appropriately in Advertising With the Subject of Drug Side Effects and Contraindications." Speaking of this category, Commissioner Dixon stated "* * * only the pharmacist ordinarily would have the opportunity of seeing the manufacturer's printed warning of side effects and contraindications for his products that appear on the package inserts."

As applied to Oretic this is a completely misleading statement. Commissioner Dixon apparently failed to investigate our promotional activities in connection with Oretic. As is our general policy, in the case of Oretic we took great care to insure that physicians were fully informed as to the use of this drug, including side effects and contraindications.

Let me briefly recite what we did to inform the doctor about the advantages and precautions associated with the use of Oretic. This product was first marketed on July 2, 1959, some 15 months prior to the advertisement referred to by Commissioner Dixon.

Simultaneously with the marketing of Oretic, we published and distributed a 16-page physician's reference booklet on this product. The subjects covered by this booklet were chemical characteristics, metabolic effects, indications, dosage and administration, how supplied, precautions and side effects, clinical studies, pharmacology, and references. There are two full pages under the heading "Precautions and Side Effects," and in addition precautions are also discussed in other sections of the booklet. This booklet was approved by our medical department and reviewed by the Food and Drug Administration. We are satisfied that it contains a thorough discussion of the proper use of Oretic.

We have distributed approximately 120,000 (as of October 16, 1961) copies of this booklet. The method of distribution was as follows: On July 2, 1959, we sent approximately 80,000 copies to our salesmen for personal delivery to physicians in connection with routine calls made by the salesmen. The balance was distributed in response to requests for additional copies or requests made directly to the company. A copy of our Oretic physician's reference booklet is attached to this statement and marked "Exhibit A."

In addition, we printed and distributed 156,000 copies of a product file card on Oretic. These were distributed at the time of announcement of the drug by direct mail to pharmacists and through our salesmen to doctors. When our supply was depleated, we reprinted approximately 38,000 additional copies of our file card. This card contained abbreviated information about Oretic and, also, in heavy print, an instruction to ask an Abbott representative for a copy of the Oretic physician's literature containing a complete guide to administration and dosage, clinical and pharmacological data, and important precautionary information.

We also sent each salesman a 16-page Oretic portfolio prepared for the purpose of aiding the salesman in his discussion of the product with the doctor. This portfolio included a detailed statement of side effects and precautions in the use of Oretic.

On June 29, 1959, we mailed over 100,000 sample packages of Oretic to our salesmen for personal delivery to doctors. Each sample package contained a printed insert with six panels of written matter, including precautions, plus a notice to the doctor to consult complete precautionary information in Oretic

professional reference literature. Additional sample packages were mailed to salesmen on request.

On July 25, 1959, our first journal advertisement for Oretic appeared in the Journal of the American Medical Association, with a circulation of 178,000 doctors. This was not an ordinary ad. It contained eight full pages, including a complete statement of precautions and side effects. The ad was in the form of an insert which could be detached by the physician and retained for future reference. In order to insure complete coverage of all physicians, we sent on September 18, 1959, to approximately 106,000 physicians by direct mail a copy of the 8-page folder which had previously appeared in the Journal of the American Medical Association. A copy of this folder is attached to this statement and marked "Exhibit B."

In our opinion, the activities described above enabled us to provide information concerning Oretic, including appropriate precautionary information, to all physicians who would be likely to prescribe Oretic, including general practitioners, internists, and selected specialists.

From time to time, of course, Abbott engaged in promotional activities, both by way of direct mail and in journal advertising, designed to remind the physician about the product. Among these activities was the placing of the advertisment referred to by Commissioner Dixon in his letter. The purpose of this advertisement was certainly not to educate the physician about the proper use of Oretic. It was not intended to be a catalog of indications, dosage, clinical studies, chemistry, pharmacology, or precautions and side effects. This could not be done on a single printed page, and to attempt to do so might very well mislead the physician as stated by the American Medical Association in its letter to the committee dated August 10, 1961, to assume that he might safely prescribe drugs solely on the basis of Journal advertisements. Rather, the purpose of the ad was to attract and remind the physician about Oretic. This was done by attempting to show that the "saluretic" effect of Oretic permits a more liberal low-sodium diet. In other words, a hypertensive patient on this drug can have some salt in his food. A copy of our advertisement, which appeared in the October 22, 1960, issue of the Journal of the American Medical Association, is attached to this statement and marked "Exhibit C."

It is inconceivable to us that a physician would undertake to prescribe Oretic solely on the basis of this type of advertisement. If we could not engage in reminder advertising of this nature, this would be tantamount to a legal prohibition against advertising, a strange thought in our free enterprise economy. After all, there is a limit to the number of times we can send a complete product brochure to the physician.

The position taken by Commissioner Dixon in his letter ignores the many ways in which physicians actually are informed about the drugs which they prescribe. For example, in the 1960 edition of the reference work entitled "Physicians' Desk Reference" there appears on Page 609 a brief summary statement of the composition, action and uses, administration and dosage, precautions, and other information on Oretic. Furthermore, there is a notice advising the physician to see product literature for complete precautionary information. Moreover, the generic drug was evaluated by the council on drugs, and this evaluation was published in the January 16, 1960, issue of the Journal of the American Medical Association. The generic drug also is described in the 1961 edition of the work "New and Nonofficial Drugs," published by the Council on Drugs of the American Medical Association. A brief summary of the council's opinion also appears in the July 8, 1961, issue of the Journal of the American Medical Association.

It should be pointed out that Oretic is Abbott's trade name for the generic drug hydrochlorothiazide. Hydrochlorothiazide is a member of a class of drugs generally referred to as "thiazides." The first thiazide diuretic was introduced by Merck & Co. in November 1957. This drug is called chlorothiazide, and is marketed under the trade name Diuril. Hydrochlorothiazide is a derivative of chlorothiazide, and was first marketed by Merck & Co. under the trade name Hydrodiuril and by Ciba Pharmaceutical Products, Inc., under the trade name Esidrix in February 1959. Actually, Abbott Laboratories was the third company to market the drug hydrochlorothiazide. When announced by Abbott in July 1959, the medical profession had already been familiar with this drug for 5 months and with the thiazide family for nearly 2 years.

As a matter of fact, we have had occasion to check the medical literature for published clinical reports made by physicians on both chlorothiazide and hydrochlorothiazide for the period January 1957 to September 1960. We have dis-

covered a voluminous number of reports, a list of which is enclosed with this statement, as exhibit D. Thus, the physician is not obliged to rely upon promotional activities of manufacturers to gain adequate information on the proper use of new drugs. Not only are there numerous reports published in the literature, but physicians also attend medical meetings where they receive firsthand information on new developments in therapeutics.

H.R. 6471 would amend the Federal Trade Commission Act so as to require that all advertisements of prescription drugs contain a conspicuous and truthful disclosure of (i) the quantitative formula of the drug with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contraindications of the drug. Commissioner Dixon recommended in his testimony given on August 2, 1961, that the bill be amended by requiring, also, the disclosure of the efficacy of the drug. In addition, H.R. 6471 directs the Federal Trade Commission to prescribe such rules and regulations as may be necessary to administer these provisions. The effect of these proposals would clearly be to radically change the function of advertising as we know it today.

Regulations issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act currently require that the labeling of prescription drugs contain adequate directions for the use of such drugs by physicians. In essence, H.R. 6471 places all advertising in the same category as labeling. To confuse the functions of labeling and advertising in this manner is actually to destroy the important function of advertising to remind and to attract. Congress should not interfere with the operation of our free economy so drastically as this on the basis of such meager and misleading evidence as has been presented.

We would have no objection, however, to a statutory requirement to include a statement in advertisements directed to physicians indicating that the physician should consult the manufacturer's literature for a full statement concerning the proper use of the drug.

We should like to conclude by reminding the committee that any legislation which it might propose should take into consideration the full story with respect to the way in which drugs are currently marketed, including the requirements of existing law. If advertising is truthful, it serves a valid function in the American society for the drug industry as well as for other industries. The Federal Trade Commission Act is not a proper vehicle in and of itself to prescribe the information which should be given to physicians.

We submit that the combination of the labeling requirements contained in the Federal Food, Drug, and Cosmetic Act, the self-interest of manufacturers acting competitively, and the exercise of responsibility by the medical profession itself, are adequate to protect the public health and insure the dissemination of full information to physicians, an objective which we heartily endorse.

We hereby request that this letter be made a part of the record of the proceedings on H.R. 6471.

Respectfully submitted.

PAUL GERDEN, *Vice President.*

Mr. SCHENCK. Mr. Chairman, if you will yield to me, as I recall, we had only a very short hearing on this bill sponsored by our colleague, Mr. Dingell, I think less than one morning of hearings.

The chairman of our subcommittee was unavoidably away from Washington and you personally presided and adjourned the hearing subject to the call of the Chair.

So, for that reason, I think the hearings have not been printed.

Mr. DINGELL. For the record, Mr. Chairman, may I say that I level no criticism whatsoever at that committee. As a matter of fact, since I was aware of the fact that this other bill was coming, I made no effort, since I thought the committee would not take further action, as we had this other measure, in which I had hoped, and it happily worked out, that the provisions were included here, so I hope this will not be taken as being either critical of the Chair or the committee, and I am appreciative of the courtesy of the Chair in holding the hearings, and, in my opinion, it has worked out better.

Mr. SCHENCK. Mr. Chairman, all I want to point out is that those hearings were not completed, and, for that reason, the hearings were not printed.

The CHAIRMAN. The Chair is always glad to accommodate members of the committee and others, when he can.

Mr. Cain, thank you very much for your presentation here this evening.

Mr. CAIN. Mr. Chairman and gentlemen, thank you.

The CHAIRMAN. Mr. Lyman C. Duncan?

Mr. Duncan, we will be glad to have your statement.

STATEMENT OF LYMAN C. DUNCAN, ON BEHALF OF THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ACCOMPANIED BY LLOYD CUTLER, ESQ.

Mr. DUNCAN. My name is Lyman C. Duncan. I am a vice president of American Cyanamid Co. with primary responsibility for two of its operating divisions, one of which is Lederle Laboratories, a manufacturer of antibiotics, biologicals and pharmaceuticals for more than half a century.

I appear before you as one of the witnesses on behalf of the Pharmaceutical Manufacturers Association. My comments will be confined to section 107, entitled "Biological Drugs," of H.R. 11581.

Biological drugs for human use include the various vaccines, sera, toxoids and so forth which are essential for the protection of man against the scourge of certain epidemic diseases for which no effective treatment has ever been devised. Such products have been subject to strict licensing controls on the part of the Federal Government since July 1, 1902. The licensing jurisdiction is vested in the Public Health Service by the Public Health Service Act of July 1, 1944.

Section 351 of that act forbids the sale, interstate shipment, export or import of any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of man unless the product has been manufactured at an establishment licensed by the Secretary of Health, Education, and Welfare to manufacture it.

Licenses for the maintenance of establishments for the manufacture of such products are issued only upon a showing that the establishment and the product itself meet standards "designed to insure the continued safety, purity, and potency" of the product, as prescribed in regulations.

Licenses for new products may be issue only upon a showing that they meet such standards. The Secretary is given specific authority to prescribe regulations for the issuance, suspension and revocation of all such licenses.

In addition to this licensing control over establishments and products to insure safety, purity, and potency, which is administered by the Public Health Service, biological products for human use are also subject to the adulteration and misbranding provisions of the Federal Food, Drug and Cosmetic Act, administered by the Food and Drug Administration. Indeed, the provisions of that act apply generally to human biologicals, except for section 505, the new drug section.

Section 107 of H.R. 11581 would basically do three things:

First, it would amend section 351(d) of the Public Health Service Act to require, in addition to the present showing of "safety, purity, and potency," a further showing that biological products are also "efficacious under the conditions prescribed, recommended, or suggested by the manufacturer," before licenses may be issued.

Second, the bill also would add a new paragraph (e) to section 501 of the Federal Food, Drug, and Cosmetic Act, under which a human biological would be deemed to be adulterated if it was not prepared in conformity with the Public Health Service Act and the regulations and standards thereunder by a licensed manufacturer and in accordance with such license, or if at any time(1) it is not in conformity with the Public Health Service Act or regulations or standards thereunder, or (2) the expiration date on its labeling has passed, or (3) the license has been suspended or revoked.

Third, the bill would add a new paragraph (n) to section 502 of the Federal Food, Drug, and Cosmetic Act by which a human biological product would be deemed to be misbranded if its packaging or labeling is not in conformity with the Public Health Service Act or with the regulations or standards thereunder.

We are opposed to these provisions of section 107 of H.R. 11581 as nnecessary and unwise and because we believe that a thorough study is required of the many complexities involved in biologicals and their regulation before any changes are made in existing law. There is time for such a study and it should be made.

In the case of biological products, the public already has the protection that this bill proposes for new drugs. The public has this protection by virtue of the strict licensing requirements, per plant and per product, that biological products for human use be shown to be safe, pure, and potent. What problems exist in the regulation of human biologicals are problems of possible overregulation, not underregulation—that is to say, whether the present regulatory system, involving as it does licensing by the Public Health Service and overlapping jurisdiction by the Food and Drug Administration, is overly complex and unduly impedes the development of new biological products needed for the protection of man against disease and infection.

The proposed amendment of section 351(d) of the Public Health Service Act, which would introduce the same concept of efficacy into biological products as section 102 of the bill proposes for new drugs, is unnecessary. Section 351(d) presently requires a showing of "safety, purity, and potency." It is difficult to see what would be served by adding efficacy to those requirements, and confusion is the likely result.

You have heard Dr. Klumpp discuss the problems involved in applying the concept of efficacy to new drugs and the need for appropriate safeguards if the concept is written into the new drug provision. The problem is drastically more difficult in the case of biological products for various reasons.

Biologicals are generally used for the prevention, rather than the treatment of disease. Therefore, you cannot show "effectiveness" by physical results, such as a reduction in fever, or a bettering or worsening of the patient's condition. Instead, the demonstration of "effectiveness" must be largely statistical or else a showing that antibodies

are produced in sufficient quantities to give a reasonable level of immunity. A statistical showing presents problems because of variations in the incidence of a disease and the extent of its severity. For example, clinical tests have demonstrated that following an influenza immunization program, the incidence of flu may be reduced by one-half.

Other tests may demonstrate the incidence to be higher or lower. Who can say, under such circumstances, how "effective" flu vaccine is? After all the years it has been used, the "effectiveness" of flu vaccine is still controversial, yet no one can question the desirability of having the product available for use in the interests of the public health.

Additional problems arise because of variations in individual response and exposure. It is well known that biological immunizing agents are not completely effective because different individuals do not respond in the same way or to the same degree to vaccines, toxoids, sera, and the like. In addition, natural exposure may be sufficiently severe to overwhelm a reasonable level of immunity.

The need to meet emergency situations must also be kept in mind. In such situations manufacturers and the regulatory agency must be able to provide products which may be effective but for which there has not been time to permit thorough clinical study of the degree of effectiveness.

A good example is the experience in 1957 with vaccine for Asian flu. That vaccine had to be produced in tremendous quantities and marketed without evidence that it protected humans against the natural disease, but simply on the basis that it produced specific antibodies in humans.

What I have said only briefly illustrates the need for maintaining flexibility in judging the value of these biological products. Such flexibility must not be compromised by adding a nebulous requirement of "efficacy."

We submit that the existing law, which requires a showing of "potency," adequately meets the needs which the draftsman of H.R. 11581 apparently thought were desirable for the protection of the public against ineffective products.

PMA also opposes the provisions of section 107 of the bill which would deem biological products which do not conform to the requirements of the Public Health Service Act to be adulterated and misbranded under the Federal Food, Drug, and Cosmetic Act. We oppose these provisions as unnecessary because the Public Health Service Act prescribes penalties for violation of its requirements and gives to the Secretary adequate authority to suspend or revoke licenses.

Also, the creation of these additional sanctions under a different act, for violation of the Public Health Service Act, will unavoidably create confusion, particularly since they are inconsistent in various respects with the Public Health Service Act and appear to be based on incorrect presuppositions concerning practices followed under that act.

For example, proposed section 501(e) would deem a biological to be adulterated if at any time the license under which it was manufactured is suspended or revoked. That is inconsistent with the last sentence of section 351(a) of the Public Health Service Act which permits the sale by a person other than the licensee after a license

has been suspended or revoked unless the Secretary gives notice to the contrary.

The proposed adulteration section also is too broad and goes too far, because a license can be revoked or suspended for reasons having nothing at all to do with the safety, purity, or potency of the product. The regulations under section 351 of the Public Health Service Act provide for the revocation of a license if the manufacture of the product is discontinued. Thus, the proposed section 501(e) of the Federal Food, Drug, and Cosmetic Act would have the absurd effect of deeming a product, which was manufactured in accordance with an effective license, to be adulterated if at any subsequent time the licensee simply discontinues further manufacture.

In view of the foregoing comments, the transitional provisions of section 108 of H.R. 11581, which provides when and how the amendments proposed in section 107 will take effect, should be eliminated as unnecessary. In addition, section 108(d), which would permit revocation of existing licenses upon a finding by the Secretary that "there is substantial doubt as to whether such product is efficacious," is objectionable for the reasons heretofore given by Dr. Klumpp in commenting on section 104(b) of the bill which would permit the suspension of effective new drug applications on a finding of "substantial doubt" as to safety or efficacy.

Section 107 of H.R. 11581 would make drastic changes in the law presently governing biological drugs. We oppose them for the reasons I have stated and because we believe that such changes, or any changes, should be made only after a thorough consideration and review by this committee. They should not be made as a result of a few days of hearings.

They should be the subject of intensive consideration of the need for them and of the possible effects which they would have on the availability of biological products. We believe that the field of biological drug regulation needs such a careful study before any legislative change is made.

If such a study is made, we suggest it should focus on two main issues: first, whether the requirements of present law unduly impede the availability of new biologicals to the public, and second, whether the dual regulatory system, involving both the Public Health Service and the Food and Drug Administration, should be continued.

The points which may be considered under those issues include such questions as: (1) Is there at this time any justification or need for continuing strict licensing control over biological products for human use? (2) Would it be desirable to control these products in a manner similar to that used to control new drugs? (3) Should the availability of a new biological product be contingent upon the necessity of the adoption of detailed specific regulations relating to such product, or do such regulations for controlling the manufacture of such product act as a deterrent to innovation and as a premium or mediocrity? (4) Does the present dual regulatory system result in needless administrative confusion and hiatus? (5) Should time limits be imposed for acting on applications for licenses? (6) Should regulations for the issuance, suspension and revocation of licenses for biological products be made specifically subject to requirements for a hearing and judicial review such as provided in section 701 of the Federal Food, Drug, and Cosmetic Act?

We sincerely urge that a careful review of these and other questions involved in the complex field of biological drug regulation be made before any legislation is enacted, and we believe that, pending such review, the adoption of piecemeal legislation as proposed in section 107 of H.R. 11581 would be extremely unwise.

(The biographical sketch relating to Lyman C. Duncan follows:)

LYMAN C. DUNCAN

Lyman C. Duncan, vice president of American Cyanamid Co., with primary responsibility for its medical affairs, has been connected with the pharmaceutical and chemical industry throughout most of his business career.

He was named general manager of Cyanamid's Lederle Laboratories Division in April 1955, and assumed his present duties in November 1960.

Mr. Duncan joined Cyanamid in 1945 as manager of the procedures department in the company's head office. In 1950, he was named manager of the priorities and allocations department and, in 1951, assistant to the president.

From April 1953 until December 1953, he served as general manager of the Petrochemicals Division, and from then until his appointment to head Lederle, he was general manager of the Organic Chemicals Division.

Mr. Duncan was born in Flat Rock, Ill., in 1910. He graduated from DePauw University in 1932 and, 2 years later, obtained a master's degree in economics from the London (England) School of Economics.

Following his graduation, he was with the Ohio Oil Co. until 1937 and an associate editor of Barron's, business and financial weekly magazine, until 1941, when he was called to active duty with the U.S. Army.

During the war, Mr. Duncan served in various administrative posts with the Chemical Corps, rising from second lieutenant to lieutenant colonel. He was discharged in October 1945.

The CHAIRMAN. Does that conclude your statement, Mr. Duncan?

Mr. DUNCAN. That concludes my statement; yes, sir.

The CHAIRMAN. It is pretty difficult for me to rationalize your statement on page 1 with your final statement.

A biological drug, I understood you to say, is a drug for human use in an effort to curtail certain diseases for which there have been no known drug treatment. Is that right?

Mr. DUNCAN. Yes.

Now, what I was trying to say was this, very briefly: That, as medical knowledge has advanced, we developed a whole series of drugs that will treat a great many of the bacterial diseases.

Now, as we narrow down the field, we still have the whole field of viruses where there is no effective drug treatment.

Antibiotics generally will not treat viral diseases. Neither will drugs we have discovered so far. So we, therefore, continue to protect the public against viral diseases by vaccination, by live and modified live and killed viruses which stimulate the development of antibodies in human beings.

I tried to make the point of distinction here as between the treatment of a disease and the attempt to prevent a disease.

The CHAIRMAN. Are you trying to say, then, that these vaccines, toxoids, and so forth, should be dispensed promiscuously?

Mr. DUNCAN. Oh, no.

The CHAIRMAN. I gather from your statement about the study that you thought ought to be made that you indicated that there was some doubt as to whether they should be subject to regulation at all.

Mr. DUNCAN. No. I really said this:

The biologicals are controlled by the Public Health Service Act. It is an act that has different provisions than the Food and Drug Act.

The last time that act was revised, I believe, was in 1944. I am not being critical.

I am just suggesting that before any changes are made, a study should be made of that act, because it is so different from the Food and Drug Act.

As things stand at the moment, the biologicals are controlled by the Public Health Service Act.

Now, technically, there is some overlapping, as I pointed out, because the Food, Drug, and Cosmetic Act also applies to biologicals as medication.

But, in practice, I think, by precedent and general agreement, the biologicals are controlled under the Public Health Service Act by Administrators in the Surgeon General's Office, whereas, of course, the Food and Drug Administration controls the administration of drugs

Now, I have said that, in effect——

The CHAIRMAN. This series of questions you raised should be studied, then, to determine whether it should be controlled under one procedure or another?

Mr. DUNCAN. Exactly; yes, sir.

The CHAIRMAN. All right.

Mr. Schenck?

Mr. SCHENCK. The only question I have to ask Mr. Duncan is that these are all prescription drugs, are they not?

Mr. DUNCAN. They are; yes, sir.

Mr. SCHENCK. All the biologicals and the rest of them?

Mr. DUNCAN. I am positive they are, yes.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. No questions, Mr. Chairman.

A very excellent statement, sir.

The CHAIRMAN. Thank you so much.

Dr. Raymond A. Bauer.

Dr. Bauer, you may proceed.

STATEMENT OF RAYMOND A. BAUER, PROFESSOR AT HARVARD GRADUATE SCHOOL OF BUSINESS ADMINISTRATION, ACCOMPANIED BY PROF. MARK G. FIELD, BOSTON UNIVERSITY, AND LLOYD CUTLER, ESQ.

Mr. BAUER. I am Raymond A. Bauer, professor at the Harvard Graduate School of Business Administration. My professional field is social psychology. I have been a consultant to the pharmaceutical industry, chiefly on problems of marketing and marketing research. I have published many papers in the area of social communications.

For a considerable number of years I did research and directed research in the field of Soviet studies, and am the author or coauthor of a number of books and many articles in this area. During the past several months I have done certain research on problems of the pharmaceutical industry. This research has been done in connection with Arthur D. Little, Inc., for the counsel of the Pharmaceutical Manufacturers Association.

One of these studies is a survey of certain contrasting problems of the American and Soviet pharmaceutical industries.

Copies of the full report, that is this document, have been submitted and I respectfully request that it be inserted into the record.

(See p. 344 for the information mentioned.)

In this study, my colaborator has been Professor Mark G. Field, formerly associate professor of sociology at the University of Illinois, who has just recently joined the faculty of Boston University. Professor Field is an authority on the sociology of Soviet medicine. He has published a book and numerous articles on Soviet medicine including the Soviet pharmaceutical system, and is presently working on a book on the organization of Soviet medicine.

Professor Field is present and will be available to answer questions on points on which he is better qualified than I am.

This study, presenting such a different way of looking at the American pharmaceutical system, illuminate certain social benefits of the American system that get overlooked in much of today's discussion. Briefly stated, the Soviet study reemphasizes in somewhat novel perspective the following social benefits of our system of drug production and distribution: getting drugs to the doctor and patient with minimal delay, assurance of good quality, and assurance of adequate quantities of drugs.

A close scrutiny of the Soviet drug system may well provide a meaningful comparison to our own system and allow us to gain some new insights into our own problems. It is indeed characteristic of any reasonably complex institutional arrangement that it has both advantages and disadvantages. The question is how to maximize the former and minimize the latter.

The lessons of the Soviet scene are intriguing. We have found in both socialist Russia and socialist Czechoslovakia strong complaints over the high prices of drugs, and this in supposedly noncommercial socialist economies. The Soviet system features very conservative promotion of drugs in contrast to our elaborate—and it is contended, sometimes, expensive—methods of promoting ethical pharmaceuticals to the doctor. Quality control of Soviet drugs primarily lies with an independent government inspection system, rather than with the manufacturer. There is no so-called needless duplication of research facilities. Research is done in independent centralized research institutes. Factories are allocated quotas of drugs to produce, for which they receive an assigned "reasonable" profit.

In a word, the Soviet situation seems to approximate the ideal institutional arrangement impiled in many criticisms of our own industry. What are the results?

The Soviet medical press contains repeated complaints over the inadequacies of the promotional system. Doctors are said not to be up-to-date in their knowledge of new drugs, with the result that treatment of patients suffers, and druggists spend needless time compounding drugs which are available in prepared form. Pharmacists are urged to go to the doctors and "detail" them on new drugs, and pharmacists who do so are praised in the press. Official sources advocate advertising drugs via newspapers, radio, and television.

The Soviet medical press also features apparently characteristic instances of batches of drugs of very poor quality caught by the inspection system. At present, active steps are being taken to build quality control into the manufacturing process, and to make it the

responsibility of the firm which produces the product, rather than of the independent inspection system. In other areas of the Soviet economy, we know that this attempt to build quality into the production process has been accompanied by the open espousing of advertised trademarks which will enable the consumer to favor those factories in whose products he has confidence. This process has not so far been extended to the Soviet pharmaceutical industry, but the basic logic of the situation seems to be identical.

I mentioned the fact that the Soviet economy is spared the expense of duplication of research facilities, as compared with this country where every major firm has its own laboratory setup. While there may be certain savings in the development of laboratory products, Soviet sources indicate that a price is paid with long delays in getting products into production because of poor communication between the research institutes and the producing facilities. Delays of 2 to 3 years are cited as typical.

Finally, there are the typical selective shortages which characterize the Soviet economy. While exotic drugs may be in good supply, there may at the same time be shortages of such prosaic items as surgical cotton or boric acid. This has to do with the fact that there is a form of profit system within the socialized economy. Prices are set for the products which a factory is assigned to produce. For reasons which the pricesetter can never fully anticipate, some products are always more profitable than others. This produces the perennial Soviet problem of the "product mix"; the factory produces that assortment of products that optimize its financial picture. The correspondence between this product mix and the planned assortment is usually imperfect.

These several characteristics of the Soviet pharmaceutical system are not a series of isolated features. They represent a systematic contrast with our own system based on brand names, and promotion not only of individual products, but of a company's range of products. It is quite likely that each system can be improved within its own prescribed framework. However, I will say this: the Soviet evidence certainly gives added plausibility to the American brand name manufacturers' defense of his own position.

Let us look back on this picture for a moment from the point of view of the American brand name manufacturer. When pressed on the profitability of individual items in his line, he typically protests that he should not be judged on the basis of individual items. Profitable items, he argues, support other unprofitable drugs which he develops and markets for the convenience of the medical profession and the welfare of patients, often with rare diseases. He will go further and state that his policy is to promote his line across the board. By identifying himself with a line of drugs, he creates confidence in the doctor in his firm and his line of drugs. Part of the cost of promotion must be assigned to establishing this identification. This, in turn, motivates the firm to maintain quality, and to produce a less profitable item. Thus, while there are characteristic costs associated with the brand name promotion of ethical drugs, the defense would contend that these costs are intimately tied to the benefits: drugs rapidly distributed and produced, informed doctors, high quality, adequate quantities.

The failure of the inadequate Soviet promotional system to keep doctors sufficiently informed on new drugs underscores a point that has been made from time to time; namely that the American promotional system must also be considered as part of the system of professional communications of the medical profession. That is to say, drug promotion, like all advertising, has two faces. On one hand, it is a way for the manufacturer to sell something; on the other hand, it is a way for doctors to get knowledge they want. Studies reveal that doctors are not naive about drug promotion. They recognize that it is intended to sell drugs, and that advertising adds to the cost of drugs. Criticism of the volume and cost of pharmaceutical promotion has come from time to time from responsible spokesmen for the medical profession. Other spokesmen, of course, have defended the industry. The rank and file physician seems generally satisfied with the existing system of promotion, except for his persistent dissatisfaction with the volume of direct mail advertising.

My intention in comparing the American and Soviet systems of drug promotion is not, per se, to defend present practices in the American pharmaceutical industry. I know many men in the industry who are actively striving to improve those practices. My intention is rather to show by comparing the American and Soviet systems that every way of doing things has both its advantages and disadvantages. The Soviet experience seems to me to be enlightening.

Before passing legislation which will tend to downgrade the importance of trade names in the United States, I think this committee should give balanced consideration to its advantages as well as its disadvantages.

The CHAIRMAN. Is this the information, Dr. Bauer, that you asked to be included in the record?

Mr. BAUER. Yes, sir.

Mr. DINGELL. Doctor, I think there is nothing in this legislation as I read it that would affect trademarks and trade names.

You might be referring to legislation appearing before Mr. Celler's committee or the Committee of the House or Senate. This has nothing to do with trademarks.

Mr. BAUER. May I say this in general? The thrust of my argument is really toward a system which is based on promotion and the identity of the company and trade names.

Now, just on the basis of the discussion here today, a part of the bill would tend to play up the generic name versus the trade name, is that not correct?

Mr. DINGELL. I do not so read it. I read the bill requires that the generic name be given on the labeling and be given in advertising, but I do not read that it plays it up.

Mr. CUTLER. The law already requires that the generic name be included in the label of the drug. What the bill would do would be to require that the generic or official name be printed with precedence and in the same size type as the trademark name on the label.

Mr. BAUER. Also, I would say that this is a much more general approach which I hope would be useful to the committee and the Congress in light of the fact that problems of this industry are of continuing concern to the Congress.

Mr. DINGELL. Very good, Doctor.

The CHAIRMAN. I see no objection to having it included in the record, although I am not too sure, Doctor, just how much it is going to contribute to consideration of this legislation. I think the general information seems to be a very good thing to have, so let it be included in the record.

(The information referred to follows:)

THE SOVIET AND THE AMERICAN PHARMACEUTICAL SYSTEMS: SOME PARADOXICAL CONTRASTS

(By Raymond A. Bauer and Mark G. Field)

In a speech delivered before the Supreme Soviet of the U.S.S.R. in February 1957, Maria D. Kovrigina, then Health Minister of the Soviet Union, complained bitterly about the retail prices of drugs in the U.S.S.R. Pointing out that over the previous 5 years the unit cost of production in the medical industry had been more than halved (the wholesale prices, for example, of crystallic penicillin had been reduced more than ninefold and of streptomycin more than thirtyfold), she wondered why this did not lead to a corresponding decrease in the retail prices of Soviet pharmaceuticals. Unfortunately this is not the case, concluded Madam Kovrigina: "the prices of some highly effective preparations are four, five, and even six times the wholesale prices. Reducing retail prices of medicines * * * is a very important step. We have made such a proposal to the U.S.S.R. Council of Ministers and we expect our request to be met".[1]

A similar difficulty exists in another Iron Curtain country. A European representative of an American drug firm has become friendly over the years with a highly placed person in Czechoslovakia's state health establishment. This friend exhibited interest in the senatorial investigation of the American pharmaceutical industry, and asked for some of the material from these hearings. "I don't want the full text," he noted, "just the rebuttal material used by your American manufacturers. They say our drug prices in Czechoslovakia are too high."[2]

These complaints have a strikingly familiar ring. In the past few years, the American pharmaceutical industry has been subjected to a great deal of criticism along a similar vein. Specifically, it is charged that:

(1) There is too great a discrepancy between production costs and retail prices of pharmaceuticals.

(2) The research done by ethical drug companies is not only wasteful, because of unnecessary duplication of facilities, but also it is trivial, since it is done mainly for competitive and commercial purposes.

The specifics of the first charge arise from puzzlement as to why advertising and other promotional costs are so high for ethical pharmaceuticals compared to similar costs in other industries. And there is little doubt that these costs are relatively high. According to various estimates, the promotion of ethical drugs amounts to around 20 percent of the manufacturer's price to the wholesaler. This expense supports a large volume of journal and direct mail advertising, and a corps of missionary detailmen whose functions are distinctive to the drug industry. In major drug firms, several hundred or more detailmen may be assigned the duty of informing doctors of their companies' products, and hopefully to persuade them to prescribe the particular products, usually brand named, produced by their firms.

Critics of the American pharmaceutical industry see little justification for price differences between these branded drugs and the unbranded "generic" drugs which are chemically identical in their main ingredients, and which usually are not promoted in any substantial way, and generally sell for less at the manufacturer's level. Regarding the expense of promoting branded drugs as especially unwarranted, the more extreme of these critics argue for reducing promotional activity to some minimum system of announcements of new drugs, with the major job of communicating the drug's characteristics and usefulness to be performed by the medical profession or the government, or both. Brand names, presumably, would be done away with, or become for all practical purposes irrelevant. In short, the first charge is that American ethical pharma-

[1] Speech by Deputy M. D. Kvorigina, Isvestia, Feb. 8, 1957, p. 5.
[2] Told by Walter A. Munns, president of Smith Kline & French Laboratories in a speech before the New York Security Analysts, Inc., New York, Jan. 9, 1962.

ceuticals are overpromoted, and that this overpromotion imposes an unreasonable and unwarranted cost to the public.

A second accusation leveled against the American drug industry concerns the use of commercial research facilities. The cornerstone of this argument is that the major discoveries on which American advances in pharmaceuticals have been based, originated mainly in Government or university laboratories, and not in the drug companies' laboratories. The contention is that certain unprofitable areas (cancer, for example) suffer neglect as a consequence of American pharmaceutical companies' interest in lucrative new drugs. It is further asserted that the secrecy attached to competitive commercial research actually inhibits the rate of discovery of fundamentally new drugs. These critics' conclusion is that as good or better research could be done more economically in independent, noncompetitive laboratories, preferably located in universities or Government institutions.

How valid are these charges? How can we appraise their accuracy? One interesting way is to take a close look at the Soviet system where conditions tend to be just the reverse of those in America. For example, in Soviet Russia drugs tend to be underpromoted and pharmaceutical research is conducted, not by individual drug firms, but entirely by Government-sponsored "institutes." This is why the complaints about retail drug prices and ineffective research in the U.S.S.R. are especially surprising, since the methods employed by the U.S.S.R. for "promoting" and researching new drugs largely parallel those advocated by some critics of the present American system.

In a sense, the Soviet Union, with its governmentally operated and financed, centrally administered, and planned pharmaceutical system, provides us with a readymade experiment on the effectiveness of an alternative method for providing pharmaceuticals to the population of a large-scale industrialized society. A close scrutiny of the Soviet drug system, then, may well provide a meaningful comparison to our own system and allow us to gain some new insights into our own problems. It is indeed characteristic of any reasonably complex institutional arrangement that it has both advantages and disadvantages. The question is how to maximize the former and minimize the latter.

Let us also state at the outset that we have no intention of raising the wornout specter of "socialized medicine," or of socialism, in general. Moreover, since some of what we have to say will seem to be critical of the Soviet medical system, we hasten to say that this is not our intention. All-in-all, we feel that the achievements of Soviet medicine are considerable.[3]

Nor is the quality of Soviet medicine entirely inferior to that in the United States. Admittedly Soviet doctors, for the most part, must content themselves with patently inferior equipment and supplies, but their effectiveness, as testified to by personal experience, and by the opinions of Soviet refugees (in most other respects critical of the Soviet system in general), is considerable.[4]

Informed observers have pointed to certain superiorities of American medical training, but here again the differences are one of degree and there is no reason to categorize Soviet medical training as generally poor.[5]

The supply of doctors in the U.S.S.R. exceeds that of the United States even on a per capita basis. Only Israel does better. There are presently over 400,000 physicians in the Soviet Union; in fact, 1 in every 4 physicians in the world today is a Soviet doctor. In the Soviet Union the ratio of doctors to 10,000 of the population is now 18, whereas the corresponding proportion in the United States in 1955 was 13.2 and declining. As a result, we must import foreign-trained physicians while the Soviet Union will soon be in the position of exporting some of its doctors.

Rather than make general evaluations of the two medical systems, in this article, we are concerned with what might be termed the "comparative institutional approach." We will examine certain specific institutional arrangements and practices that could, if we so desired, be introduced into our mixed economy without moving us along the road to socialism. We shall attempt, as far as

[3] Cf. Field, Mark G., "Medicine in Soviet Land: Its Realities and Challenge." Modern Medicine, vol. 27, No. 14, July 15, 1959, pp. 196–207, and Field, Mark G., "Health Services in the U.S.S.R.," Soviet Survey, No. 35, January–March 1961, pp. 100–105.

[4] Cf. Field, Mark G., "Doctor and Patient in Soviet Russia" (Cambridge: Harvard University Press, 1957), pt. III, pp. 183–220; also "Former Soviet Citizens' Attitudes Toward the Soviet, the German, and the American Medical Systems," American Sociological Review, 20 (December 1955) pp. 674–679.

[5] Cf. The report of the U.S. public health mission to the Union of Soviet Socialist Republics, U.S. Department of Health, Education, and Welfare, Washington, D.C., 1957.

possible, to look upon these arrangements as being analytically distinct from certain features peculiar to Soviet society and the Soviet economy. Empirically, of course, such a separation cannot often be made.

We also feel it is quite significant that the Soviet health authorities themselves are searching for, and to some extent stumbling upon alternatives of their own without abandoning either socialism or socialized medicine. Many of these solutions have a distinctly "capitalistic" flavor. There is little doubt, furthermore, that on the Soviet as on the United States medical scene, the pharmaceutical question is an important and as yet unsatisfactorily resolved problem. In a recent review of the pharmaceutical situation, it was said:" * * * if one follows the medical press carefully over a period of time, the single most important cause of complaints is the poor work of the pharmaceutical industry and (to about the same degree) of the medical instruments industry".[6]

"UNDERPROMOTED" DRUGS

One major criticism of the American ethical drug industry centers, as we have seen, around the high costs of promoting drugs, together with the practice of maintaining brand names and brand lines. The assumptions behind this criticism are more complex than generally recognized, and seem to imply the following propositions:

(1) An adequate noncommercial source of information about drugs can be established without too much difficulty.

(2) If information is reasonably available, physicians will take the initiative to see that they are kept up to date.

(3) The well-informed physician will not be concerned with the reputation of the firm producing the drug, but only with the drug's properties as described in an official pharmacopoeia.

(4) Adequate quality can be insured at reasonable cost by a Government inspection system.

(5) An adequate supply of pharmaceuticals will be produced if reasonable profits are allowed on individual drugs. (This final asumption which at first glance seems remote is a counter to the contention of American industry spokesmen that high profits on some drugs make it possible to maintain a relatively full line, including some medically critical but less profitable items.)

One way of finding out whether these propositions are likely to prove true or false is to see whether they hold true in the Soviet system where drugs are not promoted. Before we do so, however, it might be wise to describe the characteristics of the Soviet pharmaceutical system. If, like the Soviet medical system as a whole, is characterized by extreme centralization and bureaucratization and by the existence of rigidities and slowness in action which, so often, go with advanced bureaucracy. Having overall responsibility for the pharmaceutical system of the Soviet Union are two specialized organizations within the U.S.S.R. Health Ministry. The Pharmacological Committee (itself a part of the Department of Specialized Medical Assistance of the Ministry) primarily an advisory and "expert" organization, has the primary duties of recommending new pharmaceutical preparations and of removing pharmaceuticals from the market when they become obsolete. Within that committee there is a commission "on instructions and informational materials" which presumably prepares literature giving knowledge about the existence and the application of new pharmaceuticals. The second organization concerned with pharmaceuticals is also lodged in the Health Ministry and is entitled the Department of Pharmaceuticals and Medical Technology with a quality inspectorate. The main functions of the department are to insure the standardization of drugs produced in the Soviet Union, to edit the Governmental Pharmacopoeia U.S.S.R. and make periodic additions to it, and to examine complaints of nonstandard production.[7]

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[6] Field, Mark G., "Pharmaceutical, Pharmacies, and Pharmacists in Soviet Russia." American Professional Pharmacist, vol. 25, January, February, March 1959 (January, p. 27); also, Field, Mark G., "Die Pharmazie in der Sowjetunion," Schweizerische Apotheker Zeitung, 95 (April 1957) pp. 303–311.

These articles are worth consulting for the general background of the Soviet pharmaceutical industry. Another useful review is: Schulz, H. G., "Contemporary Conditions in the Soviet Medical Industry," Review of Eastern Medical Sciences (Munich) April–June 1956, pp. 7–17.

[7] For a more thorough description see "Uchebnik Organizatsii Farmatsevticheskogo Dela" (Textbook on the Organization of Pharmaceuticals) (Moscow: Medgiz, 1961).

Neither of these organizations seems to incorporate a specialized, active, and dynamic system for disseminating information about new drug products to the physicians practicing in the U.S.S.R. that in any way parallels the work done by the American drug industry's detail men. Rather the picture appears to be one of general announcements in the medical and sometimes the lay press and other media of mass communications,[8] when a new compound or agent is cleared for production. Special information supplied to physicians often amounts to nothing more than simple one-page "flyers." These steps, it is clear, makes the information minimally available, and presumably the physician with initiative and interest could keep informed thereby.

Unfortunately, this assumption about the physician's initiative and his ability to keep up with new medical products seems to be as unfounded in Soviet society as it is in the United States. The belief that if information or products are made available, he will automatically make use of them is not borne out by the evidence. The expectation that he will dutifully note such drug innovations and promptly prescribe them to the next patient to which they apply seems to be expecting too much under contemporary conditions.[9] Rather, it would seem that more active methods are necessary to force feed this information to physicians. And to some degree, the Soviet medical literature reveals that Soviet medical authorities are well aware of the communication problem and are attempting to take certain steps that will remedy it. Complaints about the inadequacy of information about new products are endemic. Eight such complaints were registered in one source "Meditsinskii Rabotnik (Medical Worker)" [10] during the first 7 months of 1961. The flavor of these complaints can be gathered from the following fairly typical extracts:

"* * * information about new drugs is given irregularly so that practicing physicians do not know about them and are deprived of the possibility of using them. The process of replacing old-fashioned drugs by new and more efficient ones, is too slow." [11]

"It is necessary to point out that as yet physicians and pharmacists are poorly informed about new drugs. Any information is purely accidental. The pharmacological council has advised the State Publishing House of Medical Literature to publish as soon as possible four publications on new pharmaceutical products." [12]

"Too much time is wasted in pharmacies on the compounding of prescriptions, and this is only because the physicians do not know about the precompounded drugs. Obviously, only very few general practitioners follow the literature in which the new drugs are described. On the other hand, pharmacy employees do not inform physicians about existing drugs. *They do not come to the polyclinic and do not promote the new pharmaceuticals.*" [13]

"The head of the Department of the Pharmaceutical Network of the Main Pharmaceutical Administration of the Ministry of Health of White Russia worries. We could invite physicians to meetings of pharmaceutical workers, but they do not come to us, do not listen to us." [14]

This picture is indeed an ironic inversion of the situation in the United States. Missing are the complaints about junk mail and pill peddlers. While there may be difficulties associated with an overpromoted drug system, the Soviet experience indicates that underpromotion produces its own characteristic problems. Clearly, the quotations cited above indicate a high degree of dissatisfaction with the speed with which information about new drugs is disseminated and put to use.

Efforts have been made, in recent years in the U.S.S.R., to give greater publicity to new pharmaceuticals. For example, polyclinics have been requested to set up

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[8] See, for example, the Medical Worker of July 12, 1960, p. 4 for an example of such announcement. Under the title "New Preparation," Dinezin is described as a new drug with antihistaminic effect. It briefly indicates the types of action it has, and the kinds of conditions for which it is indicated. The dosages and form in which the drug is available are given, as well as suggestions for its use. In Medical Worker of Jan. 12, 1962, p. 3, it was announced that the Pharmacological Committee of the Health Ministry U.S.S.R. had assigned new names to some already compounded pharmaceutical preparations of a complicated nature. The chemical compositions were given.

[9] The difficulty of the physician's task of keeping informed while attending to his other tasks is spelled out in Bauer, Raymond A., "Risk Handling in Drug Adoption," Public Opinion Quarterly, vol. 25, winter 1961, pp. 546–559.

[10] Published semiweekly.

[11] Medical Worker, Apr. 4, 1961.

[12] Ibid, June 6, 1961.

[13] Ibid, May 19, 1961, italic added.

[14] Ibid, July 20, 1961.

special exhibits or displays of new pharmaceuticals. According to the Soviet press, however, these displays are often nonexistent. Nor are there listings of currently available drugs, presumably due to the intervals between the appearances of new editions of the official pharmacopoeia.[15]

Not only is the system of dissemination of information taken to task by Soviet critics, but so are the recipients of such information, the physicians themselves, who are criticized for not displaying enough initiative. Recently the Health Minister of the U.S.S.R. said:

"It is absolutely necessary that every physician should know what precompounded drugs there are on the market. It is our important task * * * to criticize those physicians who think that the knowledge they acquired at the university will suffice for their whole life." [16]

As we have seen, some of the remedies proposed by the Soviets (and to some degree implemented by them) appear to be quite orthodox by our standards: publication of pamphlets, exhibits, listings by the Health Ministry and so forth. Even more interesting and significant, however, is the fact that representatives from the pharmacies or from pharmaceutical warehouses or subdepots are now being sent out to the clinics to inform physicians on what new pharmaceuticals are available and, in turn, to find out their needs and requirements. A rose by any other name, these representatives are, doubtless, the functional equivalents of the U.S. drug industry's detailmen. And, significantly, Soviet criticism is leveled at those pharmacies that do not use detailmen, or do not engage intensively in promotional activity, and praise heaped on those that do. For instance, an article in the Medical Worker (Sept. 20, 1960, p. 3) approvingly described how a representative from a pharmacy periodically visited physicians and appeared before assemblies of doctors and provided information about drugs.[17]

Such assemblies make it possible, of course, for the representative to reach a wide range of physicians, since these assemblies take place periodically at the district polyclinics where physicians in the community, all working under one roof, see their patients. One might well wonder, however, whether such mass presentations adequately can replace the person-to-physician presentation provided by the U.S. detailman.

There is a definite but subtle overtone of unsocialism to complaints that representatives of pharmacies are not sufficiently diligent in promoting new drugs. But, even more unorthodox is the proposal of vigorous advertising. Historically, advertising has been regarded by Soviet authorities as a socially wasteful device for foisting off on people goods they did not need. Since this attitude has, of late, undergone some modification, the advertising of pharmaceuticals has come to be advocated as a means for keeping doctors informed. For example, an article toward the end of 1960 complains that new pharmaceuticals do not become immediately available to practicing physicians. Why? Because of "a lack of well established information about medical novelties." The article advocates an information service via press, radio, TV, leaflets, and so forth.[18]

A more recent article entitled "The New Form of Advertisement," had this to say:

"* * * together with such methods of advertising as advertising in the local newspapers, through radio, exhibitions and lectures about new pharmaceuticals * * * advertising in pharmacies will undoubtedly have to be perfected and improved. The most convenient and efficient forms of advertisement must be exploited. There is no doubt about it that these forms of advertisement, radio and tape-recorded announcements, will find most widespread application in our country." [19]

Import for the United States

Soviet experience with a functionally inadequate informational service for pharmaceuticals, and the recent Soviet awareness of the role that can be played by various forms of advertisement (whether detail men or increased advertising activities in the mass media) should not be taken as justification, per se, of any level of expenditure on any one promotional practice. It should alert us, however, to a closer examination of the byproduct of promotional activities in

[15] Medical Worker, June 6, 1961.
[16] Aptechnoe Delo (Pharmaceutical Affairs) No. 2, 1961, p. 65.
[17] On presentations to assemblies of physicians also see the Medical Worker, May 24, 1960, p. 3.
[18] Medical Worker, Nov. 11, 1960, p. 4.
[19] Pharmaceutical Affairs, No. 2, 1961, p. 65.

the selling of pharmaceuticals. A distinction between manifest and latent functions may be useful in this context.[20] The manifest function of promotion, advertising, and detail men, at least in our society, is to sell doctors by persuading them to prescribe a certain product by its brand name. But this, as we have seen, is often looked upon with suspicion as a kind of maneuver that eventually increases the prices of pharmaceuticals. Furthermore, such activity has been criticized as being of no social value and should, therefore, be eliminated. Overlooked is the latent and probably largely unintended consequence of such promotional activities, that is, they serve as transmission belts for new information from the manufacturer to the consumer (i.e., to the physician and his patient). That such a latent function is not superfluous is indicated by the inadequacies (in this respect) of the Soviet system in informing the medical profession about pharmaceutical innovations, and by the efforts made by the Soviet health authorities to create an institutional system that would remedy these inadequacies. In the light of this examination, then, the question arises about the wisdom of a frontal and wholesale assault on current American practices in the Pharmaceutical field. One might ask whether the promotional practices of the ethical drug firms are as antisocial in their consequences as some would have us believe. One might even raise the question as to what might be the social "costs" involved in eliminating these practices. There is no doubt that, in some instances, abuses have taken place. The question is whether the baby should be thrown out with the bath water. Considering the richness of our economy and the value attached to human life and welfare in the United States, we presumably would be even less disposed to tolerate slippage between availability of drugs and their use in practice than the Soviets.

SOVIET NONCOMMERCIAL DRUG RESEARCH

In both the Soviet Union and the United States, the second large area of complaint centers around pharmaceutical research. We have already seen the charges leveled against the American industry. But, what is the Soviet complaint? It is essentially that unnecessary delays are experienced in getting valuable results of pharmaceutical research into effective use by doctors and patients owing, first, to problems in communication between institutes of research and production establishments, and second, to bureaucratics delays, sometimes severe, between governmental testing and evaluation of new drugs and ultimate approval for production.

We hasten to add that the only sure thing about research is that it is inefficient. The very best of organizational setups would almost certainly be marked by easily noticeable inefficiencies. Hence, we would not use these Soviet charges as "proof" of the superiorities of the American research establishment; nor would we argue for or against the virtues of university or governmental research in comparison with commercial research. We submit, however, that the Soviet experience shows that critics of the American industry have glossed over the problems involved in the transition of a drug discovery from research into production.

To anyone familiar with a reasonably technical industry, the steps between laboratory research and production are far from trivial.[21] Under the best of circumstances this involves the close day-to-day collaboration of laboratory, engineering, and production personnel, involving adjustments, redesigning, and rethinking that may go on for months, and perhaps in extreme cases for years before the laboratory product has been debugged in production.

Since Tsarist times, scientific research in Russia and the Soviet Union has been carried out primarily in research "institutes" separate from universities and industry. The closest approximation in the United States might be a Government organization such as the National Institutes of Health. Research in pharmacology takes place in institutes mainly under the aegis of the Academy of Medical Sciences and of the Ministry of Health of the U.S.S.R. Production, on the other hand, takes place in organizations that now are under the control of regional economic councils called sovnarkhozy. An approximate parallel in the United States would result of research were performed in university and Government laboratories, and production accomplished by private firms.

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[20] The clearest exposition of what is meant by these terms can be found in Robert K. Merton's "Manifest and Latent Functions," in Social Theory and Social Structure (Glencoe: The Free Press, 1949) pp. 21–81.

[21] A description of the organizational problems of handling this transition in the American pharmaceutical industry can be found in Lawrence, Paul, et al. "Organizational Behavior and Administration," Haig Chemical Co., pp. 496, ff., Irwin, 1961.

As a result of the Soviet arrangement, there are difficulties of communication and coordination between institute and factory which constitute, if we may take the word of Soviet sources, a major bottleneck in getting pharmaceuticals into production. To quote a recurrent theme in the Soviet medical press: "* * * it is essential * * * that research and production be brought closer together so that research accomplishments may be put into practice more rapidly." [22] A measure of the seriousness of this problem is the fact that in the first 9 months of 1961 this topic was brought up five times in the Soviet monthly journal, Medical Industry.

The picture that emerges is that of an institutional arrangement definitely inadequate to the complexities of converting a laboratory product into something that can be produced economically in volume. Note the tone of the following complaint:

"* * * the chemico-pharmacological establishments are slow in bringing a number of the new pharmaceuticals into production. Many pharmaceuticals which have been approved for use in general practice are not yet on the market. The planning bodies do not perceive clearly enough the conditions which exist in the factories when pharmaceuticals are produced. Representatives of the factories noted that the technical instructions received from the institutes frequently do not meet present day requirements. Quite often when they are followed they cause great difficulties and high financial losses." [23]

Not only are the instructions received from the research institutes often impractical, but apparently it often takes a good deal of time to develop an adequate set of directives.

"It is obligatory that the quality of instructions and other technical documents from the institutes to the pharmaceutical factories be improved. There are cases when factories have to waste considerable time, sometimes even a year, in getting the instructions from the institute spelled out." [24]

Perhaps we may grant the wrap-up of this particular complaint to one Dr. Timakov who spoke as follows:

"* * * We have too few scientific research institutes concerned with the search for new pharmaceuticals. It is a secret from no one that in our country the period from the birth of a new preparation in the laboratory to its introduction into practice is on the average from 3 to 4 years. In some cases it is 7 years." [25]

Dr. Timakov then called attention to a Soviet discovery which was being produced abroad while the technique of production had not yet been mastered at home. He mentioned 14 preparations which had been approved, but only two of which were being produced, and then launched the standard complaint about the extraordinary delays resulting from the institutional separation of research and production.

It may be, of course, that Soviet critics of their own system are over-reacting to its difficulties. But, to some Soviet authorities, at least, the liabilities of the present institutional arrangement are obvious. If it were matched against the American system it is conceivable, but certainly not proven, that the Soviet arrangement could produce, on a ruble-for-ruble, or man-for-man basis, as many or more laboratory products as could the U.S. industry. But, the testimony of the well-informed Soviet sources is that the separation of research from production tends to produce substantial delays in the availability of drugs to physician and patient.

The speed with which the American ethical drug industry can move a drug from research into production offers a sharp contrast to Soviet slowness. Under ordinary circumstances, an American pharmaceutical manufacturer will begin to work on production problems as soon as laboratory and clinical tests suggest the clinical and commercial worth of the drug. The development of production methods, and, in fact, the stockpiling of stores of the drug are usually done in anticipation of approval by the Food and Drug Administration. Thus, in most cases, lag between Government approval and the availability of the drug is nonexistent. Again, one may wonder at the social costs that might result, in the American situation, from an institutional separation of research and production.

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[22] Meditsinskaia Promyshlennost' (Medical Industry), No. 9, September 1961, p. 13.
[23] Medical Industry No. 5, May 1961, p. 63.
[24] Medical Industry No. 9, September 1961, p. 14.
[25] Meditsinskii Rabotnik (Medical Worker) July 5, 1960, p. 3.

The separation of drug research from production in the Soviet Union is not the only cause of delay. An additional cause is the elaborate bureaucratic procedure for the screening of new drugs.[25a] Here, once more, we find repeated complaints in the medical press. The reasons for delay seem to be several: the complexity of the procedure, the conservatism of the criteria employed, and some overloading of personnel and facilities. We find, for example, a Dr. N. Levin complaining in Medical Worker that: "Already 4 years have elapsed since biliarin was proposed. This interval is sufficient to study the drug from all sides, to test it clinically and, having established its useful action, to legalize it and place it into the practice of medicine. But this has not yet been done. The Pharmacological Committee until now has not delivered the drug its 'right to life' and this is why it is not being produced anywhere." [26] Or, that "The Mechnikov Institute has been waiting 2 years for the verification of the immunity of the vaccine * * * " The Soviet reporter attributed the disagreement between representatives of the Controlling Institute and the academic body of the Mechnikov Institute to the lack of a common method of control testing, combined with an adamantly negativistic point of view on the part of the representatives. "They speedily developed a doctrine which amounted to 'to forbid'." [27]

Examples, such as these are probably extreme. We have seen no estimates of the average time required for the screening of a drug. However, the lesson involved is sufficiently straightforward that there is no point in further documentation or elaboration. Neither in this country nor in the Soviet Union has any responsible person denied the need for some form of official screening of drugs. But in both countries there are complaints that introduction of drugs is unduly delayed. Obviously, there are a series of factors to be balanced off against each other: the cost of a more adequately staffed and equipped screening system, the dangers of passing unsafe drugs, the dangers of delaying the introduction of new drugs, and so on. Any such screening system will always consume some time; therefore, proposals to extend the responsibilities of Government screening authorities must be made with realistic consideration of the delays involved and the need for increased facilities and personnel.

Of more interest, in the light of what is known about problems of quality throughout the Soviet economy, is the question of the quality of drugs produced by Soviet production establishments. Unfortunately our direct knowledge is quite incomplete. However, what we do know fits so well with the rest of the Soviet scene that we can perhaps venture to fill in some gaps from our generalized knowledge.

Complaints in the press about the poor quality of Soviet pharmaceuticals are frequent. "The struggle for better quality drugs was renewed with greater strength after the 22d Party Congress," writes one critic.[28] Another asserts, "Our industry does not always produce medicaments of good quality. And so it happened, for instance, that from the overall number of pharmaceuticals which were sent this year for evaluation to the Central Pharmacological Research Institute, more than half were rejected, mainly ampules. The rejects were found especially often in the products of the Khabarovsk and Novosibirsk factories, in the Kharkov factory called 'Zdorovie Trudiashchikhsia,' and in the Moscow factory named 'Semashko.' The above examples show that the workers of the chemicopharmacological industry do not always work conscientiously." [29]

The head of the Biological-Chemical Laboratory for the Standardization of Drugs of the Central Pharmacological Research Institute complained: "Every year, there is an increase in the production of various drugs in our country. Many of them are sent for evaluational testing to the Central Pharmacological Research Institute. In the last year, for example, 112 various drugs were sent to us—ampules, tablets and others. And, it is deplorable that 75 percent of them did not meet the requirements of the official Governmental pharmacopoeia and the technical standards. In the first 3 months of the current year, the Institute received some dozens more of pharmaceuticals and this time again, from the 74 tested, 58 did not meet the requirements." [30]

[25a] Cf. Schulz, op. cit. pp. 10–11 for a description of this system.
[26] Aug. 16, 1960, p. 3.
[27] Ibid.
[28] Medical Worker, Dec. 22, 1961.
[29] Medical Worker, Feb. 24, 1961.
[30] Medical Worker, July 14, 1961.

The fact that there is an endemic problem of quality facing the Soviet drug producers cannot be doubted by anyone familiar with the medical press of that country. The reasons for this problem seem also to be clear. As is generally true in Soviet industry, quality control is not well built into the manufacturing process.[31] The Soviets rely on testing done by an independent inspection system, in this case the "Controlling Analytical Laboratories of the Pharmacological Administration."[32]

Efforts to maintain quality control by policing via an external inspection system has been one of the conspicuous failures of the generally successful Soviet economy. In various ways this failure is being acknowledged throughout the economy. The first signs of corrective steps that might be taken in the pharmaceutical industry have occurred recently. One writer in the Medical Worker stated:

"At the present time, the testing of the quality of medicaments is carried out, as a rule, in the Controlling Analytical Laboratories of the Pharmacological Administration. This work ought to be done first of all in the factories themselves by their technical control branches. It is really there that the necessary conditions should be created for the continuous control of the quality of the entire output. * * * The time has come when we are justified in demanding that the medical industry deliver production only of the first quality. For this purpose it is indispensable to organize closer contact between the industry and the network of pharmaceutical specialists. The managers of factories should give detailed accounts at the meetings of pharmaceutical societies. In the immediate future there will take place an all-union scientific convention in which representatives of the chemico pharmaceutical industry, of research institutes, and pharmaceutical workers will take part. The convention is devoted to the problem of the improvement of the production and control of quality of the medicaments in ampules."[33]

This attempt to get the producing organization to take responsibility for quality has become relatively familiar in recent years in the Soviet Union. To gain perspective, we must both back up a few years and look at the Soviet economy in its overall aspects.

Until the Russian revolution, the experience of both Marxist and non-Marxist economists had been exclusively with capitalistic economies. There was among all economists (among Western non-Marxist economists whose experience is conditioned by modern capitalism there still is) a tendency to take quality for granted. Four decades of running a socialist economy have cured Soviet economists and administrators of this disposition. The central feature of this experience has been the extraordinary difficulty in maintaining quality of products in a socialized economy.

Until relatively recently the task of inspection was left in its virtual entirety to the Government bureaucracy. There were three difficulties with this system: (1) Quality remained substandard. (2) Minimum standards also became maximum standards. Manufacturers had no economic incentives (and Soviet manufacturers do operate according to economic incentives) to produce any quality beyond the minimum required by the established standards. (3) In addition to the fact that quality continued to be unsatisfactory, the system of inspection proved to be both cumbersome, expensive, and, to a large extent, ineffective.

Recently, The Soviet decision has been to pass on this inspection function, at least in part, to the manufacturer and the consumer. Each factory has been required to affix to its products some identifying mark. It will be remembered, for example, that in the complaints about poor quality mentioned above, the factories of origin were mentioned by name.[34] At present, manufacturers in many areas are being urged to adopt a trademark which really is a somewhat more overt version of the production mark, this making it still easier for the consumer to identify the factory; the hope here is to instill in the producers a sense of identification and pride in their product and a feeling of responsibility for their quality. It is hoped further that each enterprise will push its quality above minimum standards in order to compete effectively with other enterprises.

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[31] This argument depends heavily on the work done by Goldman, Marshall I., "Product Differentiation and Advertising: Some Lessons From Soviet Experience." The Journal of Political Economy, August 1960, pp. 346–357.

[32] Cf. Medical Worker, Nov. 28, 1961.

[33] Ibid, Nov. 28, 1961.

[34] Often the responsibility also tends to be personalized by the publication of the factory manager's name.

In support of trademarking, two Soviet economists have delivered remarkably capitalistic sounding proclamations:

"* * * the trademark makes possible for the consumer to select the goods which he likes, the one which is produced by one firm out of a number of homogeneous * * * goods made by other firms."

"This forces other firms to undertake measures to improve the quality of their own product in harmony with the demands of the consumer. The trademark promotes the drive for raising the quality of production." [35]

At the present time, we have no evidence that the Soviet Union is pushing trademarks or brand names in its pharmaceutical industry. To the best of our knowledge, all Soviet factories producing the same type of drug use the same name for it, and often the same type of packaging. While no factories have made a deliberate attempt to publicize their names, it is nonetheless true that the consumer can identify from a careful reading of the package which factory or which economic regional council is responsible for its manufacture. It should, perhaps, be indicated at this point that there are some differences between the pharmaceutical firm in a socialized economy and in a capitalistic economy. In the first instance, the factory comes into being as a result of a specific decision on the part of the appropriate authorities. Its function is to produce certain goods. Its manager or managers stand to benefit (through bonuses) from an overfulfillment of production plans. But there is much less stress on control of qualitative indexes, and the life of the factory (in the economic sense of a profitable institution) is not so much at stake as it would be in a capitalistic competitive economy.

At the same time, recent developments on the Soviet economic scene would lead one to believe that the situation in the pharmaceutical industry may not be essentially different from that in the consumer goods industry where trademarks have been, or are in the process of being, developed. If responsibility for quality control is to be placed prominently on the factory, the logic of the situation would be that the factory would then try to give itself a distinctive identity in order to capitalize on the superior quality of its products. We are arguing here that if we take on face value the logic for trademarks that Soviet authorities have employed in other areas of the economy, it would appear to apply equally in the pharmaceutical industry. Soviet experience with quality, both in the pharmaceutical industry and in other parts of the economy, would not encourage us to dismiss casually the use of brand names for drugs.

Interestingly, a similar problem arises with respect to the selective shortages of some drugs, though to the best of our knowledge no student of the Soviet economy has yet interpreted this specific phenomenon in the terms we are about to use. The general problem is well known.

Since the midthirties, Soviet pharmaceutical manufacturers, like other Soviet enterprises, have been on a "profit" (xhozrashchet) basis. They are assigned quotas of goods to produce, prices are put on the various products, and the enterprise earns a "profit" for meeting and surpassing its quota. Pricing systems being what they are, some products usually turn out to be more profitable than others. From this factor grows the perennial Soviet problem of the "product mix." Sanctions are employed (or attempted) to get the required mix of products out of the enterprise. But, in one way or another, factory administrators manage to evade controls on the product mix so as to maximize their profits.[36]

Soviet press reports regularly complain of shortages of drugs and medical supplies. Among these shortages are frequently the most prosaic of items such as glucose, talcum powder, tincture of iodine, bicarbonate of soda, and even saccharin.[37] In fact, Soviet pharmacies seem to prefer to stock costly medicines which will produce a high profit for a small turnover, as is obviously the case for the antibiotics whose high retail prices so scandalized the Health Minister.[38]

On the basis of what is standard practice across the board in Soviet industry, it must be assumed that selective shortages in production occur as a result of the most profitable items.

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[35] Genkin and Fialkov, quoted by Goldman, op. cit., p. 351.

[36] For a description of the intricate games that a factory manager can play in this system see Berliner, Joseph, "Factory and Manager in the U.S.S.R.," Harvard University Press, 1957.

[37] Medical Worker, July 22, 1960, p. 4.

[38] Field, "Pharmaceuticals, Pharmacies, etc.," February, p. 107.

Comparative production experience

Keeping these probable circumstances in mind, let us turn back to the American scene and consider the parallel situation. Perhaps the best starting point is the brand name manufacturers' contention that we must not look at the profitability of his individual products. If someone accuses him of making unduly high profits on a particular item, he counters by answering that these profits make it possible for him to carry some items which are essential to the medical profession but which give the manufacturer little or no profit, or may even sell at a loss. In terms of his overall strategy it makes sense for him to carry such low-profit items because he attempts to promote himself and his line of products across the board. An inverted way of describing this situation is to say that "customer (i.e. doctor) control" compels him to produce a fairly wide range of items, as well as to maintain quality.

The brand name manufacturer's picture of his situation is certainly validated at least in part by the franker statements of the generic drug manufacturers.[39] They say, in substance, that they limit their efforts to producing generic versions of only those drugs which can be sold profitably. Such manufacturers are quite specific in stating that there are certain drugs which they will not manufacture. Furthermore, they are equally direct in acknowledging the effort and cost that must be undertaken to educate (or, to use the more commercial term "promote") doctors to the use of a new drug. In a word, the economic motivations of American generic drug manufacturers and their role in promotion are surprisingly similar to those we have attributed to the Soviet manufacturers.

But this raises another interesting question relative to deciding to manufacture a drug whose demand is quite limited, and whose production is costly. We have seen that in the American situation, according to the statements of brand name manufacturers, it makes sense to carry a reasonably full line even though certain items of that line will be marketed at a loss. The loss will be recouped with the other items that are in wider demand. The logic of competition here appears to force the manufacturer to turn out some items that individually are unprofitable. As long as the situation remains as described, the public in the long run benefits. In the Soviet situation, on the other hand, the issues are drawn in a different kind of array. The logic of the situation in the Soviet economy would impel the medical authorities to act like generic drug manufacturers. Insofar as decisions to produce this or that item are highly centralized, the likelihood is that in many instances drugs that are in restricted demand and which require high capital investments for their production may not be put into production at all. The absence of competition makes it also unlikely that another manufacturer would undertake such a production, so that in the end the drug may not be manufactured at all, and the general assortment of drugs from which the physician may choose may be quite limited. Scattered observations of the Soviet pharmaceutical scene would tend to confirm this. For example, C. Wesley Scull writes: " * * * Although the Soviet medical workers are entirely familiar with the newer cortico-steroids, only cortisone and hydrocortisone have been made generally available. The same applies to phenotropic agents." [40]

It is, therefore, a moot point whether a decision with respect to the production of a full line taken by a central governmental body (with its criteria of economy) would be more favorable to the public welfare than a decision made by a pharmaceutical firm competing on a market and desirous of impressing its brand name on the medical profession. Here again it seems that the manifest function of promoting a brand name has the latent effect of encouraging the production of certain unprofitable items. An analysis of the Soviet pharmaceutical situation shows that we cannot take for granted that wise and rational decisions are to be naturally expected from a central governmental or quasi-governmental body, or even that such decision per se will lead to the provision of certain items to the population.

To sum up, the Soviet experience with problems of quality, quantity, and assortment gives added plausibility to the importance of "customer control" in the drug industry—the "customer" in this case being the physician-prescribing population. If the manufacturer is to take the problem of quality seriously, he is most likely to do so if he believes that he personally (or, if you will, his firm)

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[39] Cf. The testimony of Herman C. Nolen, president of McKesson & Robbins, before the Senate Subcommittee on Antitrust and Monopoly, Dec. 13, 1961.

[40] Scull, C. Wesley, in the Journal of the American Medical Association, Aug. 23, 1958, p. 2121.

will be associated with that quality and that this will do him some good with his customers. Similarly, the probability of a manufacturer carrying a reasonably full line covering relatively low-profit or loss items is greater if he feels that this gives him a customer franchise. This, manifestly, can happen only if the doctor recognizes the full line as an entity, or, to speak plainer English, if the line of drugs is promoted under a single name.

CONCLUSION

A paper such as this is an open invitation to the reader to perceive us as having said many things which we had no intention of saying. For example, we have not defended or even commented on the profit level of the American ethical pharmaceutical industry. Nor, have we advocated any particular level of expenditure for drug promotion and/or research. We repeat the thought with which we began this article: among the various ways of doing things that reasonable men are likely to try, there are likely to be both advantages and disadvantages. Being acquainted both with the Soviet medical system and to a lesser extent with the Soviet drug industry, and with the American pharmaceutical system we thought it might be instructive to match these two systems against each other to see what could be learned.

Specifically, we were interested in seeing whether Soviet experience threw any light on the alternatives that have, at times, been proposed to the policies of the American pharmaceutical industry. We found that these alternatives as practiced in the Soviete Union seem to have their own built-in liabilities. It is our guess that these liabilities are not necessarily linked to the other features of Soviet society. There are, of course, difficulties of the drug industry that are distinctive of the Soviet scene. For example, drug distribution is at times grossly inadequate because of inefficiencies in the overall distribution and retailing system. Some aspects of shortages are due to the Soviet system of planning and allocating supplies, etc. We have not dealt with these distinctively and exclusively Soviet phenomena, but solely with those which might realistically or semi-realistically be tried in our economy, and which in our judgment might tend to produce similar problems if transplanted.

Perhaps the journey overseas was not necessary. It could be argued that a reasonable man might well have anticipated our conclusions, namely:

1. Separation of research from production, whatever its other merits may be, slows up the process of getting laboratory items into production.
2. An underpromoted pharmaceutical system leads to substantial lag in the introduction of new drugs.
3. Quality control belongs preferably with the manufacturer and is more likely to take place if he has a significant realistic motive for undertaking it. Customer preference is such a reason.
4. Customer preference is also a stimulus for maintaining a full line of items, some of which may be unprofitable.

It may be that social policy will demand substantial reforms in the American pharmaceutical industry. Before we undertake them, it might be wise to remember Herbert Spencer's gentle admonition about remedial measures:

"You see that this wrought-iron plate is not quite flat: it sticks up a little here toward the left * * * how shall we flatten it? Obviously, you reply, by hitting down on the part that is prominent. Well, here is a hammer, and I give the plate a blow as you abvise. Harder, you say, still no effect * * * the prominence remains * * * as great as ever—greater, indeed * * * look at the warp which the plate has got near the opposite edge. Where it was flat before it is now curved * * * instead of curing the original defect, we have produced a second. Had we asked an artisan practised in 'planishing' * * * he would have told us that no good was to be done, but only mischief, by hitting down on the projecting part * * * the required process is less simple than you thought. Even a sheet of metal is not to be successfully dealt with after those commonsense methods in which you have so much confidence." [41]

This quote, is not a plea for inaction. It is only a plea for wise caution and careful analysis.

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[41] Herbert Spencer, The Study of Sociology, New York, 1875, pp. 270–271.

RAYMOND A. BAUER

Dr. Bauer is professor of business administration at the Harvard Graduate School of Business Administration and a consultant to Arthur D. Little, Inc. He has been a consultant to business, government, and semi-public organizations on problems of social communications, market research, organizational functioning and administration, and international relations. He has taught and done research on consumer behavior, social and mass communications, social psychology, research methodology, and administrative practices. He also has considerable experience in the administration of social research.

Dr. Bauer is the author or coauthor of many studies on topics mentioned above, including two books (one forthcoming) on American business and foreign trade policy, and four books on Soviet affairs which are in a considerable measure concerned with the functioning of large-scale organizations.

In 9 years' work in industry, he served as shipping clerk, foundry laborer, materials tester, stock clerk, and chemical analyst of ferrous metals.

Dr. Bauer served in the Naval Reserve during World War II as a Russian language officer.

He received his Ph.D. in social psychology from Harvard University and has taught at Massachusetts Institute of Technology and the College of Liberal Arts at Harvard, as well as doing research at the Russian Research Center, Harvard, and the Center for International Studies, MIT. In addition to being a member of various professional organizations, he holds elective offices and various committee posts in the American Psychological Association, the American Association for Public Opinion Research, and other such societies.

Among his professional honors are: Fellow of the American Academy of Arts and Sciences, and fellow of the Centre for Advanced Studies in the Behavioral Sciences.

MARK G. FIELD

Dr. Field is associate professor of sociology at the University of Illinois and a consultant to Arthur D. Little, Inc. He is currently teaching at the Harvard summer school. Dr. Field has participated in research work concerning general and medical sociology, Soviet social institutions, and Soviet medical organizations. He has had considerable experience in directing and carrying out research projects in these areas.

Dr. Field received his A.B., A.M., and Ph. D. degrees from Harvard University. In his graduate work he concentrated on Soviet affairs by studying in the regional studies program (Soviet Union) and participated in the Harvard project on the Soviet social system sponsored by the U.S. Air Force and carried out by the Russian Research Center.

He has visited the Soviet Union twice and also Czechoslavakia and Poland pursuing his research work in the field of Russian medicine. In addition he has participated in two extensive research projects: one on hospital utilization as affected by the use of so-called wonder drugs sponsored by the Health Information Foundation; and the other on mental illness sponsored by the U.S. Congress.

Dr. Field served in the U.S. Army in 1944 through 1946 primarily as an interpreter in liaison work between American and Soviet forces.

He is the author of "Doctor and Patient in Soviet Russia" (1957), and joint author of "New Perspectives in Mental Patient Care" (forthcoming). He is currently at work on "An Introduction to Soviet Socialized Medicine." He has also published, in addition, numerous articles on the Soviet social and medical scene. He has lectured to numerous groups including the National War College, the Army War College, and the Judge Advocate General's School.

Among his professional honors are fellow of the American Sociological Association, and member of the American Association for the Advancement of Slavic Studies.

The CHAIRMAN. Mr. Dingell, do you have any questions?

Mr. DINGELL. No questions, Mr. Chairman, thank you.

The CHAIRMAN. Mr. Schenck.

Mr. SCHENCK. Thank you, Mr. Chairman.

I am not quite certain just what Dr. Bauer is trying to say. I do not know yet whether he thinks that the American system is better than the Soviet system or vice versa.

Mr. BAUER. I was quite aware of the fact that the most probable question that would be thrown to me was that. I have tried very assiduously to avoid any question as global as that.

Mr. DINGELL. Doctor, you do not need to be fearful of being a capitalist in this committee.

Mr. BAUER. I still have to maintain my posture as a scholar.

What I have tried to do is to point out that certain institutional arrangements have produced the type of consequences you have in the Soviet situation. I am sure we have our problems too, and I do not want to have to explain those two guys who were flying around upstairs last week on the basis of the fact that our pharmaceutical system seems to work a little better. So I have not taken a stand on the overall economy, but I have tried to spell out what the implications of certain institutional arrangements were.

Mr. SCHENCK. It seems to me, Dr. Bauer, that the tenor of your statement here is that the socialistic system of manufacturing drugs by allocating certain preparations to certain factories at a given rate of profit is better, and yet you also stated—what about the cost of these to the people?

Mr. BAUER. I actually think that their system is functioning worse for them now than ours is functioning for us. By allocating these quotas and setting prices, they are not getting the drugs out that they want in either the quantities they need, nor are they getting the quality because the factory manager fudges in order to maximize his profits.

The familiar example of this in the Soviet situation, I shift to tractors because the example is easier to communicate, is, a fellow will get such and such a price for delivering tractors and such and such a price for delivering spare parts. It usually turns out that it was more advantageous to him to deliver tractors, so he did not deliver spare parts and you had tractors breaking down all over.

As far as we can tell, apparently the same thing is happening in the pharmaceutical industry. This is analogous to the generic manufacturer who produces each drug on its own profitability, and when he does that, why he produces the most profitable drugs and lets the least profitable ones go.

Now the gentlemen we have had here today all come from companies which are producing a range of drugs and they are producing many drugs which are not as profitable for them because they want to maintain their reputation with the doctor.

Mr. SCHENCK. The American system is also highly competitive. Apparently here you take out competition. Apparently here you remove the incentive.

Mr. BAUER. There has been a quotation in the New York Times within the last few months in which a Soviet Communist has lamented the fact that we have competition and this serves as a yardstick for judging our products and keeps our producers on their toes. I could not be clear from the New York Times article whether this fellow was actually advocating return to a competitive system or whether he was just weeping, but he obviously was aware of the fact that there were some advantages to a competitive system.

Mr. SCHENCK. Do I understand that under the Soviet system here that they use the generic name?

Mr. BAUER. For practical purposes, they use the generic name. That is, each factory does not have a separate name. Chloramycetin I think is promoted as Chloramycetin, which is a brand name here but it is the only name available there, so it is for practical purposes the generic name. It is not a chemical name, but it is the same name regardless of which factory produces it.

Mr. SCHENCK. From the few generic names that I have looked at, if we require generic names to be put on to the label of a prescription drug here, we are going to have to increase the size of the container.

Mr. BAUER. This is a problem.

Incidentally, they are actually traveling the road in the opposite direction from us. They have the factory put its name on the box so that the factory can be located, but as I have indicated, there is good reason to suspect that they may be going for brand names in drugs fairly shortly because they have been doing this in other parts of consumer goods, so that competition, in effect, will take place.

Mr. SCHENCK. When the physician, if he is free to prescribe, does prescribe a certain drug over there and the patient goes wherever he goes, the drugstore——

Mr. BAUER. The drugstore, yes.

Mr. SCHENCK. To get that prescription filled, is the pharmacist required to put the name of the company from which the drug came and also the generic name and so on onto his label if the druggist buys it in a quantity?

Mr. BAUER. I could turn to Dr. Field for that.

Mark, do you want to check me on that? You have had this happen to you.

Mr. FIELD. The drug's name——

Mr. SCHENCK. Might you identify yourself for the record?

Mr. FIELD. Mark G. Field, assistant to Dr. Bauer in the work we did on the Soviet comparative material.

If the prescription is for a prepackaged item, then, of course, the generic name will be printed on the item. If the prescription is for an item which is compounded by a pharmacist, then the generic name or whatever the name of the drug is would be written on the prescription and on the label of the drug itself.

Mr. SCHENCK. Then in that case the druggist does not remove the label of the manufacturer and put it on the prescription label?

Mr. FIELD. No, sir.

Mr. SCHENCK. Is that correct?

Mr. FIELD. Yes, sir.

Mr. SCHENCK. All right, Mr. Chairman.

From what you have said here, it seems to me that you have only proven that the U.S. pharmaceutical manufacturers and the medical profession and health care system in the United States is far superior to the Soviet Union.

Mr. BAUER. I am delighted you came to that conclusion.

Mr. FIELD. I was thinking that this was an example, what Mr. Schenck said, an example of what was pointed out to the committee earlier this afternoon with reference to giving authority to the Food and Drug Administration to determine the efficacy of a drug, because there are so many different opinions about it.

Now I got the impression from your statement that you tried to be perfectly objective about it and not show any prejudice for the purpose of this statement to the American system or the Soviet system, but when you wound up with that short punch paragraph saying: "Be very careful before you change our system, you might get into the other system," I gathered from what you said finally that you used this analysis to impress upon us that we should not make the changes because we might tend to go in some other direction.

Mr. BAUER. This is the professorial soft sell; I hope it worked.

Mr. SCHENCK. Mr. Chairman, I call attention to the fact that Dr. Bauer is a psychologist.

The CHAIRMAN. I also notice from reading his biographical statement that he is professor of business administration at Harvard University.

Mr. SCHENCK. That ought to really fix it up.

Mr. BAUER. It is really three people.

The CHAIRMAN. Doctor, you said factories are allocated quotas of drugs used for which they receive an assigned "reasonable" profit.

Mr. BAUER. Yes. Well, the reasonable profit, you know——

The CHAIRMAN. Is this done in Russia?

Mr. BAUER. Actually, what the factory gets assigned is a certain quota to produce and they get two quotas. One is a physical output quota and the other is a financial quota, and prices are assigned to each of the items.

Now once they have met their quotas, the factory manager particularly gets premiums for exceeding that quota.

The CHAIRMAN. In other words, what you meant, he got a bonus for doing an exceptionally good job?

Mr. BAUER. It was a little bit too long to develop the point fully. I figured that the reasonable profit in quotes would communicate the essence of this.

The CHAIRMAN. Thank you very much.

Mr. SCHENCK. Dr. Bauer, you would indicate that the Soviet system is a planned economy?

Mr. BAUER. They try.

The CHAIRMAN. I am like a lot of other people you know. I spent 3 weeks in Russia one time and I found out all about their operation. But from what I have heard and observed they do a pretty good job of their planned economy too.

Thank you very much for your statement.

Professor Field.

Mr. FIELD. The only comment I would like to make on the planning system is that on the surface it looks very rational, very logical, very economical.

In practice it is often just the opposite. I am reminded of a metaphor that was used by, I believe, Dr. Carl Polani on the beauties of rational planning. Let's say you have a pile of potatoes that you are trying to place into a sack with the least amount of waste space. There are two ways you can do it.

One way you can make profiles, cuttings, and calculations on each potato available, code them on IBM machines and find out the best and most rational and most economical way of doing it. It would

take about 6 months and perhaps half a million dollars, but it could be done.

The other way is simply to dump the potatoes and shake the sack. I mean the result will be within a few percentage points of the first one.

And I have seen quite often that the free enterprise system with the mutual adjustment, mutual regulations of competition, does the job much better than the so-called rationale and overcomplicated, overcentralized, and overbureaucratic system.

This is a personal opinion, of course.

The CHAIRMAN. Thank you, Mr. Field.

I think that is a good note on which to end these hearings for today.

Mr. SCHENCK. Mr. Chairman, also, if you mash the potatoes, you can put them in a smaller sack.

The CHAIRMAN. Mr. Cutler.

Mr. CUTLER. Mr. Chairman, on behalf of the pharmaceutical manufacturers, I would like to thank you and your colleagues on the committee for your patience that you have shown in permitting us to make such a full statement and the interest you have had in our views.

Thank you very much, sir.

The CHAIRMAN. Let me say on behalf of the committee to all of you who have appeared here in behalf of the pharmaceutical industry that we thank you for the contribution that you have made to this record.

We think that this has been a very profitable day and I hope the entire committee will be much better off with this record. The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 9 p.m., the committee recessed, to reconvene at 10 a.m., Tuesday, August 21, 1962.)

DRUG INDUSTRY ACT OF 1962

TUESDAY, AUGUST 21, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

The first witness this morning will be Mr. James F. Hoge.

STATEMENT OF JAMES F. HOGE, ATTORNEY (ROGERS, HOGE & HILLS, ESQS.), ACCOMPANIED BY WILLIAM F. WEIGEL, ATTORNEY

Mr. HOGE. Mr. Chairman, may I have my partner to sit by me?

The CHAIRMAN. Yes.

I think you should identify him for the record, Mr. Hoge.

Mr. HOGE. Mr. Chairman, this is Mr. William F. Weigel, a partner in my firm of Rogers, Hoge & Hills in New York.

The CHAIRMAN. Very well, Mr. Weigel. We are glad to have you with the committee.

Mr. Hoge, you may proceed.

Mr. HOGE. Mr. Chairman and gentlemen of the committee, my name is James F. Hoge. I am a member of the bar of the State of North Carolina and of the State of New York. I am a native North Carolinian and practiced law in that State for about 8 years before going to New York in 1930. My address is 41 East 42d Street in the city of New York and I am engaged in the active practice of law as a member of the firm of Rogers, Hoge & Hills. I appear on behalf of the Proprietary Association, the address of which is 1717 Pennsylvania Avenue NW., Washington, D.C. I have been the general counsel of this association since 1934.

The association was organized in 1881 and has been in continuous existence since. Its active members—97 in number—are engaged in the manufacture and distribution of proprietary medicines—medicines which are completely compounded, packaged, and labeled for use by consumers. They are over-the-counter items not restricted by law or practice to prescription sale.

I would like to take a moment or two, Mr. Chairman, to say something about proprietary medicines. The term is one that is not readily defined. In fact, it is very difficult to find an authoritative definition of it.

The effect of the Durham-Humphrey amendment to the act, which was before this committee in 1951, an amendment to section 503(b)

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of the law, divided drugs into two classes. That was the effect of the amendment. One class is prescription drugs sold only on prescription, and the other class is over-the-counter drugs.

Now, the over-the-counter drugs really divide themselves into two classes: one, the so-called ethical; and the other, the one usually referred to as proprietary, although there is no exclusive on that term. The ethical over-the-counter drug is not necessarily prescribed, but it is advertised only through professional journals and circles, and the patient usually hears of it first from the doctor, either by prescription or by verbal direction to go get it.

It is with respect to the proprietaries, as they are usually called, those drugs which are advertised directly to the public which are not limited in any way to prescription sale. It is for that class which I appear.

I would like to go one step further with respect to proprietaries. So much of this legislation is applicable to the prescription drug. The drugs for which I appear perhaps do not rest upon the same high plane that a prescription drug does, but they are important, and I would like to read you just a line from a speech recently made by Dr. James F. Hundley, Assistant Surgeon General for Plans of the U.S. Public Health Service.

In May of this year he said:

> Remedies that are safe, effective, easily obtained, easily used and not easily abused are necessary and an important part of our scheme of total health care for the foreseeable future. Entirely aside from mental and physical benefit, such remedies prevent available health resources from being swamped by patients with real or imaginary symptoms which do not require skilled professional attention.

And one further word on that score, Mr. Chairman: These proprietary drugs went through a great transformation as a result of the 1938 law which was passed through this committee and by the Congress. As a result of that law, many so-called proprietary medicines came off the market. All of them underwent radical changes as to formula, labeling, and general distribution, so that this association for which I speak ardently supports the food and drug law. It ardently supports the administration of it, and it commends the Food and Drug Administration for the type of administration which this law has had at its hands over these years.

There are also 120 associate members in this association. They are companies which do not manufacture and distribute proprietary medicines but which are interested, as suppliers of various materials and services, in such manufacture and distribution.

The association must—at this time—be cast in opposition to this bill. But it is more agreeable to our sentiment, and closer to the fact, to say that we are for a revision of the bill. The association is not opposed to amending the law; is not opposed to keeping it up to date. The association and its members were very active during the 5 years that the present law was worked out in the Congress. The evolvement of the present law began with the bill introduced on June 12, 1933—S. 1944—generally referred to as the Tugwell bill. It was enacted on June 25, 1938, after numerous hearings and revisions in both Houses of the Congress.

It was before a subcommittee of this committee chaired by Mr. Chapman of Kentucky from June to September, 1935. From May 1935—when the bill passed the Senate—until the passage of the act

in June 1938, this association for which I speak was an active supporter of the legislation, and on August 10, 1935, I appeared before a subcommittee of this committee, Mr. Chapman's committee, already referred to, and stated the association's support of the bill which eventually became the law.

There were several bills before the subcommittee, some of which had been introduced here in the House, but the principal bill, and the one which, after revision, became law, was S. 5, which, of course, had been introduced in the Senate (74th Cong., 1st sess., H.R. 6906, H.R. 8805, H.R. 8941, and S. 5, pp. 694–698; S. 5 having passed the Senate on May 28, 1935).

SCOPE OF PROPOSED AMENDMENTS

H.R. 11581 proposes numerous amendments to the Federal Food, Drug, and Cosmetic Act—amendments which are extensive and complex. We think some are more extensive and complex than they need be, and it is to them that we direct our opposition and our request for revision. In their present form they would change the character of the law and, to a substantial degree, at least, replace a system of defined private responsibility with one of detailed governmental regulation, or license.

Some of the manufacturers of proprietaries have an interest in all of the drug provisions because they include affiliated companies or corporate divisions which manufacture prescription items. As to those, however, the Pharmaceutical Manufacturers Association has given particular study and made a full representation.

They were here, of course, yesterday with numerous witnesses. And I think I may, and I would like to say, Mr. Chairman, that this association associates itself with the position stated by Mr. Eugene Beesley in his statement yesterday in which he listed eight objectives or concepts of this bill with which his association is in agreement. And this association is in agreement with those concepts, too, and, like Mr. Beesley and his witnesses, our being here today is to ask revision in some of them and not to oppose the concept of improved food and drug legislation.

I shall, therefore, confine my statement—certainly in principal part—to the application of the bill to drugs which are made and sold for self-medication, the ones usually referred to as proprietary medicines.

SECTION 101, PAGES 2 AND 3, ADULTERATION, OR LICENSE?

The bill's first amendment applies to section 501 of the law. That is the section which defines adulteration of drugs. Under the amendment, section 501(a) would read as follows—the new matter being italicized:

"SEC. 501. ADULTERATED DRUGS AND DEVICES.—A drug or device shall be deemed to be adulterated—

"(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(4) if it has been prepared, packed, or held under insanitary

conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (*B*)—

and this is the new part—

*if it is a drug and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) (i) to insure that its identity and strength do not differ from, and that its purity, quality, and efficacy do not fall below, those which it purports or is represented to possess, or (ii) to insure that it will not be injurious to health when used in accordance with directions for use on its labeling, or when used in accordance with a prescription of a licensed practitioner (which prescription is consistent with its labeling), or (iii) to insure that its labeling is not such as to cause it to be adulterated or misbranded; * * **

Since 1938 the law has provided that a drug shall be deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health, and we have no objection to extending this to include inadequate methods, facilities, and controls.

Mr. Chairman, that language came into the law in 1933 to 1938 largely from the food provisions of the act. It was pointed out by numerous people that adulteration of a drug consisted really only in the change of its identity and quality and purity, but there were witnesses who suggested that these provisions about sanitary control from the food sections of the law might well be brought over to the drug provisions, and there was no objection to it. They were written into the law, and they have been there ever since, and we have no objection today to the amendment insofar as it adds methods, facilities, and controls.

However, the proposed amendment goes far beyond that and constitutes what is, in effect—in my view—licensing. On the manufacture, processing, packing, or holding of drugs, it would impose regulations—to be later made by the Secretary, and presumably to be changed from time to time, as he thinks they should be changed—as to facilities, personnel, methods, and controls. Often there is properly a choice between methods which may be used in making a given product. Manufacturers should have freedom of choice, as to which method they use, provided the end product meets the requirements of the law.

Facilities include machinery and other equipment, and often there may be different machines and equipment for making the same article. Here, too, manufacturers should have freedom of choice provided the end product is as it should be.

Our objection so far is to the Secretary doing this by regulation. But this amendment goes further. It even authorizes regulations whereby the Secretary would determine the adequacy of personnel employed by the manufacturer or processor. A proper judgment on the ability of individuals to perform their duties in the manufacture and processing of drugs should be, and usually is, based on close and long observation. It is a subjective judgment and cannot be made on arbitrary standardization. It is part of a manufacturer's right and responsibility to select personnel of character and ability.

The bill would rest these controls on a presumption. It would deem a drug to be adulterated if it does not comply with the Secretary's requirements as to methods, facilities, controls, and personnel. It need not—and may not—be actually adulterated at all. Personnel should not be included in the amendment. Methods, facilities, and controls should be, but the adequacy of them should not be left to administrative discretion as proposed.

The amendment goes on to deal with labeling. It proposes to control labeling—I suggest—by licensing. I think the effect of this section, as it is presently worded, is a matter of license, and under the fiction of adulteration.

Now, I use the word "fiction" not in any invidious sense at all. But to deem an article adulterated, if it is made under unsanitary conditions, or if it is made by inadequate machines and so on, I repeat, may not really affect the article; it may not adulterate it; but we create this legal fiction, and we say that it shall be deemed to be adulterated if it has been made by inadequate facilities, machinery, and the like.

The bill proposes at this point, therefore, to control labeling under this fiction of adulteration, and there is a prototype for it. It was in one of the early bills preceding the enactment of the 1938 statute. It was in S. 2800, which was introduced on February 6, 1934.

The Food and Drug Administration proposed in that bill—or perhaps I should say the bill proposed—that a drug should be "deemed" to be adulterated "if it is dangerous to health under the conditions of use prescribed in the labeling thereof".

It also appeared in S. 5, which, after revision, was passed by the Senate. Prior to passage by the Senate on May 28, 1935, the provision was taken out of the section on adulteration and put into the section on misbranding (S. 5, sec. 402(b)). As finally enacted into law, the provision appeared, as it does now, as section 502(j) and defines a drug as misbranded—

> if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Mr. Chairman, may I say that that was heralded as a forward advance in the food and drug law. I remember so distinctly the advocacy of it. It was represented that here is a provision which will enable the Food and Drug Administration to apply an elastic test; that, after being specific about labeling and about adulteration and all of these matters, if the drug, as a matter of fact, is dangerous when it is used according to the directions on the labeling, then that drug is misbranded and subject to regulatory action.

It was, I say, heralded as a very forward advance in the making of food and drug laws.

The law presently has extensive provisions in section 502 for the control of labeling. That is the misbranding section of the act, and, in addition to 502(j) which I called the elastic provision, it has a great many specific, detailed regulations as to name and address, directions for use, warnings against use and other matter contained in that section.

The amendment in clauses (ii) and (iii), which I read to you a moment ago and which appears on page 4 of my statement which was handed up, seemingly is designed to "insure" (to use the word

of the amendment) that the labeling complies with section 502. In other words, where the act now imposes upon a manufacturer the duty to obey the requirements of section 502 of the law as to the correct labeling of his product, the amendment would impose upon him the duty to obey the regulations of the Secretary, would enforce that duty under the stigma and the penalty of "adulteration," and would be effective to make prior compliance with the Secretary's regulations a condition to the marketing of the article.

That is one of the reasons why I say this particular section is in effect licensing, because we are not waiting, as the present law does, to see what the manufacturer does. We are telling him in advance what he has got to do, and if he does not, his article will be adulterated and subject to the various sanctions—and to the stigma—of adulteration.

And there are drastic sanctions, among them seizure pursuant to libel (sec. 301 of the act). The law permits multiple or unlimited seizures as to adulteration. It limits seizures for misbranding to a single action except when the misbranding has been the basis of a prior judgment in favor of the United States or when there has been a finding of danger to health or when it is misleading in a material respect to the injury or damage of the purchaser.

Mr. Chairman, that was worked out in those years of 1933 to 1938, and this, briefly, was the idea. Misbranding is a matter of language. It may be serious or it may not be serious. It may be the matter of a misplaced word or the necessity for some further wording. In any event, and usually, it is something that can be corrected. It does not go to the inherent nature of the drug.

Therefore, the sanctions pertaining to it should be different from those pertaining to adulteration. Everyone back in those years was in favor of getting an adulterated drug off the market peremptorily, swiftly and without any limitation on the power of the Government to seize, but with respect to wording—misbranding, as we call it—you did write into the law at that time that there should be some limitation on the number of seizures which might be made in the first instance.

Now, this amendment would undo all of that. This amendment would carry us right back and would provide that a drug which is not branded according to the Secretary's directions, if you please, will be deemed to be adulterated and will be subject to multiple seizures and to all the other sanctions, criminal prosecution, injunction, and all.

With several notable and proper exceptions—and I emphasize the word "proper"—such as the new drug provisions, the existing law has not been one of license. The original design of it was to state, wherever possible, the duties of manufacturers and distributors and to empower the Food and Drug Administration to prosecute infractions of the law's requirements. Since enactment of the statute, there has been a tendency—justified by circumstances and acquiesced in reluctantly—to move away from that concept and toward one of licensing, to some extent. The new drug section did that. So did the food additives and color additives amendments, and the amendments with respect to antibiotics.

Now, I am not critical of those provisions of the law. I realize there must be exceptions to all rules, as we say, and that licensing at

times is proper and necessary. I am not critical. I am pointing out to you there has been this tendency; that the proposed legislation would accelerate that tendency and go far toward transforming the statute into one of Federal licensing.

Unless that is the purpose—and we do not believe that it is the purpose; I do not think it is the purpose of this committee, certainly—the bill should be revised on page 3, line 3, to read as follows. There would be the opening sentence:

> A drug should be deemed to be adulterated—
> (B) If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding are not adequate to assure that its identity and strength do not differ from and that its purity and quality do not fall below that which it purports or is represented to possess.

What I have done in that suggestion is to delete the reference to personnel which appears in the amendment and to delete the clauses (ii) and (iii) at the end which refer to labeling and construe labeling as adulteration.

Then we come next to section 102, which appears at pages 3 and 4 of the bill, and has to do with efficacy, and I address myself at this point particularly to the amendment to section 201(p) of the existing law. That is the definition of "new drug" in the present law.

The amendment would amend that definition to include the words "efficacy" and "efficacious" in the definition of "new drug."

The definition presently relates only to "safety". The amendment would define a new drug as one which, to quote it in full:

> is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety *and efficacy* of drugs, as safe *and efficacious* for use under the conditions prescribed, recommended, or suggested in the labeling thereof. [New matter italicized.]

This amendment of the definition is, of course, related to amendments, later in the bill, which would add a determination of "efficacy" to the new drug controls in section 505 of the law. These amendments would be accomplished by the provisions appearing on pages 4 to 10, inclusive, of the bill. The basic change in section 505 would be to require affirmative approval or rejection by the Secretary of a new drug application and to condition approval on proof of efficacy as well as safety. These are important changes and have provoked considerable discussion.

But even if section 505 should be amended to make some provision for a showing as to efficacy as well as to safety, there is no need to amend the definition, and to do so may present serious trouble for proprietary medicines and particularly for those which have been on the market for many years—articles which have been generally recognized and considered to be safe but have not been through a new drug proceeding with respect to efficacy. The amendment of the definition is not necessary because—if efficacy is added to section 505—a new drug as presently defined (one which is not generally recognized as safe) will have to make the required showing on efficacy.

The only difference would be that under the present law, if you amend it to put efficacy in section 505, the machinery will not start until we pass the point of safety.

That is, any article which is not generally recognized as safe—and that is the present test, Mr. Chairman. The test is not that an article

is not safe: the test is that if an article is not "generally recognized as safe," then it must go through this proceeding, and if you amend 505, as has been proposed here, the Department would then go into questions of efficacy as well as safety.

The law now demands that the manufacturer of a proprietary drug make no claims beyond the efficacy of his product, but the amendment would prevent the marketing of the article until and unless the Secretary had approved the claims of its therapeutic worth. This could be very difficult for the manufacturer of an article to be used in self-medication. We must remember, as I just said, that the test proposed is that the article be—

recognized among experts qualified by scientific training and experience to evaluate the safety *and efficacy* of drugs, as safe *and efficacious* * * *.

Again, I am not critical of that language, but it is difficult language. It was difficult when it was worked out many years ago, and everybody knew it was difficult, but I suppose no one could think of anything better. There may be quite a big difference between a thing being actually safe and being generally recognized as safe. But the law has been these years that it is not generally recognized by experts.

Such experts, who in most instances, presumably, would be physicians, are sometimes loath to acknowledge articles for self-medication. They may concede—and they usually do as to the products of which I am speaking—the safety, or the harmlessness, of the article, but they frequently assert that the efficacy of medicines depends on the accuracy of diagnosis and the skill of the attending physician.

If the definition is to be amended as the bill proposes—our position is that the definition should not be so amended—then efficacy should not be included in the definition, and that was the position taken yesterday by the representatives of the Pharmaceutical Manufacturers Association. But, as a second line of defense, if you please, if the definition is to be amended as the bill proposes, then there should be an adequate grandfather clause. There is such a clause in the existing law, and there is the semblance of one in the bill. I call it semblance because I do not think it goes very far.

Section 108(c) (p. 15, line 20) provides that some of the amendments made by sec. 102 would not apply to articles on which there were effective new drug applications at the time of the enactment of the bill. But even there the clause is not applicable with respect to efficacy. It expressly excludes the amendment on efficacy, so that articles on the market prior to the enactment of the bill would be subject to new drug controls on efficacy.

Most proprietary medicines have not been subject to the new drug requirements and would become so now—if at all—solely because of the injection of the word "efficacy" in the definition. When the existing law was passed in 1938 it contained, as it still does, a grandfather clause. It is in section 201(p), which is the section defining a new drug, and provides that a drug—

shall not de deemed to be a "new drug" if at any time prior to the enactment of this Act—

the 1938 act—

it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.

If the new drug definition is to be amended now to include efficacy, then the grandfather clause should be updated so as to cover drugs complying with the existing law at the time of the enactment of this bill. This could be accomplished by amending section 108(c) (p. 15, line 20) by inserting at the beginning of said subsection the following language:

The amendment made by section 102(a) of this Act to section 201(p) of the Federal Food, Drug, and Cosmetic Act shall not apply to any drug intended for use under conditions prescribed, recommended, or suggested in its labeling at the time of the enactment of this Act.

Mr. Chairman, that does nothing more than update the existing grandfather clause, and, insofar as I could, I adapted it to the exact language of the present law.

Now, under the present law and under the regulations pursuant to it, a drug may become a "new drug" if you change the formula or if you change the claims and the directions for use; that is to say, if such change in formula or directions breeds a question of safety, then an old drug would become a new drug for the purposes of the act.

So that is the reason for the language which I have suggested here: that as long as an article on the market, when this bill is enacted, has the same formula and the same directions and claims, then it will not be subject to the revised definition of "new drug," and that is precisely what the 1938 act did.

The manufacturers represented by the Pharmaceutical Manufacturers Association make the prescription drugs and are more closely concerned with the new drug provisions of the law than are the members of the Proprietary Association. Here, again, I would like to associate ourselves with the recommendations made by that association in the statements before this committee yesterday for amendments of the law.

While prescription drug manufacturers have in the past met the new drug provisions far more frequently than proprietary manufacturers, it would not be accurate to say that those provisions are unimportant to the proprietary people, and it is quite necessary to say that the proposed amendments may make the new drug provisions critically important to the proprietaries, and that is particularly so with respect to the definition.

PREVIOUS PROPOSALS ON "EFFICACY"

This is not the first time that a proposal to inject "efficacy" and "efficacious" has been before this committee. The Durham-Humphrey bill (H.R. 8289, 82d Cong., 1st sess.) proposed an amendment to section 503(b) of the law which would have provided that if the Administrator of the act—and it was then the Federal Security Administrator—found a drug—

to be unsafe or ineffective for use without the professional diagnosis or supervision of a practitioner licensed by law—

then the drug should be dispensed only on writteen prescription. The Senate bill (S. 1186, 82d Cong., 1st sess., in the nature of a substitute) provided for prescription dispensing of any drug which the Admin-

istrator determined "to be safe and efficacious for use" only under professional supervision, and he was authorized to make his finding—

on the basis of opinions generally held among experts qualified by scientific training and experience to evaluate the safety and efficacy of such drug.

There was much opposition to these provisions. On behalf of the Proprietary Association, I appeared before this committee and objected to such extension of the Government's authority (transcript of hearings, p. 194, May 3, 1951).

The reference to efficacy was stricken from the bill on the floor of the House on the motion of Representative Roberts of Alabama on August 1, 1951 (Congressional Record, p. 9544), who said:

Mr. Chairman, when this bill was being considered in committee there was quite a difference of opinion as to the meaning of the word "efficacy" and the meaning of the word "efficacious". Webster's dictionary defines efficacious to mean possessing the quality of being effective. Many of us feel perhaps that it is too broad, and, in fact, many of us voted to strike those words out of committee. I feel the bill will be just as good and will accomplish the same purpose and will answer some of the objections being made along the line that we are giving too much power to the Administrator.

The word "efficacy" came into the law with the amendment for batch testing of insulin and antibiotics (secs. 506 and 507). The law requires the testing of these articles for safety and efficacy of use. "Efficacy" in connection with those drugs relates to potency and, as I understand it, does not involve judgment as to therapeutic use.

In testifying recently before a subcommittee of the Judiciary Committee on the House on H.R. 6245, which is the companion bill to Senator Kefauver's Drug Industry Anti-Trust Act which was introduced by Mr. Celler, Commissioner Larrick was asked by Congressman Meader:

Just what was meant by efficacy, and just what authority is sought by the Food and Drug Administration with respect to efficacy? Is it only to determine whether or not the claims of the manufacturer as to efficacy are supported by evidence, or does it go beyond that and place the Food and Drug Administration in the position of determining therapeutic value in the absence of * * *?

Commissioner Larrick answered:

The sole purpose of our proposal is to place the burden of proof on the prospective manufacturer to show, in connection with his new drug application, that the drug will do what he claims it will do.

Mr. Meader asked:

And that is the limit?

Commissioner Larrick answered:

And it stops there.

Now, if that is the extent of the proposed amendment, it does not go beyond the substance of what the law now contemplates with respect to proprietary medicines. Procedurally—as to a new drug—it would shift the burden of proof. But if the labeling of a proprietary medicine today contains claims beyond what the medicine will do, it is misbranded and subject to the various, numerous, stated sanctions of the law. If the amendment means more than the Commissioner said it does, then the specter of licensing rises again.

PRIOR APPROVAL

The bill would amend the law to require "affirmative approval" of new drug applications (p. 7, line 8; p. 8, line 3). Under the law as it now stands, an application becomes effective on the 60th day after the filing (subject to postponements) unless the Secretary refuses "to permit the application to become effective." A requirement for affirmative approval could result in protracted delay in clearance, due to a predisposition against taking the responsibility for clearance, particularly in view of the unavoidable public inference that drugs approved by the Food and Drug Administration have been officially recommended. Affirmative approval was definitely and deliberately avoided in the development of the present statute.

That, of course, is not controlling upon us today, but it may be interesting. This new drug section got into the law under a sensational development. There was a drug down in Tennessee that combined sulfonilamide with, I think it was, diethylene glycol, as a solvent. It was an ethical drug; it was a prescription drug. There were some very unfortunate incidents, and the Congress was urged to adopt legislation to meet it, and the new drug section was worked out just prior to passage of the 1938 act.

I was present, and I remember the deliberations. It was no accident that the provision was put in this sort of negative or passive form, as it is, whereby a new drug application becomes effective if the Secretary does not reject it. The Food and Drug Administration in those days did not want the responsibility for affirmative approval; it did not want what amounted, virtually, to licensing.

Now, the Food and Drug Administration may have changed its mind by this time, and it has a perfect right to do so, but I thought I might say to you that it was not by accident that the law was put this way in the first place.

DOUBTS AND WITHDRAWAL

The bill (pp. 8 and 9) would also authorize the Secretary to withdraw this approval if it later appears to him that there is "substantial doubt" as to the drug's safety or efficacy—and it is largely the word "efficacy" that makes that phrase difficult. The bill would authorize suspension of the approval prior to hearing when the Secretary finds that there is imminent hazard to the public health. Appeal from the Secretary's order denying or withdrawing approval would go to the U.S. Court of Appeals rather than the District Court as is now the case.

With the injection of "efficacy" in the definition (sec. 201(p)), these amendments could affect over-the-counter medicines very seriously. These amendments would likely transform the present status of proprietary medicines (wherein the manufacturer has the responsibility for complying with the law) to a status of prior Federal licensing with consequent post-licensing controls.

SECTION 111, PAGE 17, ESTABLISHED NAMES

The bill, at this point, would create a new section to be identified as section 508. It would authorize the Secretary, by regulations, to specify a "standard name"—which would be the "established name"—for a drug whenever he considers is necessary or desirable in the interest of achieving usefulness or simplicity of drug nomenclature, or because there are two or more nonproprietary names for the same drug or for identical drugs, or because the "common or usual" name is not satisfactory.

Nomenclature in the present law includes "the name recognized in an official compendium" and the "common or usual name" (secs. 501(b), 502 (e) and (g)). The term "official compendium" means the U.S. Pharmacopeia, Homeopathic Pharmacopoeia, and National Formulary. There is, at present, no authority for the Secretary to specify the name of a drug to be used in an official compendium or elsewhere. The law requires that if a drug is not designated solely by a name recognized in an official compendium its label must bear the "common or usual name" of the drug, if such there be; and in case it consists of two or more ingredients, the "common or usual name" of each active ingredient.

As the section of the bill is worded, the Secretary's authority would apply to all drugs—prescriptions, over-the-counter, ethicals, proprietaries. It would also apply to "official" drugs, i.e., those listed in the compendia. The Secretary could establish names other than those by which drugs are there listed. With respect to proprietary products, most of them do not have "official" names. They are primarily unique preparations consisting of a combination of ingredients. Even where formulas are similar, the end products usually differ, sometimes substantially due to their excipients, binders, diluents, and dosage forms. It would be difficult and confusing to fix single established names for them. A very real objection arises upon the grant of this authority—unless the section is so amended as to limit it—in that the Secretary might determine the trademark associated with a drug to be its "established name." The bill, therefore, should contain a proviso against designation of trademarks as "established names."

Fear of the Secretary using such authority to appropriate trademarks is born of experience. In 1941 the Federal Security Administrator, who then enforced the act, proposed regulations under section 502(d) designating as habit-forming certain chemical derivatives of substances named in that section. The proposed regulation, as published in the Federal Register on January 30, 1941, page 680, stated:

> For the purposes of section 502(d) of the Federal Food, Drug and Cosmetic Act, each of the chemical derivatives hereinafter listed under its common or usual name, followed in certain cases by its chemical name, is hereby designated as habit-forming.

The proposed regulation listed numerous chemical derivatives of barbituric acid. At least 20 of the so-called common or usual names so listed were trademarks—many of them registered in the U.S. Patent Office. Pursuant to section 701 of the act, hearings were held from March 3 to March 12, 1941; 1,310 pages of testimony were transcribed. Briefs followed and thereafter the regulation was promulgated. It did not designate the trademarks as "common or usual names." It did,

however, list the trademarks as the "names" of the chemical derivatives.

Not until 1957 was there a correction. In 1957, the regulation was revised to list the substances in three parallel columns: First, the chemical description of the derivative; second, the "common or usual name"; and third, some "trade or other names." So it is now in this third column that trademarks properly appear (CFR title 21, sec. 165.1).

The bill makes no provision for hearings or appellate procedure with respect to the Secretary's designation of "established names." If this authority is to be vested in the Secretary, then in addition to there being a restraint against his designating trademarks as established names, there should be a provision that the designation should be subject to the provisions of section 701 of the act with respect to hearings and appeals.

May I just say that when this was attempted in 1941, there was not one word in the act to authorize the Secretary to designate the name of a product for any purpose. The Secretary could then, as he can now under the law, bring a proceeding in which he may charge that a trademark is in fact the common or descriptive name, and if he has the evidence and can prove his case he prevails. But there is not authority for him by regulations or otherwise to designate names for drugs.

SECTION 112, PAGES 18–20, ESTABLISHED NAMES VERSUS TRADEMARKS

This section of the bill is closely related to the preceding section. The importance of the authority to fix "established names" becomes clear here for section 112 would revise section 502(e) of the existing law to provide that a drug will be misbranded unless its label bears "the established name" (if such there be) and, in case the drug is fabricated from two or more ingredients, "the established name and quantity"—the words "and quantity" are brand new—"of each active ingredient." The "established name" of such drug or ingredient on the label and "on any labeling on which a name for such drug or ingredient is used" must be "given precedence in position over any proprietary name or designation for such drug or ingredient" and must be used "in type at least as large and prominent as that used for such proprietary name or designation."

Mr. Chairman, I think I should call your attention to the fact that the word "labeling" in this act has been construed by regulations and upheld by the courts to include all matter "accompanying" a drug. It doesn't have to travel in the same package or in the same freight car. If some matter for display on a druggist's counter arrives by some other means but it gets to the same place the drug does, it has been held that that material is "accompanying" or "accompanies" the drug and is thus labeling. I am not critical of that, Mr. Chairman. I simply am trying to explain the scope and extent of this amendment. And so to read the amendment on the label—and on the "labeling," meaning all of this other material—the "established name," as the bill calls it, would have to be given precedence over the trademark. I suppose that means that wherever the trademark appears it would have to yield precedence to the "established name," be it on a label or in context matter or what.

Now as to some of this I may not understand the full scope of what the bill is saying. I am trying to read the wording of the bill and see if I can discover what it means. "Established name" for a drug or for an ingredient thereof means (1), so says the bill, the standard name established under section 508 (the preceding section of the bill), or (2) if there is no such name and such drug, or such ingredient, is recognized in the Compendia, then the Official Compendia name, or (3) if neither (1) or (2), then the common or usual name, if any, of such drug or of such ingredient.

Particular attention must be directed to the word "ingredient." Does the amendment mean that where there is no established name for the drug itself, the ingredients must be given precedent in position over the proprietary name of the article and be displayed in type at least as large and prominent as that used for the proprietary name? The importance of that question is related to the requirement, brought forward from the present law, that articles made up of two or more ingredients must be labeled to disclose the "common or usual name" of each active ingredient. That is all right—and if that is what the amendment would mean, it is all right—unless the amendment has the effect of requiring the names of these ingredients to be given precedence in position over the proprietary name of the article and to be shown in type at least as large and prominent as that used for the proprietary name.

Many proprietary products have many ingredients. Some of them—I am looking at two small ones here, a bottle of Murine and a tube of Mentholatum—have anywhere from 6 to 12 ingredients. Now there is no common or usual name for an article of this sort. It is a combination of ingredients. Murine is its trademark. It may have a descriptive term. It is an eyewash. I guess that is accurate enough. That is a descriptive term that identifies the nature of the article, but there is no name in any book for this article, and it has some nine ingredients. Now I don't know that the bill means this, Mr. Chairman, but there are many people who think that it does; that the way it is worded today, where there isn't a common or usual name, there would have to be these nine ingredients listed, and listed in precedence to the trademark, and listed in type of the same size as the trademark.

I must say to you candidly I can't believe that that is what anyone has intended, but we are working on a proposed statute and are trying to revise it to accomplish what is intended by the Congress. So it is a fair question, and it is one which is raised very frequently by people who are studying this bill today. Likewise, with this little package, a little package of Mentholatum, it has no common or usual name. It is a salve. It is a salve for colds. It has seven ingredients, but there is no common or usual name—there is a descriptive term. It is a salve, and you may modify that to call it a cold salve or something of that sort. And so with proprietary medicines there are descriptive terms: Antacids, analgesics, laxatives, and so forth.

The CHAIRMAN. Isn't Mentholatum the name of it?

Mr. HOGE. Mentholatum is a trademark. That is just what I was worried about a moment ago. Suppose under this power without some restraint the Secretary construes, and by regulation declares, that Mentholatum is the "established name" of this article, do we go one step further and inquire whether that would be for this particular article or for any article similar to it.

Now, many articles may be and are on the market similar to it. They may even have the same active ingredients. They might not have the same quantities of the active ingredients or they might have the same quantities of the active ingredients but have different inactive ingredients which would have a material effect upon the action of the article. So quite aside from the injustice that might be done to the owner of the trademark, confusion would be opened up wide. And that is true of practically all of these proprietary articles. Very few of them are single chemicals. That is true frequently with the ethicals, and yet it isn't always true with them. It certainly isn't always true with the ethical over-the-counter items. They too may be combinations.

Mr. Chairman, labeling under these requirements would be difficult at best, and if some of my questions are apt, it would be grotesque at worst. These provisions are an offshoot from the so-called generic name proposals contained in S. 1552 introduced by Senator Kefauver, and H.R. 6245 introduced by Mr. Celler. Both bills having been the same at the time of introduction and both having been entitled "Drug Industry Anti-Trust Act," the avowed purpose for these provisions in those bills was to discourage prescribing medicines by trademarks. It was represented that these provisions in those bills would thus be effective to reduce the price of prescription drugs.

Proprietaries weren't considered in those bills or in the hearings at all, but this was represented and, as I think in a statement just here the other day, it is repeated now that provisions of that sort would reduce the price of prescription drugs.

The proposals were not advanced in the Kefauver and Celler bills or in the hearings on them as being essentially protective of the public health. They were economic in character and were to apply only to drugs sold on prescription. In H.R. 11581, these provisions would apply to all drugs. And this bill is concerned primarily not with price but with the traditional province of food, drug, and cosmetic legislation, i.e., public health. The existing law has ample provision for informative labeling.

I say to you, sir, I am not dogmatic about it. I haven't any objection to some change if the Congress thinks there should be a change, but I say to you for the moment—so we will be informed—the existing law does have provision, and, in my opinion, ample provision for informative language. Section 502(c) provides that a drug is misbranded if any information required by the act—

> to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

I can say to you out of my private practice, Mr. Chairman, that the Food and Drug Administration has been constantly diligent and active under this provision of the law. They have been very constructive in the way they have gone about it. There haven't been a great many criminal prosecutions and serious offense charges of that sort, but there have been innumerable situations where manufacturers and distributors are cited to come in before the Food and Drug Administration, hear its criticism and make adjustment. Adjustment is usually made—in my experience almost always made—by revising

the language to conform to what the Department wants in size of type, in prominence of position, in coloring of background, and that sort of thing. That has been, and is today, a very active area of administration, and I think a very constructive one and a very effective one.

Section 112, the one we are discussing, would require formula disclosure of proprietary medicines (p. 18, line 23). Drugs composed of two or more ingredients must under the bill be labeled to show "the established name and quantity of each active ingredient." This is a throwback to the original food, drug, and cosmetic bill introduced on June 12, 1933 as S. 1944 and generally known as the Tugwell bill. It provided (sec. 8(e)) that a drug would be misbranded if its label failed to bear (1) "the common name of the drug, if any there be," and (2) "the name and quantity or proportion of each medicinal or physiologically active ingredient thereof." This was vigorously opposed and the bill was amended and enacted in the form of the present law which, at section 502(e) requires only the listing of the names of the active ingredients and the quantities of certain specified ingredients such as alcohol, chloroform, bromides, strychnine, and perhaps 10 or 12 others.

The quantitative formula is a trade asset—frequently a very valuable one. The label disclosure of it not only destroys the property right of the owner but it opens the door of opportunity for counterfeiting, substituting, and passing off. The bill, therefore, in the provisions of section 112 would—if enacted—seriously impair and frequently destroy proprietary rights. It takes a dual approach to this end: (1) The dilution of the trademark by the labeling predominance for generic names, and (2) the public disclosure of the formulas.

I emphasize the word "public" there, Mr. Chairman, because in a moment when I come to factory inspection I am going to suggest our willingness to expose to the inspectors quantitative material on the formula. That is one thing. It is another thing to put it on the label.

Now, quite aside from giving up trade assets, a favorite way of counterfeiting or substituting or even price competition is for competitors to take two packages and say: "You see, they are the same thing. The ingredients on each package are the same and even the quantities are the same, this one is cheaper, so buy this one." That is quite common in fields of unfair competition other than this.

The monetary value of trademarks and trade secrets is very great indeed. The value of them for purposes of identifying desired products, guaranteeing their quality and uniformity, fixing responsibility, and protecting consumers against spurious goods, is even greater. Trademarks and proprietary rights are vital parts of the private enterprise system and much of our economy has been built upon the recognition and protection of them.

I understood, Mr. Chairman, there was a witness before you last night—I didn't hear him—speaking of the turn in Russia, turning back to trademarks for identified merchandise and names.

Let me say to you that trademarks constitute one of our most ancient economic institutions. Etruscan vases found in Italy today bear the trademarks of people long ago. So do things unearthed at Pompei. I am thinking of one in particular that was labeled—it would seem modern—Scaurus' brand of jelly. That is on an exhibit

in Naples today out at Pompei. Heraldry merged with trademarks because a knight going into battle had to be identified with his visor down and so he had to be marked with a color or emblem. Hallmarks for silver came from being registered in the Guild Hall in London. Thus we have "hallmarks."

Trademarks have figured as long as we have any record for fixing responsibility, for identifying. They were important in the old days in the case of shipwrecks. And so when we talk on this bill, and on the bill in the Senate, about generic names and trademarks, we are dealing with a very ancient institution.

In the making of drugs, some manufacturers are not satisfied with the minimum requirements of the compendiums. They set higher standards for their products and they seek to discover and formulate new products. The incentive to excel is inherent in the system.

The section could be appropriately amended by striking out the words "and quantity" in line 23 on page 18, and by striking out lines 3 to 11, inclusive, on page 19. Those lines have to do with the precedence of position and the same size of type.

I come now to the last section that I ask your indulgence on. Section 201, pages 30–32, "Inspection of Factories and All Things Therein": Here the bill would amend section 704 of the act to authorize employees designated by the Secretary to inspect factories, warehouses, establishments, consulting laboratories—and consulting laboratories I suppose would take in universities, colleges, hospitals, establishments of all sorts—vehicles and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

Up to that point except for the inclusion of consulting laboratories, it is the same as the present law, but now we go on—

> And all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded * * * have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this act.

This would authorize unlimited inspection, and no one—layman or lawyer, manufacturer, consultant, processor, warehouseman, wholesaler, retailer or carrier—could refuse inspection of anything. It is a criminal offense (sec. 301(f)) to refuse "to permit entry or inspection as authorized by section 704." And by the amendment the authorization is so wide that one would be afraid to refuse any inspection. The catchall phrase (p. 31, lines 8 and 9) "otherwise bearing on violations or potential violations of this act" underscores that the proposed power is for carte blanche inspection.

It is important that the discussion of the proposed amendment be introduced by a reference to (1) the fact that the Food, Drug, and Cosmetic Act is a criminal statute, and (2) that the fourth amendment to the Constitution of the United States assures—

> the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures * * *

The statute is indeed a criminal one. Violations of its many complex, technical requirements—many of which are framed by future regulations of the Secretary's making—are punished as crimes by fines or imprisonment or both—as misdemeanors, and as felonies with a $10,000 fine and 10 years in prison—and guilt does not depend upon

guilty intent and is not avoided by innocence of intent. Indeed, so strict and severe is this statute that criminal punishment may be inflicted upon corporate officers personally even when they have no personal knowledge of the offense or even of the shipments involved, and this may happen even when the officers' corporation is found not guilty. (*United States* v. *Dotterweich*, 320 U.S. 277; 1943.)

The president of the corporation was convicted on two out of three counts, I think. For some unexplained reason—I believe that it is so stated even in the books—the corporation of which he was the president was found not guilty, but the president was. He had no knowledge whatsoever of the shipment. But he was the president. He was the overall boss of the works, and he was convicted and the Supreme Court upheld the conviction.

Factory inspection, as it is presently constituted in the act, is the result of an amendment in 1953 before this committee following the *Cardiff* case (*United States* v. *Cardiff*, 344 U.S. 174). At the time of that case, section 704 of the act authorized entry and inspection "at reasonable times" and—this was the important line—"after first making a request and obtaining permission" of the operator. Section 301(f) then, as now, prohibited refusal "to permit entry or inspection" as authorized by section 704.

The Supreme Court held that the statute—in making inspection dependent on consent and making refusal to give that consent a crime—did not give the factory owner fair warning of the criminal nature of his refusal to give consent and was too vague for judicial enforcement. The Court affirmed the Court of Appeals for the Ninth Circuit (194 F. 2d 686) which reversed the district court and ordered an acquittal of the defendant. Amendments to overcome the effect of this decision were proposed in several bills which were the subject of hearings before this committee on May 19 and 20, 1953 (83d Cong., 1st sess.) H.R. 2769, H.R. 3551, H.R. 3604. H.R. 5740 was prepared after the hearings, reported by the committee, and enacted after debate on the floor.

In the *Cardiff* case, Mr. Justice Douglas said—

Before I quote that I want to say to you, Mr. Chairman, that I am sure you and other members of the committee remember the searching consideration given to that amendment in this committee in 1953, and the extensive floor debate which was had in this House. It was more extensive in this House than it was in the Senate, but there was floor debate and a good deal of committee consideration in the Senate too. So, what we have in the law today came as a result of some very searching inquiry and examination by this committee.

Now, in the *Cardiff* case, Mr. Justice Douglas said:

> The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid (citing cases) may be as much of a trap for the innocent as the ancient laws of Caligula.

In *Boyce Motor Lines, Inc.* v. *United States*, 342, U.S. 337 (1952), the Supreme Court said:

> A criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation.

Does the proposed amendment meet these tests? Will a manufacturer or his lawyer dare refuse the inspection of anything? In an-

swering these questions, we may go back to the *Cardiff* case. Prior to that, the Food and Drug Administration maintained that the comparatively limited inspection of section 704 covered every feature of a factory's operation. The administration contended that the section even then authorized inspection of private formulas, complaint files and qualifications of technical personnel. The following is taken from the Government's petition for certiorari in that case:

> Factory inspection of a drug plant may include observation, photographing, and appraisal of the following factors on the premises: (1) Conditions of sanitation, (2) raw materials, (3) formula cards, (4) actual manufacturing worksheets, (5) batch records, (6) weight and measuring controls, (7) packaging techniques, (8) sterility and pyrogen controls, (9) potency controls, (10) coding system, (11) facilities for maintaining separate identity of each drug, (12) cleaning of equipment between batches, (13) quarantining of drugs until after clearance with control laboratory, (14) qualifications of technical personnel, (15) the complaint file of the firm. In addition, samples and labeling of doubtful materials are purchased from the factory for analysis and appraisal by food and drug scientists, and shipping records relating to sources of raw materials as well as to destinations of finished products are examined and copied to facilitate the removal of offensive merchandise from interstate commerce.

The then Commissioner of the Food and Drug Administration, Charles W. Crawford, testified before this committee that the language of section section 704 did authorize the inspection of numerous items described in that quotation. (Hearings, May 19 and 20, 1953, pp. 84–86.) If the proposed amendment that we have before us now with no limitation in it, should be interpreted in the ratio in which the limited language of the law was interpreted in that certiorari petition, the range of future inspection can be as wide as the imagination.

In these circumstances, it would be better to specify what is subject to inspection. The law, as presently worded, and even more so as administered and as acquiesced in by the industry, already permits extensive factory inspection.

We are not opposed to factory inspection. We would just like to have some limitation, or some security against unwarranted demands for inspection.

With respect to proprietary drugs, we think the inspection provisions of the law are now adequate. But the members of the association are not opposed to inspection except the sort which the bill proposes, the sort which would amount to fishing expeditions and would constitute unreasonable searches.

We suggest the following revision of the proposed amendment—and we make this suggestion, Mr. Chairman, with advice of factory people, in an effort to be constructive and to suggest something that would accomplish what the Food and Drug Administration wants and would give the industry protection.

So we would suggest that the section read:

> SEC. 704. FACTORY INSPECTION. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such

factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein—

and this would be new—

and all pertinent sanitation methods, analytical reports on unfinished materials, quantitative formula data for active ingredients, qualitative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredient assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantine of drugs until after clearance with control laboratory and file of complaints from licensed medical practitioners and licensed medical institutions. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Mr. Chairman, that would give the Food and Drug Administration the substance of what it said it had in the petition for certiorari in the *Cardiff* case.

Some of it would read exactly on it; some other would read in substance, but it is fair to say, I think, that what we have proposed here would give the administration practically everything that they said the law in 1953 gave them in this Cardiff certiorari petition, and, at the same time, it would enable a man to know what he must show. It would enable a lawyer to tell his client that you can safely refuse inspection on this without the danger of criminal prosecution.

I include by saying that I hope that I have indicated the sweep and the substance of this legislation, and the need for thoroughgoing and analytical study of it by this committee. Mr. Chairman, it has been my privilege to appear before this committee a number of times over the years, and I know at first hand the care with which this committee studies its legislation, and I thank you for hearing me this morning on this bill.

The CHAIRMAN. Mr. Hoge, thank you very much for your very full and apparently complete statement and your analysis of this proposed legislation.

You have been so thorough in your description that I cannot imagine there will be too many questions to be asked by the members of this committee.

Mr. Roberts, do you have any questions?

Mr. ROBERTS. I agree with the chairman.

I think it has been a very complete and comprehensive statement. I am sorry I was not here when Mr. Hoge began his statement, but I would like to go back to the area where you talk about the over-the-counter items such as Mentholatum, Murine, and similar-type products.

Is it your contention there that present labeling in most instances is sufficient, and that to go with the type of labeling that you think might be required would bring about a very difficult situation. I believe you used some words which I assume to mean that some of these articles are so small in packaging that it would be very difficult to show the ingredients in the same type as you show the trade name.

Is that the point you are making?

Mr. HOGE. This is in addition, Mr. Roberts, if it means what I suggested that it may mean. If it should mean that these seven or eight ingredients had to be shown in letters the same size and type as the word "Murine," it would make a packaging job—I used the word

"grotesque" advisedly. I think it would be grotesque. It might not even be possible to do it. But, at best, it would be a very difficult job, and would literally destroy, I think, the trademark value of the labeling.

Mr. ROBERTS. You made the further point that these requirements are economic in character and have very little to do with public health, in your opinion.

Mr. HOGE. That is my opinion, Mr. Roberts, but it also—I have as my authority for it, the statements made by the gentlemen in the Senate who advocated these provisions which appeared there before they came here. The chairman of the subcommittee there stated, and on numerous occasions, that these provisions were for the purpose of reducing the price of prescription drugs. He had no reference whatever to these proprietary items.

Mr. ROBERTS. Now, go back to this statement that you had with reference to the power sought in the new bill as far as personnel is concerned.

I would like for you to discuss that just a little bit, where you talk about facilities and equipment. I believe you say that, in your opinion, this would give the Administrator a great deal of power over the personnel of a manufacturer, and you propose to strike from (a) (1)——

Mr. SCHENCK. Where are you reading?

Mr. ROBERTS. I am on page 4 of the statement.

You propose to strike subsections 2 and 3?

Mr. HOGE. Yes.

Mr. ROBERTS. Under (B)?

Mr. HOGE. Yes. That is just on labeling.

Mr. ROBERTS. You propose to strike a part of (B) also, do you not?

Mr. HOGE. The word "personnel."

Mr. ROBERTS. "Controls used for," you propose to strike?

Mr. HOGE. No, sir; only the word "personnel." "Controls used for, facilities, methods," I would leave in.

Mr. ROBERTS. You take out "personnel"?

Mr. HOGE. "Personnel," yes, sir. It seems to me, Mr. Roberts, that there is a big difference in the Government regulating and supervising, to some extent, to the proper extent, let us say, machinery, sanitation, housing. It is another thing to get into the personnel, the qualifications of personnel, how long they have worked for us and whether they have got college degrees or have not got college degrees. We are dealing with people, and I think a different test is indicated.

The CHAIRMAN. You say that is on page 4?

Mr. HOGE. Yes, sir.

Mr. ROBERTS. Page 4 of his statement, the third underscored line which says "facilities or personnel." Also strike subsections 2 and 3 under (B).

Mr. HOGE. Mr. Roberts, I would also strike the power of the Secretary to prescribe these things by regulation. The present law does not do that, and I would strike "personnel," and then two lines below it we have, "regulations promulgated by the Secretary."

Mr. ROBERTS. You would also strike that?

Mr. HOGE. Yes, sir.

Mr. ROBERTS. You want the law to stay as it is at the present time?

Mr. HOGE. Well, no.

The law at the present time comes down to the underscoring. The law at the present time covers unsanitary conditions. Now, the amendment, with the striking that I have suggested, would add to sanitary controls the "methods used in," the "facilities or controls used for;" would put them in the same category with the sanitation control.

Mr. SCHENCK. Will the gentleman yield for a question?

Mr. ROBERTS. I yield.

Mr. SCHENCK. Mr. Hoge, it was my impression that the personnel referred to here was the description of the qualifications of the personnel, their training, experience, and ability of personnel.

Do you object to establishing certain qualifications of that nature?

Mr. HOGE. Yes. I think that is a matter for the manufacturer in employing his people and in studying them over a long period of years to determine whether he has competent personnel. I do not think the Secretary ought to do this.

Mr. SCHENCK. You do not think the matter of competence should enter into this?

Mr. HOGE. Well, necessarily, it enters into it, and it is a part of the manufacturer's responsibility, of course, to have competent help, but I think, to put that under governmental control is a different thing than charging him with the responsibility.

Mr. SCHENCK. Thank you.

Mr. ROBERTS. That is all I have, Mr. Chairman.

The CHAIRMAN. Do you object to giving the Secretary the authority to determine by regulation on the basis of good manufacturing practice as to whether or not a particular person is qualified for the job?

Mr. HOGE. Yes.

The CHAIRMAN. Do you think that the manufacturer should determine the adequacy of the personnel?

Mr. HOGE. Yes; I do.

The CHAIRMAN. And his employment?

Mr. HOGE. Yes.

The CHAIRMAN. That is what this would do, would it? It would permit the Secretary to have that authority?

Mr. HOGE. That would give it to the Secretary; yes.

The CHAIRMAN. Do you interpret this to mean that even though a given person employed by the manufacturer may be well qualified as to background, the Secretary could determine that that person was inadequate——

Mr. HOGE. Well, now, let us see, if he made regulations, I doubt that he could make regulations as to individual persons. He would have to try to standardize. He could not deal with personalities at that point. If he did not have the regulations, then he might in a given case attack the competency of the personnel. But the way it is here, I think it would be a matter of some form of standardization. I do not know what it would be. I would just be guessing.

The CHAIRMAN. It would be based on good manufacturing practices. That would be the key words, I would think.

Mr. HOGE. I have no objection to the language, but I do have objection to the Secretary making the determination. Now, charge the manufacturer, if you please, with having controls and facilities in accordance with good manufacturing practice, and if he does not do it, then make him responsible under the act—his article is adulterated as you have it here—but let us not give the Secretary the authority to standardize these things by regulations.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Mr. Chairman, just to pursue that a bit further, my impression of the matter of controlling the personnel was the establishment of standards of education or fitness for a given job, not necessarily a personality or a person, but merely broad qualifications, educational and otherwise.

Is this the provision to which you object?

Mr. HOGE. It is the provision, but, Mr. Schenck, I think that it is fair to say that when we are writing this language, we have to consider the growth of it under administration. Now, I happen to know from conversations had respecting this language—I do not think it would be fair for me to quote someone because I cannot document it—that some people advocating this would like to know whether employees had Wasserman tests.

"Well, what has that got to do with it," I asked.

"Well, it may have a lot to do with it."

They would like to know whether the employees had Wasserman tests. They said "We would like to prescribe that they have Wasserman tests."

Well, I am not against Wasserman tests, but I wonder if we are going to have the Federal Government getting into that sort of control. Now, let me say again, Mr. Schenck, that we are not discussing a State or a city ordinance. You might have one situation there. But is Federal, central control to be carried to that extent in this sort of regulation?

Mr. ROBERTS. One more question.

Mr. SCHENCK. Mr. Hoge, it would seem to me that almost all marriage laws require certain health standards. Would you feel that that would be improper in the manufacture of some proprietary medicine?

Mr. HOGE. I think there is a difference.

Mr. SCHENCK. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I am going to be very brief with my questions.

I would like to know what procedure these proprietary drug concerns go through. What standards do they have to have before they can market their product?

Mr. HOGE. The proprietary drugs are subject to the new drug provisions of the law, just as all drugs. I would have to go farther to answer that. A new drug is one which is not generally recognized as safe by experts and so on. Now, if you bring out a proprietary drug today, consisting of ingredients generally recognized, well known, and on good advice there is no question of safety, all you do is bring the drug out, put it up in the proper labeling with directions and warnings and all of the other things that the law requires, and market it, you do not go through any form of pregovernmental control.

Mr. FRIEDEL. You do not have to get the FDA's approval?

Mr. HOGE. No, sir; you do not, unless there is a question of safety. That, of course, poses this situation for the company and its adviser. If there is any doubt about the safety, if one has any question that he may run afoul of the law, then he would file a new drug application, and, very likely, the Food and Drug Administration would report back that: "We do not thing the section applies." You then have had your assurance. But that is just a matter of precaution. Now, if you were combining two well-known things and recommending them for time-honored conditions, you would not file any application of any kind.

Mr. FRIEDEL. You would have to have no proof of tests to show that the article is——

Mr. HOGE. You would not if you were dealing, as I say, with these old drugs which are, to use the words of the act, generally recognized.

Mr. FRIEDEL. For example, you just had some salve there. What is that?

Mr. HOGE. One is the Mentholatum salve.

Mr. FRIEDEL. And you stated that it might be a cold salve or it might be a pain salve. Who would determine that?

Mr. HOGE. It is an external ointment according to its directions, "to be used as a vaporizing unguent and balm applied for relief."

Well, the manufacturer determines it, but he does it, of course, on the advice of his chemists, his pharmacologists, and others that he seeks out. And, of course, he may make tests, Mr. Friedel, and probably does. But the law does not require him to file for a new drug unless is is not generally recognized as safe.

Mr. FRIEDEL. This leads to my question. On page 15 of your statement, the bill, pages 8 and 9, authorizes the Secretary to withdraw his approval if it later appears to him that there is substantial doubt as to the safety or efficacy of the drug, to authorize the suspension of approval prior to the hearings when the Secretary finds that there is imminent hazard to the public's health.

Now, are you opposing that?

Mr. HOGE. The place I have it there in my statement, Mr. Friedel, would apply to a drug which is on a new drug application. Now, these proprietary articles, most of them now are not on new drug applications. My point along there was that if you change the definition to include efficacy, so that a new drug is now one which is not generally recognized as efficacious and safe, it might bring in some of these proprietary articles on which no one has any question of safety, but some expert, as the law calls him, might say, "Well, I don't think it will do you any good; I don't think it is harmful; I don't think there is anything unsafe about it, but I don't think that it will do you any good, and, therefore, it is a new drug." And now you have got to go through all of this new drug procedure. Now, those matters on page 15 apply to a drug which, however it got there, is under a new drug application.

Mr. FRIEDEL. Getting away from the proprietary drugs, to a new drug, if the Secretary of Health or the Food and Drug Administration would find that it would be an imminent hazard to the public health he could order suspension of approval without a hearing?

Mr. HOGE. That is right.

Mr. FRIEDEL. That you are opposed to?

Mr. HOGE. Yes.

That is an awful lot of authority.

Mr. FRIEDEL. Do you not think the Secretary would notify you that they have complaints on it or something, prior to withdrawing the drug?

Mr. HOGE. Well, it puts in one man an awful lot of power to say that without a hearing he can just pull this article off the market, on which one has invested, well, somebody said yesterday, I think, about $5 million to get a new drug on the market.

Mr. FRIEDEL. I do not want to prolong this, but I think in your testimony here you said you had such wonderful cooperation with the Food and Drug Administration?

Mr. HOGE. Yes, we do.

Mr. FRIEDEL. Very few cases have gone to court. They just come in and notify you.

That is why I cannot understand why you are opposed to this, when they have shown in the past that they do cooperate.

Mr. HOGE. I am glad you said that because, in my considered opinion, having worked with this law for many years, I think the great cooperation that the industry has with the Government is due to the fact that this law back there in the 1930's was worked out as a law which stated the obligation of the industry and gave the power, gave power to the Administrator to enforce it, so that both parties have approached this work over the years with respect for each other.

The Food and Drug has assumed its burden and gone about its duty, and the industry has tried to assume its burden and gone about its duty under the law.

I think this statute has been one of the finest statutes that I have ever had any experience with for the reason that it was worked out so carefully back there in the 1930's, and does so clearly state the requirements that are upon us and the duty that is upon the Administrator.

That is what I am asking you to do now with this amendment, is to keep the law that way by revising it—I am only asking for revision, Mr. Friedel. I am not opposing amendment to the law at all except in the details which I have discussed.

Mr. FRIEDEL. That is all, Mr. Chairman.

I would like to pursue it further, but I know we have other witnesses and other members want to ask questions.

The CHAIRMAN. Do you think there should be some procedure, Mr. Hoge, whereby a drug, if there are obvious reasons, could be temporarily withdrawn from the market until after a hearing and such other procedure as may be necessary to determine its safety?

Mr. HOGE. I think you can do that now by injunction, Mr. Chairman.

The CHAIRMAN. Do you think that would be sufficient authority for the Secretary to go to court?

Mr. HOGE. Well, I think so, and I would say this:

That if there is any doubt about it, then I think the act might be revised to make it clear that he could go to court.

You mentioned yesterday the cranberry incident. It is no criticism of the Administrator to say that these things can happen. He is only human, and he has to delegate with this large organization to

people all down the line, and they are just as likely to go off sometimes as we are.

I think that, just generally, to have a court or to have somebody that is not immediately interested in it, either from the industry's standpoint or the Food and Drug standpoint, to pass upon it is a safeguard which we have long recognized in our system of jurisprudence.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

Mr. Hoge, you made the statement that your relationship with the FDA was very satisfactory and with the industry and under the law you knew your responsibilities, they knew theirs, and you have gotten along very well and produced good drugs.

Mr. HOGE. That is correct, yes.

Mr. YOUNGER. Is that a fair statement?

Mr. HOGE. That is a fair statement.

Mr. YOUNGER. Then why, in your opinion, are these changes proposed?

Mr. HOGE. You mean the changes that I have proposed?

Mr. YOUNGER. No, the changes which this law proposes.

Mr. HOGE. Oh, well, I think that they, like ourselves, learn by experience, and, as we go along, we see need for updating the law. We did it here in 1951 with Durham-Humphrey. Experience had taught us that some different controls were needed with respect to prescription drugs and we worked them out. We were here on factory inspection in 1953 because of the Supreme Court decision.

We have been here on food additives because of what we learned in those respects. I think it is just a matter of growth, a larger industry, a larger population, and the things that Food and Drug has learned in administering and the things we have learned in trying to obey the law.

As with this unfortunate thalidomide case, we have all learned something. I am not sure, and, in fact, I have read that it perhaps could not have been prevented. I do not know whether the regulations which the Government has adopted now will prevent it in the future, but on what we have learned the Food and Drug Administration has now proposed some regulations which have been shaped in the light of what has been learned, and it is hoped that they would prevent anything—well, it really did not happen, but it might have happened—and they would prevent anything like it happening again.

That is the reason for it, and I am quite in sympathy with updating this law, Mr. Younger.

Mr. YOUNGER. Primarily, if I understand your statement, you want these changes expressed in the law?

Mr. HOGE. Wherever possible.

Mr. YOUNGER. And not left to administrative regulations of some kind that may change at any time without hearing or without due process?

Mr. HOGE. That is quite true, and I will say to you that there have to be exceptions. I know that, that you cannot deal by express statute with every detail. We have to have regulations. We have to have food standards, as an illustration.

But wherever we can write these matters into law, let us do it and let us not avoid it simply because it may be a little inconvenient to the Food and Drug Administration, or it may be easier for them to do

it themselves rather than to go to the court. Those are not good reasons. They can give you good reasons why they ought to make food standards, rather than have them enacted here in the statute. But, wherever we can, we should write the requirements in the law. That would be the only way I can answer that question without being dogmatic about it.

Mr. YOUNGER. Just one other question.

It is not clear in my mind what you mean when you say that under this law the Administrator or the Commissioner may say that the trademark is the name of the drug. Is that true?

Mr. HOGE. Yes.

There is nothing in the bill, as prepared, that would prevent it, and, as I said in my statement, my anxiety about it is born of experience, because they did attempt that very thing 20 years ago.

Mr. YOUNGER. To follow that just one step further, if the Commissioner were to say that Mentholatum is the name of this product, then would it follow that any manufacturer could take those same ingredients and produce Mentholatum and violate the trademark which the original manufacturer had?

Mr. HOGE. If the Commission declared that Mentholatum was the name of that product, however he would describe the product, if he declared that that was the name of the product, then every manufacturer who put out that product would have to call it mentholatum.

Mr. YOUNGER. Regardless of the trademark?

Mr. HOGE. Yes, sir.

Mr. YOUNGER. Regardless of the protection which the trademark gives to the original manufacturer?

Mr. HOGE. If the law is amended this way, he would have to. As the law is today, no.

Mr. YOUNGER. That is all, Mr. Chairman. That was not clear in my mind.

Mr. SCHENCK. Mr. Chairman?

Mentholatum or Murine or other products you mentioned are compounds, are they not, Mr. Hoge, not drugs?

Mr. HOGE. Yes.

Mr. SCHENCK. Is a compound a patentable item?

Mr. HOGE. Well, practically not today, sir. I do not know of any of these things that are patented. We call them patent medicines frequently, but they are not.

Mr. SCHENCK. In other words, it is a proprietary compound, the knowledge about which is a complete and personal knowledge held by the manufacturer who produces it under a trade name or a brand name or a trademark name, is that correct?

Mr. HOGE. That is true.

It is know-how, we call it, which is so important, and which sometimes is reflected in such unexpected places. For instance, as I said to you in factory inspection, it is one thing to let the inspector see the quantitative formula. It is another to let him see the qualitative formula because the effect of these things is frequently materially influenced by the inactive ingredients, the binders that are used, or the diluents, and much of the trade secret is in those things, the temperatures, the batch controls and so on.

Mr. SCHENCK. Thank you.

The CHAIRMAN. Did I understand you to say, Mr. Hoge, that if this law were to be enacted, that hereafter Vick's salve would become Mentholatum?

Mr. HOGE. Mr. Chairman, I ardently hope that would not be the case. I have represented Vick's salve for a great many years.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. No questions.

The CHAIRMAN. You have been very responsive to the questions, and certainly have shown you know your subject, Mr. Hoge.

The committee wishes to compliment you for it and extend our thanks.

Mr. HOGE. Thank you, Mr. Chairman and gentlemen of the committee.

The CHAIRMAN. The committee will recess until 1:30.

(Whereupon, at 12:05 p.m., the hearing was adjourned, to reconvene at 1:30 p.m., of the same day.)

AFTERNOON SESSION

Mr. ROBERTS (presiding). The committee will please be in order.

The next witness is Mr. D. L. Bruner, executive secretary of the Animal Health Institute, 512 Shops Building, Des Moines, Iowa.

You may proceed, sir.

STATEMENT OF D. L. BRUNER, EXECUTIVE SECRETARY, ANIMAL HEALTH INSTITUTE, DES MOINES, IOWA, ACCOMPANIED BY B. H. LEBEIS, COUNSEL

Mr. BRUNER. Thank you.

Mr. Chairman and members of the committee, I am appearing today on behalf of the Animal Health Institute, of which I am executive secretary, to express the views of AHI on H.R. 11581.

AHI is an association of more than 80 firms engaged in the manufacture and distribution of animal drugs—animal health and nutrition products. Our membership accounts for the major share of the production of these products in the United States, the sales value of which approximates $300 million annually.

Mr. Chairman, the Animal Health Institute is deeply committed to the principle of protecting the health of consumers by legislation requiring manufacturers to establish the safety and effectiveness of new animal drugs. At the same time, we submit that any such legislation should encourage the development and marketing of animal drugs for all safe and effective uses.

The health and productivity of our livestock and poultry populations are dependent, in great measure, on the flow of our industry's products to the farm. Research has made that flow of safe and effective animal drugs possible. Continued research will provide even better products for the future, and help to lessen the tremendous annual livestock losses which, in 1959, were $2.5 billion. The research effort required to develop these products and make them available

must be encouraged, if we are to have an adequate food supply at reasonable prices for our expanding population.

For further information concerning the economic importance of animal drugs to the farmer and to the consumer, the members of this committee may wish to refer to the testimony of Dr. Don Paarlberg, Hillenbrand professor of agricultural economics, Purdue University, given August 7, 1962, before the Subcommittee on Health and Safety of this committee on H.R. 12437 and H.R. 12420. Dr. Paarlberg's testimony is brief and I have attached it to my statement for easy reference.

Mr. ROBERTS. It may be received for the record.

(The statement referred to is as follows:)

[Attachment to statement of D. L. Bruner]

TESTIMONY OF DR. DON PAALBERG, HILLENBRAND PROFESSOR OF AGRICULTURAL ECONOMICS, PURDUE UNIVERSITY

My name is Don Paarlberg. I am a professor of agricultural economics at Purdue University where I engage in research and teaching in a number of fields including livestock economics. During the previous administration I held various positions: Assistant Secretary of Agriculture, Special Assistant to President Eisenhower, and Food-For-Peace Coordinator.

I am here as a professor of Purdue University, at the expense of the University. The Animal Health Institute invited me to attend but has no financial stake in my presence or in what I shall say. My purpose is to make clear to this subcommittee the importance of the livestock industry and the importance of medicants and other drugs to that industry. In making this statement I have in mind the well-being of our Indiana farmers, who receive nearly three-fourths of their income from the sale of livestock. Nationwide, more than half the gross income of American agriculture is from sales of livestock.

In 1960 the various classes of livestock accounted for farm receipts of the following magnitude:

Cattle and calves	$7,396,000,000
Dairy products	4,737,000,000
Hogs	2,857,000,000
Eggs	1,728,000,000
Chickens	1,125,000,000
Turkeys and other poultry	431,000,000
Sheep and lambs	329,000,000
Wool	111,000,000
Other livestock and products	224,000,000
Total	18,938,000,000

Modern methods of livestock production make the use of pharmaceuticals absolutely imperative. Efficient large-scale production of broilers, for example, with thousands of birds kept in close confinement, would be impossible without medicants. Epidemic disease would decimate these flocks in short order. According to the Journal of Animal Science, 70 percent of the beef cattle on feed are either fed or implanted with diethylstilbestrol, a hormone known to have a favorable effect on the rate of growth. Benefits, according to this same source, are of the magnitude of a 17-percent increase in weight gains and a 12-percent improvement in feed efficiency, as compared with untreated animals.

In hogs, Professor W. M. Beeson of Purdue University found that the inclusion of streptomycin produced an 11-percent increase in daily gains.

One economic effect of these pharmaceuticals is to lower livestock production costs and reduce the price of meat, milk, and eggs to the consumer. At the lower prices, more meat is purchased. Much of the improvement in the nutritive level of the American diet in recent years is attributable to the efficiencies which have resulted from the tremendous strides made in the use of pharmaceuticals.

The following brief table is an indication of the advances in efficiency for various classes of livestock:

	1925–29	1959
Pigs saved per litter	5.7	7.0
Lambs saved per 100 ewes	86.0	96.0
Calves saved per 100 cows	76.0	87.0
Live weight of hogs produced per sow	1,154.0	1,487.0
Live weight of lamb produced per ewe	58.0	76.0
Live weight of cattle produced per cow	390.0	629.0

These striking increases are attributable, to some indefinable degree, to better disease control, better nutrition, the use of hormones, better breeding, better management, and the use of better equipment. Pharmaceuticals relate directly to the first three of these.

No one can say for certain how much higher would be the price of beef roast without veterinary drugs. No on can say how much the cost of poultry meat would rise if there were no medicants, or how much pork prices would increase if there were no antibiotics. Farmers and, I am sure, consumers, hope there never will be need to learn. One thing is sure. Whatever price increase occurred would come from higher production costs, the result of greater mortality and morbidity, and slower rates of gain. All of these would be abhorrent to the farmer.

It is perfectly clear that many veterinary drugs are not in question and are not affected by the legislation before this committee. But some of them are.

The health and safety of the consuming public is properly the major responsibility of this committee. Even though this is the major and indeed the overriding concern, it cannot very well be the only consideration. My purpose is to emphasize that economic considerations also are important. They are important from at least these views: Production costs to farmers, food costs to consumers, and incentives for research in the pharmaceutical industry.

There is undoubtedly a very large sector within which efficient production and human health are wholly compatible. I am sure this committee will do its best to define and protect this area of mutual interest.

Mr. BRUNNER. The AHI associates itself with the testimony provided by PMA on H.R. 11581. My comments, accordingly, will be limited to (1) describing the unique impact of existing law and of H.R. 11581 on animal drugs as distinguished from drugs for human use, and (2) suggesting means for correcting the regulatory nightmare which now seriously impedes the clearance of new animal drugs and which would worsen substantially if H.R. 11581 were enacted without amendment.

The adverse impact of existing law on the clearance of new animal drugs was discussed in considerable detail in my statement submitted August 7, 1962, on behalf of AHI to the Subcommittee on Health and Safety of this committee on H.R. 12437 and H.R. 12420, with particular reference to pages 4 to 14 of my statement. At this time, I will briefly discuss the operation of existing law in this field.

TRIPLICATION OF CONTROLS

A major problem, shared by drug manufacturers, feed manufacturers, livestock and poultry producers, and, ultimately, the consumer, is the triplication of controls under the Federal Food, Drug, and Cosmetic Act as presently interpreted and administered. We feel that such triplication is consigning to oblivion the incentive to conduct research and to develop new animal drugs.

Duplication and triplication of legislative provisions applicable to the clearance of new animal drugs has created a top-heavy superstruc-

ture of administrative regulations. This is not necessary in order to adequately protect the public health, and is completely unjustifiable from the point of view of the public welfare or sound legislation.

New animal drugs are subject, first of all, to the clearance provisions of the new drug section, section 505, of the act. As applied to animal drugs, this section requires manufacturers to demonstrate the safety of new animal drugs under the conditions of use proposed for such drugs, which includes establishing their safety when mixed in animal feeds and fed to animals.

Second, the same new animal drugs, when used in combination with certifiable antibiotics, must also be cleared under the regulations promulgated pursuant to the antibiotic section, section 507, of the act. This section requires the batch certification of certain specified antibiotic drugs. It does not purport to create duplication in regulations, but it has led to this result, even though the statute authorizes FDA to exempt any drug or class of drugs from the requirements of section 507. We believe this statute has been distorted because the FDA regulations on the one hand do exempt animal drugs from batch certification but on the other hand subject many of them to detailed clearance procedures, even when such drugs have already been cleared under section 505.

As the law is construed and applied by FDA, every feed and formulation must be cleared under regulations promulgated under section 507, if it contains, among other drugs, a certifiable antibiotic drug. The feed formulation thereupon becomes exempt from batch certification and only then may be marketed.

Third, new animal drugs are subject to the clearance procedures contained in the food additives section, section 409, of the act. This section was intended to apply mainly to chemicals added to human food, which are not otherwise subject to any clearance procedures. Like the antibiotic section, the food additives section was not designed to produce duplication in regulations. Thus, the statute exempts from food additives regulation articles which have been granted prior "sanction or approval" under the act. However, this exemption is so strictly construed that drugs having such a "sanction or approval" by virtue of prior clearance under sections 505 or 507 nevertheless must be cleared under section 409 when used in animal feeds in combination with new drugs not having such an exemption. And the exemption does not apply to any drug whatsoever developed after 1958.

Accordingly, animal drugs are subject to three separate statutory procedures for the same uses involving three separate regulatory divisions of the FDA. These three sections of the law have differing provisions, are subject to differing interpretations, and the actions taken under one are not always consistent with the actions taken under the others.

As a result of this situation, there has, in our opinion, developed an unreasonable distortion of regulatory effort which is totally unjustified and which may seriously retard further progress in agricultural technology.

FDA construes the law to require feed manufacturers, as well as drug manufacturers, to file new drug applications. In effect, this enables FDA to license the use of individual feed formulations of individual feed manufacturers even though the drugs used in those

formulations have previously been cleared as safe for such use. Thus, the regulations go beyond the establishment of safety of drugs in animal feeds and actually undertake the licensing of the feed manufacturing industry.

Not one of the three preclearance sections of the act was designed primarily to cover the use of animal drugs. However, their combined operation in this field has produced unreasonable delays, overlapping jurisdiction, and extreme confusion within the drug and animal feed manufacturing industries. They can produce serious dislocations, particularly for small manufacturers. Because of the cost and time involved to obtain the multiple-type clearances presently required by FDA, animal health products of a demonstrable utility will sometimes die at their inception.

A PROPOSED SOLUTION

Accordingly, we urge Congress to enact a new section to the Federal Food, Drug, and Cosmetic Act which would govern the preclearance of new animal drugs. A bill for this purpose could be entitled "Premarketing Clearance of New Animal Drugs." It would amend chapter V of the act by adding thereto a new section, and it would contain other conforming amendments to the act, as well as appropriate transitional provisions. Under our proposal, new animal drugs would henceforth be exempt from the preclearance requirements of the food additives, new drug, and antibiotic sections of the act, inasmuch as the preclearance of such drugs would be governed by the newly created section of the act specifically geared for animal drugs.

By such an amendment, Congress can establish a proper basis for the accomplishment of both of the following purposes:

(1) To protect the health of consumers by requiring manufacturers of new animal drugs to pretest any potentially unsafe drug for use in animals other than man; and

(2) To advance agricultural technology by permitting the use of animal drugs at safe levels.

At the present time, the second of these purposes is being unreasonably thwarted. This second purpose should be specifically recognized by Congress now, in the same manner that Congress adopted a similar purpose in connection with the Food Additives Amendment of 1958. (See H.R. 2284, 85th Cong., 2d sess., July 28, 1958.) Under present circumstances, it is imperative for Congress to take positive steps to reestablish its intention to provide for advancement of agricultural technology.

The new section of the act governing the preclearance of animal drugs would be patterned after the new drug law, section 505 of the act, so that the firm intending to market a new animal drug would be required to present evidence of safety for the proposed use or uses of the drug and obtain an effective new animal drug application prior to marketing the drug. Other provisions necessary to fully protect the public health would also be incorporated in the section.

In addition, we would recommend that the bill we are suggesting for enactment contain provisions which would require the registration of all establishments manufacturing animal drugs or mixing such drugs in animal feeds for sale. Each registered establishment would be subject to inspection and would be required to be inspected at least

once in each 2-year period. We would also support a provision in the bill that an animal drug or feed containing such a drug would be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug or animal feed has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Under these provisions, it would no longer be necessary to require the filing of new animal drug applications for individual feed formulations needed by individual feed manufacturers once the safety of the basic drug and combinations of drugs had been established.

IMPACT OF PROPOSED LEGISLATION

Section 105 of H.R. 11581 proposes to extend batch certification procedures under section 507 of the act (now limited to five specified antibiotic drugs) to all antibiotic drugs and to products such as animal feeds containing such drugs. We strongly oppose such a change.

Under existing procedures, such extension will only lead to the imposition of more meaningless clearance within FDA for antibiotic-containing feed products, with no concomitant gain to public health. A number of additional feed formulations not now covered by the antibiotic regulations would be brought under these regulations in addition to other regulatory procedures to which they are subject.

There is no justification for the application of batch certification requirements to animal drugs. No batches of antibiotics used in animal feed are actually certified, even today, and none would be certified under extension of batch certification as proposed in H.R. 11581. But, as discussed earlier in my statement, the so-called exempting regulations issued by FDA amount to licensing controls over individual feed formulations.

As has been previously pointed out to this committee, the original law providing for the batch certification of penicillin was adopted as a temporary measure until satisfactory manufacturing methods, tests, and controls to assure uniformity among batches of different manufacturers could be established. The legislative history of section 507 clearly shows that batch testing controls were to be discontinued when no longer necessary to accomplish this objective. Since today antibiotics can be produced with the same assurance of uniformity and quality as other drugs, the entire batch certification procedure has become an anachronism.

In any case, H.R. 11581 should be amended so as to make it clear that section 105 thereof be limited in its operation to drugs for human use, in the event this committee decides to retain this section in the bill.

Mr. Chairman, may we emphasize that prompt action by Congress is necessary to clarify the legislation and regulations applicable to the use of animal drugs. We appreciate the opportunity of appearing before you today and presenting our views on this important legislation. You may be assured that AHI stands ready to assist this committee in any manner possible.

The CHAIRMAN. I notice you have a document attached to the statement. Do you desire that to be included in the record?

Mr. BRUNER. Yes, sir; if you please.

The CHAIRMAN. It will be included in the record. Does that conclude your presentation?

Mr. BRUNER. Yes, sir.

The CHAIRMAN. Any questions?

Mr. YOUNGER. Just one.

Mr. Bruner, as far as the Animal Health Institute is concerned—and I take it you speak for the industry——

Mr. BRUNER. Yes, sir.

Mr. YOUNGER. You would prefer to have a separate section in this bill dealing solely with the preparation of animal foods?

Mr. BRUNER. Right.

Mr. YOUNGER. And drugs?

Mr. BRUNER. Yes, sir.

Mr. YOUNGER. Mr. Chairman, I wonder if he would prepare a suggested section to the bill and send it to us for our study?

Mr. BRUNER. We would be happy to, Mr. Younger. That is going to take a little time, but we will start working on it, I assure you.

Mr. YOUNGER. Thank you.

(The requested information was not available at the time of printing.)

The CHAIRMAN. Of course, there is some overlapping in your presentation here and in the consideration of the other bill H.R. 12437, on which hearings were held a few days ago.

Mr. BRUNER. That is right.

The CHAIRMAN. The committee will have to take that into consideration, too.

Mr. BRUNER. Mr. Chairman, we did not complete our testimony on August 7 before the committee, and, as I understand it, that Committee on Health and Safety was adjourned upon call of the chairman.

So, while our statement is in the transcript of proceedings, it has not and might not be printed, and we would like very much to have our entire presentation, with the exhibits that were attached, included in the record, in this record.

The CHAIRMAN. Very well.

(The statement referred to, together with the attachments, is as follows:)

TESTIMONY OF D. L. BRUNER, EXECUTIVE SECRETARY, ANIMAL HEALTH INSTITUTE

My name is D. L. Bruner, and I am appearing today on behalf of the Animal Health Institute, of which I am executive secretary, to express the views of AHI on H.R. 12437.

AHI is an association of more than 80 firms engaged in the manufacture and distribution of animal drugs—animal health and nutrition products. Our membership accounts for the major share of the production of these products in the United States, the sales value of which approximate $300 million annually. The health and productivity of our livestock and poultry populations are dependent, in great measure, on the flow of our industry's products to the farm. Research has made that flow of effective animal health and nutritional products possib'e. Continued research will provide even better products for the future, and help to lessen the tremendous annual livestock losses which, in 1959, were $2.5 billion.

This, Mr. Chairman, is the credo of AHI—that through the advances and breakthroughs made in the research laboratories of our member firms, we will be able to do an increasingly better job of protecting the Nation's livestock

from disease and nutritional deficiency. Great strides have been made toward these goals in recent years, particularly through preventive therapy by means of incorporation of animal health and nutritional products in animal feeds. The bulk of manufactured feed, in fact, now contains such drugs in minute amounts for disease prevention and growth promotion.

These drugs have been a major factor in revolutionizing feed technology. They have improved the efficiency of feed conversion and affected the organization of production on the farm, with a resulting higher production of meat, milk, and eggs than would otherwise be possible. At a symposium held in 1956, representatives of the National Institutes of Health stated that the main direct benefit to mankind from the use of medicated feeds is the present availability of more and better foods at relatively less cost to the producer and to the consumer.

However, much remains to be done—new and improved animal health and nutritional agents must continue to flow from the research laboratory, through development and ultimately to commerical production and to the farm. These agents are needed—indeed, they are indispensable if we are to have an adequate food supply for our expanding population. The research and development effort required to find them make them available must be encouraged.

Before dealing with the specific provisions of H.R. 12437, I wish to summarize as clearly and as briefly as possible the effect of the Federal Food, Drug, and Cosmetic Act as currently in force on the incentive for research and development of animal drug products. We believe that the proposed legislation should be viewed in that context, because in our opinion the act as presently administered is curtailing such incentive.

Furthermore, we wish to invite the subcommittee's attention to two measures now pending before the full committee and amounting to a major revision of the Federal Food, Drug, and Cosmetic Act. These are H.R. 11581 and H.R. 11582. These proposed bills, we believe, would in several respects result in further curtailment of research incentive.

H.R. 12437 addresses itself to the food additives amendment of 1958, as do H.R. 12420 and sections 302(a) and 303 of H.R. 11582. In fact, it is limited in its application to ingredients in animal feeds. Therefore, we must assume that the broad problems arising from the application of existing law to animal drugs and the need for legislative remedy therefor have been assigned to this subcommittee.

TRIPLICATION OF CONTROLS

The Federal Food, Drug, and Cosmetic Act as presently interpreted and administered is narrowing down and, we fear, consigning to oblivion the incentive to research and develop new animal drugs—through a triplication of controls. This is a major problem which is shared by drug manufacturers, feed manufacturers, livestock and poultry producers, and ultimately, the consumer. The protection of the public health does not, in our opinion, require such a top heavy superstructure of regulatory clearances as presently exists.

The premarketing clearance of new drugs for safety was first incorporated into our basic food and drug law with the enactment in 1938 of the Federal Food, Drug, and Cosmetic Act. The new drug section of this statute, section 505, was written primarily to require the pretesting of drugs for use in humans. While many such drugs were known to be useful in the field of animal health, subsequent research established the usefulness of incorporating drugs as ingredients in animal feeds for promotion of growth and prevention and treatment of animal diseases. The FDA found it necessary to interpret the then existing law so as to make it apply to these new uses of drugs for which the law had not been specifically designed. This was accomplished by applying fundamentally the same criteria to those drugs as had been established for drugs for use in humans.

One of the basic criteria for the clearance of a new drug application is the control commitments which will insure that the marketable finished dosage form would be identical to that which was tested clinically. This is justified in the case of human pharmaceuticals. However, this concept was carried over into drugs incorporated into animal feeds by requiring that each feed manufacturer submit and obtain an effective new drug application for his medicated feed. This over and above the requirement that the basic drug manufacturer establish the safety of the drug in the first instance. Thus, the FDA saw fit to exercise controls going beyond the establishment of safety of drugs for use in animal feeds, a result which was never contemplated by Congress.

Following World War II, Congress added to the act section 507, requiring the batch certification of penicillin and subsequently four other antibiotics and their derivatives. As in the case of the new drug section, the antibiotic section of the law was primarily designed to provide that such drugs would be safe and efficacious when used in humans. Subsequently, these antibiotic drugs were discovered to be useful when incorporated as ingredients in animal feeds. However, it was obviously impractical to require the certification of each batch of an animal feed containing a certifiable antibiotic. The law authorized FDA to exempt any drug or class of drugs from the requirements of the antibiotic section when such requirements are not necessary to insure safety and efficacy of use. Therefore, once the safety and efficacy of an antibiotic drug intended for use in animal feeds have been established it would have been appropriate for FDA to have exempted such a use of these drugs from any further requirement of the antibiotic section.

However, following a line of reasoning similar to that adopted under the new drug section, the FDA actually proceeded to promulgate regulations, which on the one hand exempted these drugs from batch certification and on the other hand established conditions which served to control the ultimate use of such drugs in animal feeds, reaching as far as individual feed formulations.

The approach the FDA took has produced a paradoxical situation. Any finished feed which contains any amount of a certifiable antibiotic is regulated as though the feed itself were an antibiotic drug. This enables FDA to subject drugs other than antibiotic drugs to the antibiotic regulations, since a preponderance of feeds currently marketed contain other drugs, and such drugs must be cleared in combination with the antibiotics. A vast superstructure of regulations was thus produced by the necessity to apply for so-called exemptions under the antibiotic section covering each individual feed formulation.

In 1958 Congress enacted the food additives amendment, section 409, of the act. This law was primarily designed to require the pretesting of chemicals used as direct or indirect additives in food for human consumption. There is no convincing evidence that Congress intended that this section should be applicable to articles such as drugs for use in animal feeds, which were also subject to the preclearance requirements of other sections of the law. However, following enactment of the food additives amendment, the FDA determined that such drugs fell within the meaning of the term "food additive". This was based upon the interpretation that an animal feed is a food within the meaning of the law, and therefore a drug incorporated into an animal feed is a food additive. The foregoing also applies to animal health products administered orally (other than in feed) and by injection when there is a residue of the drug in the tissues of food byproducts of the animal.

The existence and administration of these provisions of the Food, Drug, and Cosmetic Act, which were written without special consideration for animal drugs, have produced a regulatory system adverse to their development and efficient use. We know of no other type of product which must face a similar regulatory hurdle. This situation does not exist in the case of drugs for human use and cannot be justified in the case of drugs for animal use.

Furthermore, animal drugs are subject to three separate statutory procedures for the same uses, involving three separate regulatory divisions of FDA.

The situation is further complicated by the fact that these sections of the law have differing provisions, are subject to differing interpretations, and the actions taken under one are not always consistent with the actions taken under the others. As a result of this situation, there has devloped an unreasonable distortion of regulatory effort which is totally unjustified and which may seriously retard further progress in agricultural technology.

This distortion of regulatory effort, stemming from triplicate statutory procedures applicable to animal drugs, is manifested by a proliferation of regulations—some duplicating others, and some in conflict with others—which must be observed prior to the marketing of these products. These regulations go beyond the establishment of the safety of drugs in animal feed and actually undertake the policing of feed manufacturing industry practices. They constitute substantial overegulation, and they have also produced unreasonable delays, overlapping jurisdiction, and extreme confusion within the drug and feed industries. While they were made possible in part by unusually restrictive interpretations of the law, these interpretations were made possible, in turn, by the application of laws intended primarily for human products to products for animal use.

The regulatory effort of FDA in this field, being split among three separate divisions of the agency, necessarily lacks positive and effective direction. Regulations are issued almost on a production line basis without regard for their necessity to establish the safety of animal health products, or even to their consistency with other regulations by other divisions of the FDA.

To illustrate, let us assume that a drug manufacturer develops a new drug for the prevention of transmissible gastroenteritis (T.G.E.) in swine, a disease for which no satisfactory treatment is presently available. Such a drug would be proposed for use in swine feeds in order to insure a steady and effective level of the drug in the animal.

The first step which the drug manufacturer must take is the preparation and submission of a new drug application under section 505 of the act. This application is filed with the Division of Veterinary Medicine in FDA. It would contain data establishing the safety of the drug to swine, safety of edible products of the swine to humans, controls guaranteeing potency and purity of the drug, and labeling providing adequate directions for use of the drug.

Since the drug is to be incorporated in an animal feed, it is a food additive and therefore must also be cleared under section 409 of the act. Accordingly, the new drug application must be considered in addition as a petition for a food additive regulation. As such, it must also be assigned to staff personnel of FDA having the responsibility for issuing food additive regulations. In order to satisfy the technical requirements of section 409, additional data not related to the safe use of the drug must also be included in the new drug application.

Let us assume that in due course the new drug application becomes effective and the food additive regulation issues, establishing the safe use in swine feed of our new drug for the prevention of transmissible gastroenteritis. Nevertheless this drug cannot yet be incorporated in swine feed, nor can a veterinarian even prescribe this drug for any herd of swine which may need the drug. In order to incorporate this drug in his swine feed, each feed manufacturer must obtain a separate new drug application, since any feed containing this drug is itself construed as a new drug product. Therefore, for each feed manufacturer the time period for the consideration of a new drug application must be further extended before ultimate use of the drug is permissible.

In order to obtain an effective new drug application, however, the feed manufacturer must submit to manufacturing and marketing controls prescribed by FDA. Thus, a law designed primarily to require pretesting to establish the safe use of drugs in humans has been distorted so as to enable FDA to establish licensing controls over feed manufacturers.

Even after all the above steps have been taken, our new drug for the prevention of transmissible gastroenteritis will still be unavailable for use in the great bulk of manufactured swine feeds. This is because such feeds ordinarily contain drugs for other diseases of swine as well as drugs for the purpose of growth promotion. Therefore, the whole process discussed above must be repeated for each combination of drugs which will appear in swine feed, in which our hypothetical new drug is incorporated, and in addition, for each feed formulation containing this drug. Thus, we could anticipate that a substantial number of separate feed formulations would require clearance before extensive use of this new drug could be achieved.

However, we still have not established clearance for the optimum use of our hypothetical new drug for the prevention of transmissible gastroenteritis. In order to do this, it is necessary to obtain clearance, under section 507 of the act, for the use of the drug in feed formulations which also contain one or more of the certifiable antibiotics. In order to obtain such clearance, an application must be prepared and submitted to the Division of Antibiotics in FDA. It will contain essentially the same basic information as originally presented in the new drug application, even though in form the application is a request for an exemption from the requirements of section 507.

Subsequently, a regulation will issue establishing the necessary "exemption" and also prescribing the conditions of use of the drug in antibiotic-containing swine feeds. No feed formulation containing our drug in combination with a certifiable antibiotic drug will be permissible in the absence of a regulation establishing an "exemption" for that particular formulation.

Furthermore, under the rules established by FDA, no such exempting regulation will be issued by the Division of Antibiotics unless and until another regulation has been issued by the personnel administering the food additives section, section 409, of the act. But this is not all. Each feed manufacturer must also submit an application to the Division of Antibiotics to enable him to use the drug

in his antibiotic-containing feeds. Therefore, in order to establish the optimum use of the drug, an additional number of feed formulations would require clearance.

Up to this point, we have assumed that all of these clearances could be obtained without undue delay, and that when obtained they will be consistent with one another. Unfortunately, this has not been the case.

First of all, we have experienced unreasonable delays extending beyond the time specified by the applicable statutes for consideration of applications and/or petitions. We have conducted a survey which, we believe, demonstrates that applications, as a general rule, are taking substantially more time than permitted by law. We are taking the liberty of attaching a tabulation of the results of this survey to this statement.

Furthermore, a number of inconsistencies in regulations have occurred to hinder clearance of drugs in animal feeds.

For example, a food additive regulation recently issued by FDA established specified levels of certifiable antibiotics for growth promotion and feed efficiency in certain animals. Millions of tons of feed containing certifiable antibiotics have been distributed during the past 12 years. They have been sanctioned under an antibiotic feed regulation. The recently issued food additive regulation, however, conflicted with the existing antibiotic regulation which has permitted the use of certifiable antibiotics at lower levels for growth promotion than those established by the foregoing food additive regulation. This discrepancy portrays how present law leads to inconsistent treatment of animal feeds marketed for the same uses.

The existence of triplicate statutory procedures applicable to animal health products can produce serious dislocations for small manufacturers. Because of the cost and time involved to obtain the multiple-type clearances presently required by FDA, animal health products of a demonstrable utility will sometimes die at their inception, particularly if only a limited market potential can be established.

This point is abundantly illustrated by the recent experience of Mattox & Moore as set forth in the letter dated June 27, 1962, from Dr. William H. Feigh of that company to this committee.

We would like to quote a few paragraphs from this letter:

"On October 19, 1961, we submitted a new drug application (NDA) to the FDA as required by law pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. This application was identified as NDA 13-187 by the FDA. After several months of review by these people during which time numerous scientific questions were raised by them, all of which we answered to their satisfaction, a conditionally effective NDA was granted on January 18, 1962. The conditions required that we follow all procedures as outlined and submit samples of the final printed label, literature, and product to be certain that in all respects our product complied with the specifications as set forth in our NDA.

"On January 24, 1962, Mr. J. K. Kirk, Assistant Commissioner of the FDA wrote us stating that he regarded our product a food additive and that it would not be legal to market until we had an approved food additive petition. We were surprised at this decision since our product is not administered via the feed or water but is injected, and we had proven to the satisfaction of ourselves and the scientific staff of the Food and Drug Administration, who permitted our application to become conditionally effective, that there are no residues in edible meat when the product is used as intended and directed in the labeling.

"Representatives of our company, including myself, visited Mr. Kirk in Washington in regard to his letter. We were told that the technical people had approved the product but that the administrative component of his food additive group, who incidentally are laymen and not scientifically trained, was of the opinion that the product should be classified as a food additive, even though as Mr. Kirk admitted they had no scientific evidence on which to base their opinion and that, therefore, our product would have to be subjected to the further tests and provisions which are required under this section of the law. The questions which Mr. Kirk's group has posed will take another 1 or 2 years to complete plus additional large sums of money. This is something a small company such as ours, which is struggling for its very existence, can ill afford to do. Further, it appears to be absurd to prove the safety of a residue which has been shown to be nonexistent."

Mr. Chairman, we in the Animal Health Institute are convinced there is every reason for the imposition of new drug type controls on products developed by our

members to prevent, control, or cure animal diseases and deficiencies. However, we submit that we are close to being smothered in the triplicate controls and varying interpretations thereof issued in FDA.

A PROPOSED SOLUTION

Accordingly, we urge Congress to enact a new section to the Federal Food, Drug, and Cosmetic Act which would govern the preclearance of new animal drugs. A bill for this purpose could be entitled "Premarketing Clearance of New Animal Drugs." It would amend chapter V of the act by adding thereto a new section 508, and it would contain other conforming amendments to the act, as well as appropriate transitional provisions. Under our proposal, new animal drugs would henceforth be exempt from the preclearance requirements of the food additives, new drug, and antibiotic sections of the act, inasmuch as the preclearance of such drugs would be governed by the newly created section 508 of the act specifically geared for animal drugs.

By such an amendment, Congress can establish a proper basis for the accomplishment of both of the following purposes: (1) To protect the health of consumers by requiring manufacturers of new animal drugs to pretest any potentially unsafe drug for use in animals other than man; and (2) to advance agricultural technology by permitting the use of animal drugs at safe levels. At the present time the second of these purposes is being unreasonably thwarted. This second purpose should be specifically recognized by Congress now, in the same manner that Congress adopted a similar purpose in connection with the food additives amendment in 1958. (See H.R. 2284, 85th Cong., 2d sess., July 28, 1958). Under present circumstances, it is imperative for Congress to take positive steps to reestablish its intention to provide for advancement of agricultural technology.

The new section 508 of the act governing the preclearance of animal drugs would be patterned after the new drug law, section 505 of the act, so that the firm intending to market a new animal drug would be required to present evidence of safety for the proposed use or uses of the drug and obtain an effective new animal drug application prior to marketing the drug. Other provisions necessary to fully protect the public health would also be incorporated in the section, which could be suitably identified under a new section of the act.

In addition, we would recommend that the bill we are suggesting for enactment contain provisions which would require the registration of all establishments manufacturing animal drugs or mixing such drugs in animal feeds for sale. Each registered establishment would be subject to inspection and would be required to be inspected at least once in each 2-year period. We would also support a provision in the bill that an animal drug or feed containing such a drug would be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug or animal feed has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Under these provisions, it would no longer be necessary to require the filing of new animal drug applications for individual feed formulations needed by individual feed manufacturers once the safety of the basic drug and combinations of drugs had been established.

As to the agency which would administer an animal drug preclearance section of the law, AHI takes no position.

Alternates that suggest themselves are (1) total responsibility in FDA exercised through a newly created Bureau of Animal Medicine; (2) total responsibility in the U.S. Department of Agriculture exercised through a similar newly created bureau; (3) a divided responsibility between FDA and USDA, with the former passing on the safety of drug residues to humans and with the latter deciding on the use of new animal drugs in agriculture—somewhat in the manner in which pesticides are now processed under the Miller amendment; or (4) any equivalent administrative treatment to insure that reasonable and practical consideration is given to new animal drug applications.

It is the strong feeling of AHI that the assignment of responsibility in this area is the sole prerogative of the Congress. Our prime concern, Mr. Chairman, is with the soundness of the law and not with the controlling administrative agency.

Because of the complexities involved and the shortness of time for preparation of this testimony, we have been unable to prepare detailed statutory language for the proposed new section 508 of the act and the other provisions which would

be incorporated in the proposed bill. We stand ready, however, to assist this subcommittee in the formulation of specific language embodying the recommendations which we have made.

IMPACT OF PROPOSED LEGISLATION

Approaching the several bills pending before this subcommittee and the full committee affecting animal drugs, it becomes immediately apparent, Mr. Chairman, that in certain respects these bills would serve to accentuate the triplication of controls and overregulation which we have discussed earlier in my statement. This is an additional reason for the prompt enactment of provisions divorcing the preclearance of animal drugs from human drugs.

I will cite two examples illustrating the unique impact enactment of these proposed bills would have on the animal drug industry.

First, section 105 of H.R. 11581 proposes to extend batch certification procedures under section 507 of the act (now limited to five specified antibiotic drugs) to all antibiotic drugs and to products such as animal feeds containing such drugs. We strongly oppose such a change. Under existing procedures, such extension will only lead to the imposition of more meaningless clearances within FDA for antibiotic-containing feed products, with no concomitant gain to public health. A number of additional feed formulations not now covered by the antibiotic regulations would be brought under these regulations in addition to other regulatory procedures to which they are subject.

There is no justification for the application of batch certification requirements to animal drugs. No batches of antibiotics used in animal feed are actually certified, even today, and none would be certified under extension of batch certification as proposed in H.R. 11581. But, as discussed earlier in my statement, the so-called exempting regulations issued by FDA amount to licensing controls over individual feed formulations.

As has been previously pointed out to this committee, the original law providing for the batch certification of penicillin was adopted as a temporary measure until satisfactory manufacturing methods, tests, and controls to assure uniformity among batches of different manufacturers could be established. The legislative history of section 507 clearly shows that batch testing controls were to be discontinued when no longer necessary to accomplish this objective. Since today antibiotics can be produced with the same assurance of uniformity and quality as other drugs, the entire batch certification procedure has become an anachronism. It has been criticized as wasteful even by a report of the Comptroller General.

Second, section 2 of H.R. 12420, which is identical to section 303 of H.R. 11482, proposes to modify the so-called prior sanction clause of the Food Additives Amendment of 1958. This clause presently appears in section 201(s) of the act. It exempts from the controls of the food additives section of the act, section 409, any additives used in accordance with a sanction or approval granted prior to its enactment. In essence, the modification amounts to this: A prior sanction accorded an additive could be revoked by FDA on the basis of substantial doubt as to its safety. In the case of animal drugs having a prior sanction by virtue of a prior effective new drug application, no hearing of any kind would be required to be given the drug manufacturer prior to the action of FDA.

Mr. Chairman, AHI strongly opposes the enactment of section 2 of H.R. 12420 and section 303 of H.R. 11582. The reasons for our opposition are as follows:

A number of animal drugs became exempt from the food additives section of the act because these drugs had been cleared as safe for use in animal feeds under the new drug section prior to enactment of the food additives section. As to these animal drugs, a measure of dual regulation was thus avoided. Under the new drug section of the act (sec. 505), provision is made for suspension of the effectiveness of new drug applications whenever the evidence shows lack of safety, and there are procedural safeguards to minimize the likelihood of arbitrary action on the part of FDA. We would agree that revocation of an effective new drug application should result in loss of any prior sanction gained by virtue of that application. But we do not think the FDA should be allowed to bypass the new drug procedures entirely and take a drug off the market without resort to the procedural safeguards set forth in the new drug section of the act.

We can see no justification in arming FDA with two separate procedures with two separate legal standards for removing drugs used in animal feed from the market. This would in effect place in the hands of FDA a second power of

revocation. This power would only serve to enhance the duplication and overlapping of regulatory procedures which already bedevil our membership.

We remind this committee again that these products of our industry only became subject to the food additives section of the act at all because residues of them may appear in the tissues or food byproducts of the animal or because they are combined with animal feed for ease of administration and because feed is construed to be food. We do not see on what basis FDA can justify having one remedy under section 505 of the act and a wholly different remedy under section 201(s) whenever it has reason to doubt the safety of a drug which had previously cleared as safe.

With respect to clause (b) of H.R. 12437, however, we note that this clause differs substantially from section 2 of H.R. 12420 and section 303 of H.R. 11582. For example, there is provision for opportunity for hearing and for appeal in accordance with the procedure established by section 505(h) of the act. Accordingly, our objections to the earlier bills on the issue of prior sanctions have in part been met.

On the other hand, clause (b) H.R. 12437 also places in the hands of FDA a second legal standard for removing drugs used in animal feed from the market. Under this bill, the FDA must find, on the basis of substantial evidence of record, that the Delaney clause—section 409(c)(3)(A)—applies to an additive in order to withdraw any sanction or approval available to it. This is in addition to power granted under section 505 to suspend the effectiveness of its new drug application.

We would prefer that FDA be required to avail itself of the remedy set forth under section 505 of the act for suspending the effectiveness of new drug applications. However, in spite of this, we do not oppose enactment of H.R. 12437 as an interim measure pending consideration of our request for basic legislation applicable to animal drugs, provided that H.R. 12437 is amended as recommended by AHI in respect of its Delaney clause provisions.

DELANEY CLAUSE AMENDMENTS

Clause (a) of H.R. 12437 is offered as a relief measure to manufacturers of animal drugs and to feed manufacturers. AHI applauds the purposes of this section.

It would amend the food additives section of the act, section 409, by broadening the power of FDA to permit the use of a substance as an ingredient of feed for animals. At the present time such power is arbitrarily limited by overly strict interpretations of various provisions in the law, including the so-called Delaney cancer clause, which appears in section 409(c)(3)(A) of the act.

Existing law operates in the following manner. Assume a substance is thought capable of inducing cancer when administered in massive doses to susceptible laboratory animals. Assume also this substance is a drug proposed for use in animal feeds. By virtue of FDA's interpretation of the Delaney clause, this drug could not receive clearance under the food additives section of the act, even though it could be proven safe under its conditions of intended use.

Now assume further that this drug was proposed for use and was cleared as safe by the FDA prior to enactment of the food additives section of the act in 1958. Let us say that it was on the market and employed extensively in animal feeds pursuant to new drug applications made effective prior to 1958. In our opinion, this drug should be construed as exempt from the food additives section of the act, and thus from the Delaney clause contained therein, on the ground that it was being used in accordance with a sanction or approval granted prior to enactment of the food additives section, and thus falls within the prior sanction clause contained in section 201(a) of the act. Thus, the continued use of the drug should not be affected by the enactment of the food additives section of the Act.

But FDA did not so interpret the law. Using its power to control individual feed formulations of individual feed manufacturers, and narrowly construing the prior sanction clause, FDA held that for certain manufacturers such a drug was a food additive—and its use barred by the Delaney clause—but for others the drug when used in the same feed formulation would be exempt from the food additives section of the act and thus permissible for use. This amounts to economic discrimination, and arbitrary restriction of the safe use of a drug.

Clause (a) deals with this problem. It proposes to exempt from the operation of the Delaney clause a substance used in animal feeds if it will not adversely

affect the animals and if it does not leave a detectable residue in food products. (Clause (c) would similarly amend the Delaney clause contained in section 706 of the act, dealing with color additives.)

If the objectives of clause (a) are to be realized, however, several clarifying amendments are essential.

First, we do not believe the term "no residue," appearing on line 2, page 2, of H.R. 12437, standing alone, is scientifically meaningful. The bill as presently written requires the applicant for a food additive regulation to prove the total absence of residue. This will not be possible in the case of additives which also occur naturally in the tissues of animals. It may not be possible to determine whether a residue is due to the naturally occurring substance in the animal tissues or to the additive. Therefore, we suggest adding the phrase "in excess of background levels thereof naturally present in the animals" following the word "found" on line 2 of page 2.

Second, we suggest deletion of the phrase "reasonably certain to be" on lines 10–11 of page 1 and substituting therefor the phrase "capable of being". The present bill calls for FDA to consider whether the conditions of use and feeding specified in the proposed labeling of an additive are reasonably certain to be followed in practice. Thus, FDA must speculate whether the customers of the drug manufacturer will obey the law prior to the marketing of the drug. We believe any infraction of the law on the part of the customer should be prosecuted without prohibiting the use of the drug for all law-abiding users.

Third, we urge the deletion of the phrase "which regulations shall not be subject to subsections (f) and (g)" on lines 4–5 of page 2. The effect of this phrase is to exempt from any necessity for hearing or review the regulations of the Secretary prescribing methods of examination necessary to determine whether there is a residue of an additive. Such an important issue—which is controlling as to the application of the section—should not be left to the uncontrolled discretion of the Secretary.

While clause (a), if amended as recommended, is unobjectionable, we submit that for the animal drug industry the purposes of this section are much too narrow. Under this section the determining factor in removing a substance from the ban of the Delaney clause is the determination of the existence of residue. The term "no residue" is not scientifically meaningful. Man adjusts to a wide variety of substances in trace amounts, detection of which merely depends upon the sensitivity of the methods of assay. We submit that the true test should be more closely related to proof of safety of the additives under actual conditions of use.

The Delaney clause departs from the basic philosophy of the food additive section of the act. The concept of safety used in the statute applies to the capacity of an additive, under the conditions of its use (including the method of its administration and the quantities consumed), to cause harm from any disease. As currently interpreted, the Delaney clause, on the other hand, absolutely precludes the Secretary from finding on the basis of the scientific evidence, that no harm will result from the proposed use of an additive which may be "found" to induce cancer. It does not matter that there may be no agreed-upon definition of the term "cancer" or the term "found," or that the evidence may clearly differentiate the conditions of cancer induction from the conditions of the use of an additive. As Commissioner Larrick of FDA previously testified before this committee, there is no more reason to single out possible carcinogenicity for specific mention in the legislation that to single out production of a host of other disorders.

Among other scientific bodies calling for amendment or repeal of the Delaney clause, the Food and Nutrition Council of the American Medical Association recently issued a policy statement concluding that the Delaney clause contributes nothing to the safe use of food additives, could prohibit the addition of certain essential nutrients and could cause many new found improvements to be postponed or abandoned.

The Animal Health Institute has previously approved a suggested amendment to the Delaney clause which would, we believe, be superior to the "no residue" proposal. This amendment would provide a mechanism through use of the Scientific Advisory Committee whereby an impartial and independent panel of scientists may evaluate scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. A copy of this amendment, and a memorandum in explanation thereof, is enclosed with this statement.

Clause (a) is also narrow in scope in that it fails to deal with the problem of triplication of controls directly. It may, of course, remove a certain amount

of discrimination produced by multiple controls. But it would leave those controls intact, and thus would not eliminate a major deterrent to the development of new animal drugs. Over the long range, therefore, the Delaney clause amendments to the food additives section of the act would not suffice to solve the problems of our industry in clearing new animal drugs.

ANIMAL HEALTH INSTITUTE,
Des Moines, Iowa, February 5, 1962.

Mr. J. KENNETH KIRK,
Assistant Commissioner, Food and Drug Administration, Washington, D.C.

DEAR MR. KIRK: As you know, the Animal Health Institute over a period of years has discussed with the Food and Drug Administration certain mutual problems, and these discussions have resulted in significant advances for both of the groups concerned. Over the past several years we in the Animal Health Institute have been gravely concerned about the length of time it has taken the Food and Drug Administration to process food additive petitions, especially in those areas that simultaneously involve new drugs or certifiable antibiotics.

At the 21st annual meeting of the institute in 1961, Mr. Winton Rankin announced that food additive petitions now were being processed more rapidly, and that following its usual cooperative approach, the Food and Drug Administration would welcome factual information where industry felt that there were undue delays.

With Mr. Rankin's invitation in mind, we have made a survey of member companies of the Animal Health Institute to determine if applications were in fact being processed more rapidly. Unfortunately, our membership has seen no improvement in this connection in the past year. Indeed, our survey indicates that recent applications as a general rule are still taking longer than the 30-day period for filing, and in certain instances longer than 180 days for final approval. Interspaced between these dates may be many requests for additional information which stop the regulatory timeclock. Some of these requests seem quite trivial to us. Of equal concern is the fact that letters asking for additional information are dated the day the letter is written, and not the date the letter is mailed. This has caused delays of 1 to 3 weeks for the company involved.

With a view toward assisting the Food and Drug Administration in determining what steps need to be taken to speed up processing of food additive petitions so that U.S. consumers may benefit from the new discoveries as quickly as foreign countries, we have compiled the attached list of examples of delays which the Animal Health Institute feels are excessive.

After you have had an opportunity to review the attached information, we shall be more than pleased to meet at your convenience to discuss more fully the importance of this problem.

Yours very truly,

D. L. BRUNER,
Executive Secretary.

FAP 140

March 9, 1960: Application submitted Food and Drug Administration.
April 6, 1960: Petition filed by Food and Drug Administration.
May 6, 1960: Letter from Food and Drug Administration received by company on May 11, 1960 (5 days after mailing), asking for certain samples.
May 12, 1960: Samples delivered personally by company to Food and Drug Administration.
October 12, 1960: Food additive regulation signed by the Commissioner.
October 18, 1960: Final regulation appeared in Federal Register.

NOTE.—The 180-day extension for this application expired on October 9, 1960, so that it was processed 3 days late.

FAP 170

June 14, 1960: Submitted petition to Food and Drug Administration.
July 21, 1960: Food and Drug Administration notified company, application incomplete.
August 12, 1960: Company submitted additional information.
August 17, 1960: Food and Drug Administration notified company application incomplete.

September 6, 1960: Food and Drug Administration notified company new drug application withdrawn and resubmitted as of August 15, 1960, but still incomplete.
September 16, 1960: Company submitted additional data.
September 30, 1960: Food and Drug Administration requested further clarification of data by telephone.
October 13, 1960: Food and Drug Administration notified company application still incomplete.
November 9, 1960: Company submitted additional data.
December 13, 1960: Food and Drug Administration notified company that petition had been filed.
January 19, 1961: Company submitted additional data.
March 10, 1961: Food and Drug Administration notified company that a 90-day extension would be necessary to process petition.
May 19, 1961: Petition approved.

FAP 180

June 22, 1960: Submitted application to the Food and Drug Administration.
July 20, 1960: FDA requested additional data.
September 19, 1960: Company submitted additional data.
November 16, 1960: FDA advised company Food Additives Branch was reviewing petition.
November 30, 1960, December 7, 1960, December 16, 1960, and January 4, 1961: Company told that FDA was in disagreement as to whether or not the product was actually a food additive.
January 12, 1961: FDA advised company that a food additive regulation would be required.

NOTE.—In this case it took FDA 115 days from September 19, 1960, to decide that the product was a food additive.

FAP 236

October 11, 1960: Submitted petition to the Food and Drug Administration.
October 20, 1960: Food and Drug Administration acknowledged receipt of this application.
November 3, 1960: Gave Food and Drug Administration additional data by telephone.
November 8, 1960: Gave Food and Drug Administration additional data by telephone.
November 10, 1960: Food and Drug Administration notified company application was incomplete.
December 7, 1960: Company submitted additional information.
February 3, 1961: Food and Drug Administration acknowledged receipt of December 7, 1960, data and gave a conditional filing date of December 8, 1960 (New Drug Branch).
February 6, 1961: Food and Drug Administration notified company of food additive petition filing of February 6, 1961.

NOTE.—Filing date is 60 days after application was judged to be complete.

May 15, 1961: Food and Drug Administration notified company that a 90-day extension would be necessary to process petition.
July 21, 1961: Food additive petition approved.

FAP 252 (CHICKENS)

November 7, 1960: Submitted petition to the Food and Drug Administration covering use in chickens.
December 19, 1960: Petition filed by FDA.

NOTE.—In this instance it took FDA 42 days to file the petition.

March 16, 1961: FDA notified company that a 90-day extension would be necessary to process petition.
July 5, 1961: Petition approved by FDA.

NOTE.—In this case FDA took 203 days from filing date to approval date, or 35 days longer from submittal date to approval date than the maximum provided by law and regulation.

FAP 252 (SWINE)

December 15, 1960: Submitted petition to the Food and Drug Administration covering use in swine.

April 18, 1961: Notification by FDA that petition had been filed on March 20, 1961.

NOTE.—Filing date is 95 days after submission date.

July 5, 1961: Petition approved by Food and Drug Administration.

FAP 446

March 10, 1961: Application submitted to the Food and Drug Administration.

April 4, 1961: Petition filed by FDA.

October 26, 1961: Food additive regulation signed by the Commissioner.

November 1, 1961: Final regulation appeared in Federal Register.

NOTE.—A total of 198 days elapsed from filing date to approval date. There were no requests for additional information during this time.

FAP 288

November 18, 1960: Supplemental new drug application submitted to Division of Veterinary Medicine, FDA for NDA 11-116.

November 29, 1960: Before FDA had taken any action on the November 18, 1960, submittal, company submitted an application for this product directly to the Food Additives Branch as an amendment to NDA 11-116.

January 11, 1961: Letter from FDA Food Additive Branch acknowledging receipt of application and noting FAP 288 was filed on January 5, 1961.

January 16, 1961: Letter from Division of Veterinary Medicine stating this supplemental application would be considered a separate new drug application and assigned a new number, NDA 12-698. The letter also states that the product was considered a food additive under section 409 of the act. The letter further notes that the food additive petition was filed on January 11, 1961.

NOTE.—The new drug application and food additive petition were not acted upon simultaneously. It took 48 days after receipt of the new drug application for filing, or 37 days after receipt of the food additive petition for filing. Also, it seems strange that two different filing dates were given by FDA for the same petition.

April 7, 1961: Letter dated April 7, 1961, from FDA asking for an additional 90 days to consider the petition.

NOTE.—This letter was dated 92 days after filing date of January 5, 1961.

May 17, 1961: Notice by FDA that they could not recommend favorable action on the petition because there were gaps in (1) the feed assay and (2) residue data.

NOTE.—Thus 132 days from filing date to determine FAP 288 was deficient in two of the fundamental aspects of any petition.

FAP 528

May 24, 1961: Application submitted to the Food and Drug Administration.

June 16, 1961: Letter from FDA indicating application is complete.

July 11, 1961: Letter from FDA stating that application had been filed on July 7, 1961.

NOTE.—In this case 44 days elapsed betwen submission of application and filing date; actually, the filing date was 21 days after the company was notified that the application was complete.

FAP 535

May 16, 1961: Submitted petition to the Food and Drug Administration.

July 14, 1961: Petition filed by FDA.

NOTE.—In this instance it took FDA 60 days to file the petition.

October 17, 1961: Notification that a 90-day extension would be necessary to process petition.

December 12, 1961: Pending.

FAP 562

July 3, 1961: Submitted petition to the Food and Drug Administration.

August 28, 1961: Petition filed by FDA.

NOTE.—In this instance it took FDA 45 days to file the petition.

November 26, 1961: Notification that a 90-day extension would be necessary to process petition.

FAP 564

May 23, 1961: Submitted application to the Food and Drug Administration.
August 29, 1961: FDA notified company that petition had been filed.
NOTE.—Filing date is 98 days after application had been submitted.

FAP 565

June 9, 1961: Submitted petition to the Food and Drug Administration.
October 3, 1961: Company wrote to FDA inquiring as to status of this petition, since there had been no written reply or acknowledgement of receipt or filing of petition.
October 12, 1961: FDA acknowledged receipt of October 3, 1961, letter and advised that the petition had been given a FAP number of 565. No mention made of filing date.
October 30, 1961: Letter from FDA stating that FAP 565 had been given a filing date of October 25, 1961.
NOTE.—In this instance it took FDA 141 days to file this petition.
December 20, 1961: Petition still pending approval.

FAP 577

August 30, 1961: Submitted application to the Food and Drug Administration.
November 20, 1961: FDA advised company that certain additional data were necessary before petition could be filed.
NOTE.—It took 82 days in this case for FDA to determine application was incomplete and could not be filed.

FAP 583

July 24, 1961: Petition received by the Food and Drug Administration.
October 16, 1961: Letter from FDA stating that petition had been filed on September 20, 1961.
NOTE.—In this instance 58 days were taken to file the petition.
December 12, 1961: Letter from FDA that an additional 90 days would be needed to study the petition.

ANIMAL HEALTH INSTITUTE

PROPOSED AMENDMENTS TO FOOD ADDITIVES LAW

I

Amend Section 409(c)(2):
Add the following sentence at the end of the paragraph:
"If an advisory committee is established as hereinafter provided such order shall be issued within the time specified in paragraph (c)(3)(B)(iii) of this section in lieu of the time specified in this paragraph."

II

Amend section 409(c)(3) in its entirety so as to read as follows:
"(A) No such regulation shall issue if a fair evaluation of the data before the Secreary (i) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: or (ii) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.
"(B)(i) No food additive shall be deemed to be safe, except as provided in this subsection (c)(3)(B), if it is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.
"(ii) In the event that the data before the Secretary suggests that a food additive for which a petition has been filed may induce cancer in man or animal within the meaning of paragraph (i) of this subsection (c)(3)(B), the Secretary shall so notify the petitioner not less than thirty days prior to the issuance of the order required by paragraph (1) (A) or (B) of this subsection (c). If, at any time prior to the issuance of the order required by paragraph (1) (A) or

(B) of this subsection (c), the petitioner so requests, or if the Secretary at any time prior to the issuance of such order deems it necessary, the Secretary shall forthwith refer the petition to an advisory committee for a report with respect to the following questions:

"(a) whether or not the additive induces cancer in man or animal, within the meaning of paragraph (i) of this subsection (c)(3)(B), and if so,

"(b) whether or not the proposed use of the additive, under the conditions of use specified in the petition, is established by a fair evaluation of the data considered by the committee to be safe from the standpoint of the cancer-inducing potential of the additive.

"(iii) As soon as practicable after such referral, but not later than sixty days thereafter, which period may be extended an additional thirty days if the advisory committee deems this necessary, the committee shall certify to the Secretary, with a copy to the petitioner, a report on such matters, together with all underlying data and a statement of the reasons or basis for its conclusions thereon. Within thirty days after such certification, the Secretary shall, after giving due consideration to such report and to all data then before him, issue the order required by paragraph (1) (A) or (B) of this subsection (c). The provisions of paragraph (i) of this subsection (c)(3)(B) shall not be applicable to such order in the event that the Secretary acting upon the advice of the advisory committee has concluded that question (b) set forth in paragraph (ii) therein should be answered in the affirmative.

"(iv) The deliberations of the advisory committee shall be conducted in accordance with regulations promulgated by the Secretary designed to assure impartial consideration of the matters set forth in paragraph (ii) of this subsection (c)(3)(B). The right to consult with the advisory committee shall be afforded to the person who has filed the petition and to the Secretary. All data considered by the advisory committee shall be made part of the record of its proceedings and shall be made available to the petitioner and to the Secretary.

"(v) The advisory committee shall consider, among other factors bearing upon the matters set forth in paragraph (ii) of this subsection (c)(3)(B).

"(a) The appropriateness and reasonableness of the tests for carcinogenicity,

"(b) The reliability of the evidence of carcinogenicity,

"(c) The concentration of the substance above any natural background level resulting from addition of the substance to foods for human consumption, and

"(d) The appropriateness of assay techniques to determine whether the substance is present in food.

"(vi) The advisory committee shall be composed of disinterested experts selected by the Secretary from a panel proposed by the National Academy of Sciences, except that in the event that the National Academy of Sciences fails to act, the Secretary shall determine the membership of the committee. Such experts shall be qualified to consider the matters referred to the committee and shall be of adequately diversified professional background, but representatives of the Department of Health, Education, and Welfare and representatives of persons directly interested in the additive which is the subject of the referral shall be ineligible to serve as members of the committee. The size of the committee shall be determined by the Secretary. Members of the advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary travel and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States."

III

Amend section 409(f):

Add the following new paragraph:

"(4) Any report, underlying data and reasons certified to the Secretary by an advisory committee appointed as provided in subsection (c)(3)(B) of this section shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The advisory committee shall designate a member to appear and testify at the hearing with respect to the report of such committee

upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing."

MEMORANDUM RE PROPOSED AMENDMENTS TO FOOD ADDITIVES LAW CONCERNING DELANEY ANTICANCER CLAUSE

The purpose of this memorandum is to describe, examine, and analyze amendments to the Delaney clause which has been proposed by the Animal Health Institute for consideration in the 87th Congress. A copy of these proposals is enclosed herewith.

By way of background, the Delaney anticancer clause contained in the Food Additives Amendment of 1958 was discussed from time to time in the course of the hearings prior to the enactment of the Color Additive Amendments of 1960. A similar clause was contained in H.R. 7624 which bill, in amended form, became the color additives law. Accordingly, the operation of the Delaney clause under the food additive law was considered pertinent.

H.R. 7624 was amended by the House Committee on Interstate and Foreign Commerce following extensive hearings held between January and May of 1960. As reported, H.R. 7624 contained a provision permitting referral to an advisory committee for a report and recommendations with respect to any matter arising under the Delaney clause if such matter requires the exercise of scientific judgment. While the House committee report indicates that the purpose of this amendment was to provide for a study and report on the question of whether a color additive is a carcinogen, nevertheless, there was considerable confusion as to the scope of the advisory committee amendment. For example, on the floor of the Senate, Senator Hill remarked, in reply to a motion by Senator Javits to reconsider the color additives bill:

"I also wish to state that the report of the group of scientists, under date of May 14, 1960, to which the Senator from New York has referred, did not recommend repeal of the Delaney amendment, as that amendment is now carried in the Food Additives Act of 1958, but did recommend that the Secretary of Health, Education, and Welfare appoint a board, advisory to him, to assist in the evaluation of scientific evidence, on the basis of which decisions have to be made as to prohibiting or permitting the use of certain carcinogenic compounds.

"I may say that the amendment to which we agreed last night not only provides for such an advisory board—they use the term "advisory committee," but an advisory board is the same thing—but gives to anyone who may feel that he needs some redress the right to have such an advisory committee consider the matter."

However, it seems clear that contrary to Senator Hill's impression, the advisory committee as set forth in the color additives legislation is not authorized to evaluate evidence on the basis of which decisions have to be made as to prohibiting or permitting the use of carcinogenic compounds.

The report referred to by Senator Hill, dated May 14, 1960, is commonly known as the report of the Kistiakowsky committee. The panel of experts constituting this committee was convened by the President's Science Advisory Committee. This committee recommended the appointment of an advisory board to assist in the evaluation of scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. It was further recommended that such advisory board consider among other matters:

"(*a*) Whether or not the tests for carcinogenicity are appropriate and reasonable;

"(*b*) Whether the substance is or is not in reality carcinogenic as determined histopathologically or by other criterias;

"(*c*) Whether addition of the substance to agricultural products would result in a concentration of the substance above the natural background level of such substance;

"(*d*) What assay techniques are appropriate to determine whether a specific carcinogen is present in food."

The report also recommended that appropriate modifications in the law be sought if existing legislation does not permit the exercise of discretion consistent with the recommendations of the committee.

That the exercise of such discretion requires amendment to the Delaney clause is clear from the discussion of scientific issues contained in the Kistiakowsky committee report. For example, the report states:

"From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work such as cited above, the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available."

The report also discusses special problems in the administration of the Delaney clause which might arise when substances useful in trace amount but carcinogenic in large doses are considered, such as selenium, inorganic arsenic compounds, and polyoxyethylene stearate. As to these problems, the committee states: "This list of examples may be expected to lengthen and each case requires scientific judgment to determine the issues involved."

Again, the committee report discussed the problem which arises when carcinogenic substances are permitted to be used under such conditions (as in the feed industry) that they are absent from human food products. As to this problem, the committee states: "Scientific judgment as well as the rule of reason are required to decide what is a proper and adequate assay method."

With respect to each of the foregoing examples, the Delaney clause, even if amended as in the color additives law, does not permit the exercise of scientific judgment recommended by the Kistiakowsky committee.

That the recommendations of the Kistiakowsky committee represent the best thinking of the scientific community is apparent. In the State of Wisconsin, "the Report on Food and Feed Additives and Pesticides of the Governor's Special Committee on Chemicals and Health Hazards," concluded, with respect to the Delaney clause:

"This legislation is extremely rigid and difficult to administer in specific instances, principally because it prohibits the presence of even traces of these compounds, although it is known that the effects of large amounts of a substance may differ profoundly from the effects of small amounts of the same substance and that a material dangerous in considerable quantity may have no measurable effect when present in minute quantities. Experience has shown that this portion of the Federal law should be modified to permit the evaluation of each substance on an individual basis by a competent board of experts."

The report further states:

"A more flexible regulation might provide that no substance with the ability to produce cancer following ingestion by man or animal be used as a food additive unless a safe level of use can be established. In this way the merits of each substance in question could be examined individually by a properly qualified board of experts. This modification of existing legislation is a rational possibility because it is highly probable that for experimental animals there do exist subcritical doses of chemicals known to be carcinogenic; in other words, chemicals known to produce cancers when fed in very large amounts for long periods of time may be completely harmless when given in far smaller amounts."

The majority of the panel of experts which appeared before the House Committee on Interstate and Foreign Commerce on April 5 and 6, 1960, went on record as favoring some modification of the Delaney clause. For example, typical of the majority opinion, Dr. Kensler, Department of Pharmacology, School of Medicine, Boston University stated:

"In my opinion, the Delaney clause, as written prevents the application of proper scientific judgment to this problem. In my opinion, it should be modified in such a way that the current scientific judgment be brought to bear on the problem whenever such judgments are appropriate, and when such information is available, not necessarily having to wait for the passage of another piece of legislation."

The reports and testimony offered in the color additive hearings led to the amendment of the Delaney clause to provide for a scientific advisory committee whose deliberations were limited to evaluating the evidence relating to carcinogenicity of a color additive at any level of administration in any species of man or animal. This amendment, of course, appears in the color additives legislation. No effort has been made to include an advisory committee in the food additives law. However, the former Secretary of the Department of Health, Education, and Welfare conceded the need for amending the Delaney clause in the Food Additives Amendment of 1958, at least insofar as animal feed is concerned. Proposed amendments to the food additives law were accordingly trans-

mitted by the Department of Health, Education, and Welfare to the House Committee on Interstate and Foreign Commerce under date of May 13, 1960. One portion of the Secretary's proposal was to amend the Delaney clause, exempting from its application the use of a substance as an ingredient of feed for animals which are raised for food production, if it is found that the additive will not adversely affect the animals for which the feed is intended, and that no residue of the additive will be found in any edible portion of the animals after slaughter or in any food yielded by or derived from the living animal. The Secretary coupled with this proposal another amendment having the effect of destroying the statutory exemption from the food additives law applicable to substances used in accordance with a sanction or approval, on the basis of a finding that there is reasonable doubt as to its safety. This later amendment would make it unnecessary to abide by the procedural safeguards which would otherwise be necessary to revoke such sanction or approval.

The proposal of the former Secretary of the Department of Health, Education, and Welfare with respect to the Delaney clause, while indicating the need for amendment of that clause, was predicated upon an assumption of questionable merit. The assumption is that it is feasible to amend the Delaney clause on a case-by-case basis each time the use of a compound or class of compounds is unnecessarily prohibited by its strict application. Of course, such an assumption is inconsistent with the basic principle of the food additives law to delegate to the administrative agency the power to determine tolerance for food additives.

There is another fault in the so-called no-residue proposal of the former Secretary. The fault is that the proposal is not consistent with the exercise of sound scientific judgment even in the case of drugs used in animal feeds. For example, it depends upon the issuance of regulations prescribing methods of assay in order to determine whether or not there is a residue of the additive in the meat, milk, or eggs produced from animals. The power to cancel an exemption merely because of the discovery of more sensitive methods of assay is inconsistent with the kind of scientific judgment which should be exercised in accordance with the report of the Kistiakowsky committee.

To give another example, the no-residue proposal is totally inadequate to deal with problems of scientific judgment arising from the use of an additive where the additive or its components have a natural background level in food consumed by humans. Since this background level may vary from product to product, from animal to animal, and from tissue to tissue in the same animal, in some cases it may not be possible to make a finding that the exemption should apply, even though the exercise of scientific judgment referred to by the Kistiakowsky committee would call for exempting the additive from the Delaney clause. Furthermore, it may be impossible to determine, upon examination of the tissue of animals, whether or not the residue of the additive or any of its components contained therein results from the administration of the additive. In that event, the requisite finding could not be made.

With this background, the Animal Health Institute, concerned lest the Delaney clause adversely affect research and technology, searched for an amendment which would, under the circumstances, best serve the public welfare and preserve scientific judgment.

Outright repeal of the Delaney clause was discarded, though substantial support might be adduced for such repeal. The effect of repeal would be to place cancer in the same position under the law as all other diseases which afflict mankind. Prior to the enactment of the food additives law, Commissioner Larrick opposed the concept of the Delaney clause. In 1957, he told the House Committee on Interstate and Foreign Commerce:

"But we see no more reason to single out cancer production for specific mention in the legislation than to single out production of high blood pressure, destruction of the blood-forming elements of the body, or production of nephritis, diabetes, or a host of other disorders. All of these things are of extreme importance. We certainly do not intend to sanction a chemical additive in the food supply unless the evidence rules out any reasonable ground for believing that the proposed use will constitute a hazard to the public health in any respect."

More recently, a number of scientists who are concerned with the protection of the food supply of this Nation, have given similar testimony. For example, Dr. William J. Darby, Chairman of the Food Protection Committee of the National Academy of Science, indicated to the House Committee on Interstate and Foreign Commerce:

"It is my opinion that the legislative action should continue to charge the Secretary with this responsibility for decision as to safety for use of any pro-

posed food additive, regardless of the kind of hazard. If it is deemed useful by the Congress to call especial attention to the potential hazard from cancer, I believe this could, in the best interest of the health and welfare of our people, be accomplished by the simple device of instructing the Secretary that in reaching a decision as to safety he is to consider evidence bearing upon the possible hazard from cancer which might result from the use of a given substance in the manner proposed.

"Such charge would then assure that he take into account all evidence obtained by methods presently available or which might be developed in the future for judging the safety or hazard for use of a given substance, and that he not only could seek but, in fact, exercise the best scientific judgment in the administration of the law."

The Animal Health Institute also discarded the former Secretary's approach of proposing new legislation on a case-by-case basis. Accordingly, the method adopted was to provide a mechanism through use of the scientific advisory committee whereby an impartial and independent panel of scientists may evaluate scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. This is similar to the approach used in color additives legislation, differing only in two major respects. First, the Secretary should be authorized to issue a regulation acting upon the advice of the advisory committee permitting the use of an additive, the use of which can be demonstrated to be safe in spite of the prima facie application of the Delaney clause. Second, there should be provisions guaranteeing that the advisory committee will truly be impartial.

Considering the first of these principal differences, it does not involve any weakening of the Delaney clause as it applies to the initial consideration of a food additive petition. It merely means that if there is a referral to an advisory committee, this committee will consider the following specific questions: (a) whether or not the additive induces cancer in man or animal, within the meaning of the Delaney clause, and if so, (b) whether or not the proposed use of the additive, under the conditions of use specified in the petition, is safe from the standpoint of the cancer-inducing potentiality of the additive. Thereupon, the advisory committee is to make a report on these questions within 60 days, unless extended an additional 30 days, after the referral. Meanwhile, the Secretary is precluded from issuing an order on the petition until the committee has certified its report. The proposed amendment specifically provides that the Delaney clause shall not be applicable to the order in the event that the Secretary, acting upon the advice of the advisory committee, has concluded either that the additive does not induce cancer within the meaning of the Delaney clause, or that the proposed use of the additive, under the conditions of use specified in the petition, is safe from the standpoint of the cancer-inducing potentiality of the additive. Under this proposal, the advisory committee is required to consider, among others, those factors specifically listed in the Kistiakowsky committee report. The Secretary is required to notify the petitioner, not less than 30 days prior to the issuance of any food additive order, if the data before him suggests that the food additive may induce cancer. The request for an advisory committee may be made by the petitioner at any time prior to the issuance of such an order, but the Secretary within the same period of time may invoke an advisory committee on his own initiative.

It should be noted that the proposal of Animal Health Institute places the burden of proof on the person proposing the use of the additive to demonstrate to the advisory committee that such use is safe from the standpoint of its cancer-inducing potentiality. Accordingly, in the situation adverted to by the former Secretary in his testimony before the House Committee on Interstate and Foreign Commerce, namely, "* * * that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer * * *," where that principle applies to an additive, the advisory committee could not determine that its proposed use is safe. However, the advisory committee would be empowered to consider, on a case-by-case basis, those instances where the application of the Delaney clause has already been shown to be rigid or might in the future be shown to be rigid.

Considering the second principal difference between the color additive advisory committee and the proposal of Animal Health Institute, namely, the impartiality of the advisory committee, we believe that a certain minimum amount of procedural safeguards must be written into the advisory committee provision. There is no provision in the color additives law which sets adequate standards applicable to the deliberations of the advisory committee. As a matter of fact, pro-

posed regulations under the color additives law, to which regulations objections have been made, do not insure that the deliberations of the advisory committee will be impartial. Among other things, persons wishing to consult with the advisory committee need not be provided with copies of material that is furnished the committee. Neither are there sufficient rules with respect to the manner of consultation or the manner in which deliberations are held.

It is evident that, with respect to the pesticide law and the color additives law, Congress conceived great weight would be placed upon the deliberations of the advisory committee. This is indicated by the provisions whereby various parties are given the right of consultation with the committee, whereby the committee is required to certify all data underlying its report and recommendation, whereby the Secretary is required to give due consideration to all these materials, and whereby all of this data shall be made a part of the record of any hearing if relevant and material. Thus, the advisory committee is in the nature of a court of appeals, for it is hardly conceivable that the recommendations of such a committee would be set aside in any judicial proceeding.

Accordingly, the proposal of the Institute specifically provides that the advisory committee shall be composed of impartial experts. Furthermore, it is provided that the deliberations of the advisory committee shall be conducted in accordance with regulations promulgated by the Secretary and that these regulations shall be designed to assure impartial consideration of the matters which are referred to to the advisory committee. It is also provided that all data considered by the advisory committee shall be made part of the record of its proceedings, as well as all interpretations of law upon which the committee relies, and shall be made available to the petitioner and to the Secretary. In the absence of such safeguards, we feel that the decisions of the committee may not always be impartial and scientific, but may on occasion be touched with politics. On the other hand, we do not believe that the legislation should specify the detailed manner in which the advisory committee should operate, but should leave these details to be fashioned by the Secretary in accordance with the standard of impartiality set forth in the proposed amendment.

In conclusion, we suggest that the Department of Health, Education, and Welfare should reevaluate its policy with respect to the food additives law and adhere in the case of possible carcinogens to the basic philosophy of that law, in accordance with the general recommendations outlined herein. The basic principle of that law is well stated in the report of the House Committee on Interstate and Foreign Commerce on the food additives bill:

"The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance."

The two-fold purpose of the legislation justifies the proposed amendment. Thus, the House committee said:

"The purpose of the legislation is twofold: (1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels."

It has been demonstrated that the Delaney clause is not consistent with these principles and objectives, and constitutes a burden to research and food technology. The opinion of the Department of Agriculture expressed in its letter of May 16, 1960, to the House Committee on Interstate and Foreign Commerce is persuasive:

"The anticancer clauses contained in the Food Additives Amendment of 1958 and in H.R. 7624 on page 10, lines 11 through 22, are flat prohibitions against the exercise of scientific and professional judgment in the determination of safety. That such a flat prohibition may present problems is well exemplified in the case of selenium, a known carcinogen. Several amounts (0.1 p.p.m.) in the diet appear to have no measurable effect upon animal health. Sheep on diets with subnormal amounts (0.05 p.p.m. or less) are not thrifty and show abnormalities of the muscular and internal organs. Excessive amounts (5 p.p.m. and above) in the diet produce poisoning. Here we have a chemical, a carcinogen, a toxicant, which in proper amount is essential to animal health. The law should not prevent proper use of such a chemical as an additive or otherwise.

"In view of the above and since we understand that the Secretary of Health, Education, and Welfare has adequate authority to withhold from use any additive that he is unable to find would be safe in regard to cancer as well as in

regard to toxicity and other factors, it is our opinion that the anticancer provisions in lines 11 through 22 on page 10 of H.R. 7624 are unnecessary. This is equally true of the anticancer provision in the Food Additives Amendment of 1958. We fully agree that the Secretary of Health, Education, and Welfare should withhold from use any additive which in his judgment would be unsafe but we urge that the decision on safety be left to him rather than being determined by law."

The CHAIRMAN. Dr. Robert J. Feeney?

STATEMENT OF DR. ROBERT J. FEENEY, DIRECTOR OF COMMERCIAL DEVELOPMENT OF CHARLES PFIZER & CO., INC.; ACCOMPANIED BY CHARLES F. HAGAN, LEGAL DIVISION

Dr. FEENEY. Mr. Chairman and members of the committee, my name is Robert J. Feeney, and I am the director of commercial development for the Charles Pfizer Co. which has its headquarters in New York.

I am a doctor of philosophy in organic chemistry and have had extensive experience with all aspects of the research and development of new drugs and antibiotics by my company.

We appreciate this opportunity to appear before you, and we will confine our remarks to the provision of H.R. 11581 which would extend to all antibiotics the certification requirements in the Federal Food, Drug, and Cosmetic Act.

I am responsible at Pfizer for the coordination of all activities—research, production, and marketing—leading to the introduction of new products, including dosage forms, for human and animal use. I am accompanied by Mr. Charles Hagan of our legal division.

Our remarks will supplement the testimony on this provision by Mr. John T. Connor, the president of the Merck Co. Let me commence by relating briefly something about our company's long experience in the antibiotic field.

One of Pfizer's most outstanding achievements, of which we are particularly proud, is the part that the company played in the development of practical penicillin production procedures during World War II. Pfizer was a pioneer with two other companies, Merck and Squibb, in the research which made penicillin available in time to save the lives of countless American soldiers. By the end of World War II, Pfizer was producing about 50 percent of the penicillin used by our military forces.

Pfizer was also one of the first companies to produce streptomycin and later dihydrostreptomycin, two antibiotics most important in the treatment of tuberculosis. Some 2 years later, in 1950, we brought Terramycin on the market. This is a broad spectrum antibiotic discovered by Pfizer scientists. It is still a mainstay of the medical profession in the treatment of a host of infectious conditions, and has also been found to be most useful in veterinary practice, as well as in animal feeds for growth promotion and for prevention and treatment of diseases.

It was the first of the important antibiotics which was not made subject to the certification requirement. No antibiotic discovered since Terramycin has been subjected to the certification procedures except those which FDA considered derivatives of the previously certified antibiotics. In 1954, we marketed Tetracyn, another broad spectrum antibiotic, also discovered by Pfizer scientists.

The company now produces and markets more antibiotic products than any other company in this country. These include the products that I have mentioned and also bacitracin, neomycin, polymyxin, triacetyloleandomycin and Viomycin.

Of the 10 antibiotics which I have just mentioned, 5 are subject to the present certification requirements in the Federal Food, Drug and Cosmetic Act—penicillin, streptomycin, dihydrostreptomycin, Tetracyn and bacitracin. The other five are not subject to antibiotic certification. All would be covered if H.R. 11581 were enacted in its present form.

In 1945 an amendment to the Food, Drug and Cosmetic Act requiring certification of penicillin was supported by members of the pharmaceutical industry as a temporary measure. This amendment was passed at a time when production and control procedures were in a crude stage of development. Today, antibiotics can be produced and controlled with uniformity comparable to that for other drug products. There is therefore no longer any meaningful reason for singling out antibiotic drugs for special certification treatment.

As a matter of fact, the Terramycin and other noncertifiable antibiotics which we produce are as uniform in purity, potency, and so forth, as any other drug which we produce. The truth of the matter is that the certification requirement has long outlived its usefulness.

Meanwhile, the burden, which the certification provision now imposes needlessly upon the industry, has increased over the years. The annual fees paid by the industry to the Food and Drug Administration are between $900,000 and $1,000,000. Proposals are now pending that would increase these fees most substantially and would require the submission of an increased number of samples for the certification of batches of antibiotics.

The 1959 estimate by the Comptroller General [1] that approximately 150 man-years of effort were devoted in that year by FDA to certification would also be substantially increased if these latest proposed regulations by FDA were adopted—and the figure would be at least double if sections 105 and 106 of this bill were enacted in their present form.

However, the certification fees are not the only expense needlessly incurred as a result of certification requirements. The delays presently caused by certification mean that our inventories must be substantially higher than justified for an efficient operation. Moreover, if the new regulations proposed by FDA are adopted our inventories of presently certified antibiotics would increase by an estimated $3 million. If certification is extended to all antibiotics, the inventories would be increased another $1,250,000. These figures represent only one of the burdens on only one company in this field.

At this point, we want to emphasize that if there were a significant problem of safety involved, the cost and other burdens would be gladly accepted. We are in favor of any reasonable proposal to advance public health and safety. For instance, we support a number of provisions in this bill which are practical and which would achieve this aim.

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[1] Report to Congress by the Comptroller General entitled "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education, and Welfare," dated September 1961.

In the case of extension of certification, however, in view of the advanced state of the art of manufacturing and testing antibiotics, there is no need for the continuation of such requirement, much less for its extension to all antibiotics.

SECRETARY RIBICOFF'S TESTIMONY

Secretary Ribicoff, in his prepared statement delivered to this committee on June 19, 1962, made four points to support extension of certification. We should like to comment briefly on each of these points:

(*a*) The Secretary said that antibiotics, more than any other drugs, are the first choice in treating life-threatening infections. We agree but the fact that antibiotics are used to treat life-threatening diseases does not distinguish them from the many other drugs which are also used to treat life-threatening diseases (which drugs, incidentally, do not require certification.)

(*b*) The Secretary indicated that his Department has had to reject numerous batches of the presently certified antibiotics. We would respectfully refer to the above-mentioned report by the Comptroller General, including the fact that during 1960 only 22 batches of antibiotic drugs were rejected by FDA out of 16,601 batches tested.

The rejection of a few batches is not surprising since it is our practice, and we believe the general practice in industry, to furnish samples of production lots of FDA for testing as soon as production is completed and before we conduct our own tests. The manufacturer's own testing of the above-mentioned 22 batches probably also confirmed the deficiencies observed by FDA. No manufacturers would knowingly market a batch of an antibiotic drug which was subpotent or unsafe.

(*c*) The Secretary indicated that the Department has had to withhold certification services from some manufacturers until their "operations" were brought into compliance with "regulations designed to insure safety and efficacy of certified lots." We are somewhat puzzled by this statement, since we know of no regulations specifying standards for equipment, facilities, et cetera, to be used by manufacturers of certifiable antibiotics. In any event, however, to the extent that the facilities and equipment of a manufacturer of any drug, are not adequate to assure its quality, potency, et cetera, the answer to this problem is not certification, but rather the answer is already contained in section 101 of H.R. 11581 which would deem any drug manufactured under such conditions to be adulterated.

(*d*) The Secretary indicated that the Department has had to suspend certification of a number of products that became unstable or otherwise unsuitable for use. Many drugs other than antibiotics are subject to deterioration under certain conditions, or merely with the passage of time, and there is ample authority under the present act to proceed to any such situation.

BURDENSOME EFFECTS OF EXTENSION OF CERTIFICATION

Extension of certification to all antibiotics, at this late date, would produce most serious difficulties and confusion for the manufacturers of those antibiotic products which are not currently subject to certification.

In order to realize why this is so, it is necessary to understand the mechanics involved in obtaining a certification for an antibiotic product.

Under the general regulations for certification of antibiotics (sec. 146.7) a manufacturer desiring to produce a new antibiotic dosage form must submit to the Department a considerable amount of information, including a full description of the methods, controls and facilities used for its manufacture, processing, and packaging, a full statement of the composition of the drug and all reports of investigation made to show whether the drug is safe and efficacious. (This is the same information required for "new drugs" under sec. 505 of the act as it would be amended by secs. 102–104 of H.R. 11581.)

If the Department is satisfied that the data submitted is adequate to demonstrate the safety and efficacy of the dosage form it issues two regulations which must be complied with in order to have batches of that drug certified.

One regulation establishes standards of identity, strength, quality, and purity for the dosage form (including prescribing, packaging, and labeling requirements) and the other regulation sets forth the tests and methods of assay for determining whether the standards in the first regulation are met with respect to each particular batch of the dosage form.

Pfizer currently markets over 60 human and veterinary antibiotic dosage forms which are not subject to certification, and there are many other manufacturers of noncertified antibiotic dosage forms.

If certification is extended to all antibiotics as proposed, presumably Pfizer will have to petition for regulations providing for the certification or exemption from certification of each of these dosage forms. This is so in spite of the fact that virtually all of these 60 or more dosage forms have already been cleared by the Department via the new drug procedures, and in spite of the fact that many of them have been on the market for 5 to 10 years, and are widely accepted by the medical and veterinary professions. Since new drug clearance for most of these products was obtained a number of years ago, and minor changes in manufacturing procedure, control procedures, labeling have occurred for many of them, there appears to be little likelihood that the Department would issue regulations providing for the certification, or exemption from certification, for these products solely on the strength of the fact that at one point they had been cleared through new drug procedures.

It can be anticipated, therefore, that FDA will re-review the data previously submitted for our dosage forms before issuing regulations providing for certification. We submit that this massive reclearance of our products will involve an entirely unnecessary waste of industry and Government manpower and will result in most burdensome delay.

When you consider that there are many companies besides Pfizer which market a wide range of antibiotic dosage forms that are not currently certified, the magnitude of the difficulties and confusion that will result becomes more apparent. There are about 30 noncertified antibiotics, and hundreds of dosage forms containing those antibiotics.

In the case of drugs for use in treating diseases of animals and for use in animal feeds, the effect of extending certification to cover all antibiotics would be particularly severe, and especially needless

from the standpoint of safety. No logical reason has been advanced to extend certification in the case of such products.

The extreme authority already exercised by the Food and Drug Administration over such products was dramatically illustrated in the testimony before the Subcommittee on Health and Safety on August 6 and 7 of this year during hearings on H.R. 12437 and H.R. 12420 which pertain to animal feed additives.

As indicated in those hearings, the extremely stringent controls over veterinary drugs and animals feeds, which are currently exercised by FDA under two separate sections of the act (the new drug section, and the food additive section) have prompted the Animal Health Institute to propose that the act be amended to provide for clearance procedures for such drugs which are separate from the procedures for clearing human drugs. To extend certification to all antibiotics used in veterinary drugs and feeds would further burden and confuse this highly unsatisfactory situation.

The principal veterinary use of antibiotics is in animal feeds and the problems just discussed are particularly acute in this area.

To extend the antibiotic certification provisions to all antibiotics so used would accomplish no worthwhile purpose whatsoever since it is entirely impractical to certify each batch of such feeds. Three of the currently certifiable antibiotics are widely used in feeds, and FDA, so far as we are aware, has certified no batches of such feeds. Instead, it has issued a maze of "exemptions" from certification. This means that the degree of governmental control is no greater than in the case of feeds containing uncertifiable antibiotics.

Because of practical considerations, if the certification procedures are extended to all other antibiotics used in feeds, it is virtually certain that such feeds will also be marketed under exemptions from certification. However, before such exemptions are granted a wholly unnecessary, wasteful and time-consuming reclearance of each of the antibiotic feed uses will presumably be required in spite of the fact that virtually all of such uses were previously cleared under the new drug procedures.

DECERTIFICATION

We now turn to our final point, the extreme reluctance of FDA to exempt from certification manufacturers who have proved their competence.

We submit that it is clear that Congress intended the certification requirements to remain in effect only as long as they were needed to protect the public. Indeed, the statute provides for the decertification of antibiotic drugs individually or as a class when such requirements are no longer necessary "to insure safety and efficacy of use."

However, FDA has taken the position that the statute as now worded would not permit them to exempt a manufacturer from the certification requirements as to a particular product but would only authorize the exemption from certification of all manufacturers of that product. That is, that decertification must be accomplished on a product-by-product basis and not on a manufacturer basis. A few antibiotic products have been decertified, but they are very few, and no antibiotics for human use have been decertified within the past 7 years.

We submit that the existing certification provisions of the act should be amended to allow individual manufacturers to receive exemptions from certification, and that specific and mandatory criteria for decertification should be set forth.

CONCLUSION

In conclusion, we strongly urge that section 105 of H.R. 11581 not be enacted.

The CHAIRMAN. Does that conclude your statement, Doctor?

Dr. FEENEY. Yes, sir.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Yesterday I had a couple of questions in mind for the pharmaceutical manufacturers, and I did not fully develop them.

When you have a drug that is in the stage of testing, do you have a list of physicians to whom you send these drugs?

Dr. FEENEY. This obviously, sir, is something that is not pertinent to my testimony, but I have had a very close association with this problem.

There is no set listing of physicians for evaluating a new drug. Each drug, whether it be an antibiotic or a drug for mental disease, would have its own particular set of experts who are most competent in the field.

We go to the leaders in medicine, the men with the greatest experience, the men with the greatest interest in advancing drug science, and the men whom we believe to be the most competent in discharging this responsibility.

So there is no set listing.

The industry selects and works in concert with the leaders in medicine in this country and throughout the world.

This is the policy.

Mr. YOUNGER. Do you know of any manufacturer who pays a doctor for conducting the testing?

Dr. FEENEY. In the sense that a manufacturer will supply certain forms of financial support to such programs, this is not unusual.

For example, new drugs are oftentimes evaluated in hospitals, and you and I have read a great deal about the high cost of medical care. Laboratory tests that are required to be certain of the safety of the drug are very expensive. The manufacturer assumes some of the financial burdens that are involved in that aspect of obtaining drug clearance.

But, in the sense that a reputable manufacturer is purchasing a good report or a positive report, this, of course, is unheard of. It is not done.

Mr. YOUNGER. I can understand how it would be natural to assume the expenses of lab tests, X-rays, and so forth, but do you know of any firms that actually pay the doctor personally for what work he does?

Dr. FEENEY. Not in the sense of the word as you mentioned it, Congressman.

The research program of a particular physician might be supported, but, in the sense that his services are purchased, I am not familiar with anything of that type.

Mr. YOUNGER. Also in connection with this experimental work, is there any other emoluments given by the manufacturer in connection with testing that you know of?

Dr. FEENEY. No, sir; none that I know of.

In my experience—and I am certain that much of this has come before the committee from other witnesses—the most satisfying part of my responsibilities, and I think one of the major roles of my company, is the development of new drugs that are going to be of value to humanity.

We embark upon it with that viewpoint: That we are going to do something positive; that we are going to extend the lives of people who are not even born; and there is so much yet to be done—I do not know how firmly the committee grasps that aspect of it—and we try to work with clinicians and with outside researchers.

My company has about 1,200 people involved in research.

Obviously, we cannot do the entire job ourselves. We try to work with men who are of a similar philosophy: That new drugs and the search for useful new drugs is a challenging and an extremely rewarding effort on our part, for me personally, for our company, and the men we work with.

My experience in a dozen years has been that this is actually the way drug development is carried forward.

Mr. YOUNGER. In your experience, have you found any of the physicians who charge for administering a test of drugs that are furnished to them free, where the physician charges the patient?

Dr. FEENEY. I have never heard of that being done, Congressman.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Glenn?

Mr. GLENN. Doctor, on pages 3 and 4 of your statement you refer to some new regulations by the FDA. Do these in any way have anything to do with this bill which we are considering here today?

Dr. FEENEY. I would like Mr. Hagan to answer that, Mr. Glenn, if you do not mind.

Mr. HAGAN. Mr. Glenn, just in that they would increase the cost of certification, sir.

One of the proposals would increase certification fees by a flat 30 percent.

Another would subject the nonantibiotic, active components of drugs which do contain a certifiable antibiotic drug as one of the other components to the certification requirement.

The net effect would be to increase the cost of certification, and I think we can predict that, since the fees of certification are intended to cover all costs of the certification program, that the fees will be a constantly increasing factor.

Mr. GLENN. But these regulations which you speak of are apt to be placed on the industry by FDA, regardless of whether we pass this act, are they not?

Mr. HAGAN. Yes, sir.

They have been pending for some time, however, without being issued, up to now.

Mr. GLENN. Thank you very much.

That is all, Mr. Chairman.

The CHAIRMAN. How extensive are those fees?

Mr. HAGAN. Well, we estimate that they would very nearly double the present cost of certification, Mr. Harris.

The CHAIRMAN. That still gets me a little more confused.

You just now said that they would be 30 percent.

Mr. HAGAN. No.

One of the three pending proposals would be to increase the costs 30 percent.

Another proposal would subject the nonantibiotic components of a drug that contains a certifiable antibiotic component to certification.

A third increases substantially the amount of testing and sample submission that has to be done.

The CHAIRMAN. In other words, the cost of those which must be certified now would be increased 30 percent?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. And to take in others that you do not have to certify now, would add to your cost?

Mr. HAGAN. That is correct.

The CHAIRMAN. Of course, if anything does not cost much, why, 30 percent does not amount to much.

Mr. HAGAN. That is right.

The CHAIRMAN. The question is how extensive is this cost.

Mr. HAGAN. We certainly do not urge the cost factor as the prime reason for objecting to certification, Mr. Harris. We feel that it is unnecessary and that any cost factor added by an unnecessary procedure should not be continued.

Dr. FEENEY. We submit, Mr. Harris, that our scientific people and those of the Food and Drug Administration might be better employed in the search for new agents and for drugs that do not yet exist.

The CHAIRMAN. Do you know Dr. John L. Harvey?

Dr. FEENEY. Yes, sir.

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Are you familiar with the speech that Dr. Harvey made to the American Bar Association meeting?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Do you recall the statement he made with reference to the reasonableness of the costs?

Mr. HAGAN. I do not recall it, Mr. Congressman, precisely.

The CHAIRMAN. He stated:

> Last calendar year certification of the antibiotics now subject to this control cost on the average about one-twentieth of a cent per dose.

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Would you say that would be about correct?

Mr. HAGAN. We have no knowledge of the cost per dose, Mr. Harris.

Our point really is that the additional cost is merely one of the reasons why we oppose extension of certification. During 1960 alone 150 man-years of scientific personnel time was taken up by the Food and Drug Administration in this endeavor. We submit that in view of the scarcity of scientific talent, this scientific talent at FDA could be put to better use.

The CHAIRMAN. Do you contend that the five antibiotics that are now required to be certified—I believe that is true, is it not?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Do you content that they no longer need to be certified?

Mr. FEENEY. Yes, sir; we do. I have attempted today to create a picture for you of the devlopment of antibiotic production. If you

recall, the urgency for penicillin for the Armed Forces during the war meant that every batch of penicillin that was manufactured, if possible, had to be put into a vial for use by the military; that these were totally new agents at that point in time; and the standards and methods for control were evolving during the course of time that penicillin was being actually distributed to the Armed Forces.

We have long gone past that point.

Antibiotics today are chemicals in the strictest sense of the word.

We would no more consider extending, I do not believe, the certification provisions to any of the drugs that are used in this country, nor would we propose to certify chemicals that go into foods, nor would we propose to certify a monomer or polymer that goes into a man's coat.

The antibiotics are chemicals. Their manufacture is thoroughly understood.

Antibiotic production can be readily controlled just as any of the other chemical processes run by a reputable manufacturer.

The CHAIRMAN. Now, what is required with reference to certification of streptomycin, for example?

Dr. FEENEY. We are still required to submit all batches of streptomycin that are manufactured.

The CHAIRMAN. What is a "batch"?

Dr. FEENEY. A batch will vary, sir. It depends upon the size of the reaction vessels and the fermenter. It could be 500 kilos. It could be 1,000 pounds. It could be 10 pounds.

It will depend upon the production operation, but, generally, it is a very substantial amount of antibiotic. A thousand pounds would not be unusual.

The CHAIRMAN. And under present law you have to provide a sample for these five?

Dr. FEENEY. We provide a sample to the Food and Drug Administration.

The CHAIRMAN. What do they do with it?

Dr. FEENEY. They proceed, among other things, to conduct certain tests. They show that the sample is streptomycin and not something else.

They show that it is biologically active; that it is an antibiotic.

They show that it is pure in the sense that it meets certain standards which relate to it as a chemical.

In the case of streptomycin they show that it is sterile; that it does not contain micro-organisms that would make it impossible to inject it.

They show that it does not contain pyrogens, which are things that cause fever in human beings, and they conduct a whole battery of tests.

We deliver a sample of streptomycin to the Food and Drug Administration, for example, within a matter of hours after we manufacture it.

We then hold the batch in quarantine, which means that we do nothing with it pending completion of our own tests and Food and Drug tests.

At the earliest possible date we start a whole battery of tests of our own which include those being run by the Food and Drug Administration, and in the case of Pfizer we go substantially further in making certain that the material lives up to our own internal standards.

At the end—and this bears on our inventory considerations—at the end of a definite point in time the Food and Drug has completed their tests; we have completed ours; and, as in the case of our statement, only 22 times last year out of 16,000-odd batches that were submitted, was there any reason for the Food and Drug not to pass on the lot that was submitted.

I believe I also made the point that since the manufacturer submits the antibiotic well in advance of his own tests, probably in all 22 of those cases, and we are not privy to the information that is involved, all 22 of those cases, or in the great majority of them, the antibiotic would not have been released by the manufacturer.

The manufacturer would have completed his own tests and decided that the antibiotic should be returned for further purification, if that were the issue involved.

The CHAIRMAN. Now, those that you do not have to submit for certification, do you occasionally find a batch that you have to turn down?

Dr. FEENEY. We have our own internal control, and we do, upon occasion, find a batch that does not live up to the standards of our organization.

The CHAIRMAN. And you take it back and redo it?

Dr. FEENEY. We do not let it out of the company. It is reprocessed or destroyed or whatever is done, as is indicated by the deficiency in the lot.

I wanted to convey to you, Mr. Chairman, that the variations in antibiotic manufacture are no different today than the variations in the manufacture of almost any other chemical.

We have heard so much of the miracle drugs and the magic of their production by micro-organisms and the development of this technology in approximately the last 20 years that we tend to think of these agents as something set apart, and the current state of the science and the manufacturing art is such that that is not the case.

We have not, to the best of my knowledge, for example, in the case of Terramycin, an antibiotic which we discovered and which we produce in enormous quantities, we have not had any instance in which a lot or a dosage form of Terramycin has been distributed to the medical profession anywhere in the world in which—and this is to the best of my knowledge and I believe I am correct—in which there has been anything wrong with the antibiotic.

The CHAIRMAN. Terramycin is an antibiotic?

Dr. FEENEY. It is an antibiotic, sir, yes.

The CHAIRMAN. Is it a drug?

Dr. FEENEY. It is a drug in the sense of the law, yes.

The CHAIRMAN. In other words, you have to get——

Dr. FEENEY. Terramycin was cleared under the new drug procedure of the act.

The CHAIRMAN. You have to clear it with the Food and Drug Administration as to its effectiveness and safety?

Dr. FEENEY. Yes, sir. This was done. The drug was cleared in 1949 and 1950.

The CHAIRMAN. And your reasoning is that since you have it cleared as safe, there is wasted motion in getting these certifications on the batch?

Dr. FEENEY. We can see nothing useful to be gained by reclearance of the antibiotics that have been cleared under the new drug procedure.

The CHAIRMAN. It appears to me that the ones that you are having to obtain certification on ought to be relieved from this procedure or else the rest of the antibiotics should be brought under the law.

Dr. FEENEY. It would appear, Congressman, that there is an inconsistency here.

There is no doubt in my mind that there is no need for certification of antibiotics in this day and age.

The CHAIRMAN. While we are talking about this, we have heard so much on the subject of efficacy, and we have had Webster's definition.

We have had the definition of this one, that one, and the other one.

We have had a lot of argument around here as to using the term and what effect it would have.

Now, you are a highly competent, well-qualified and experienced individual, I assume. I do not say that to pat you on the back, but I say it because you so impress me.

What is your definition of the meaning of "efficacy" and how is it different from the meaning of the word "effectiveness"?

Dr. FEENEY. Mr. Harris, you back me into a corner.

The CHAIRMAN. I know what people do when they get in a corner.

Dr. FEENEY. I am impressed with the multiple interpretations of the English language.

In the last several days I have had an opportunity to marvel at the way it is used by lawyers, and I am a scientist.

Although there are some gray areas in science, most things are black and white.

I was most impressed yesterday with Dr. Klumpp's statement, and it is the one that I subscribe to.

He attempted separately to define both terms, and I am in agreement largely with the way he handled the matter. I would say, though, that, in short, it is what the manufacturer claims for the drug.

The CHAIRMAN. I would assume from that, after having listened to these lawyers, that what the industry is disturbed over now, and as it was in 1951 and 1952, is how the agency will construe the meaning of the word "efficacy." Is that the real problem?

Dr. FEENEY. I would say that that is at the heart of the discussion for the last several days.

The CHAIRMAN. The witness this morning, I believe, used the phrase—I have to paraphrase it, I do not know that I could quote it verbatim, but he used the phrase that efficacy was the extent of the effectiveness.

That gave me the impression that the true meaning of the term must be about the same.

Dr. FEENEY. There is another approach to this, Mr. Congressman.

I told you that I was a Ph. D. in organic chemistry, and everything is either black or white in organic chemistry. It is a pretty exact science. I do not think the word "science" in Webster's dictionary allows for inexactness, but if you have been as close as I have been to medicine for the last dozen years, you become enormously impressed with the fact that some aspects of medicine and the practice

of medicine and the effects of drugs upon human beings are so highly variable that you will find a very wide difference of opinion among physicians as to whether drugs act on certain patients under certain circumstances.

One witness here yesterday, as I recall, said that he was concerned as to what kind of drugs were effective in rheumatoid arthritis, and another witness said categorically that steroids did one thing, and phenylbutazone did another thing, and aspirin did something else.

Within my own experience I have seen this. There is a wide difference in medical opinion on this matter. Medicine is not an exact science. If it were, there would be no need to argue about the English language.

The CHAIRMAN. Well, of course, as a layman and one who does not claim to have any knowledge of these subjects except as a layman would have knowledge, it seems to me the answer is that a particular drug or antibiotic would have different effects on individuals.

Now, the makeup of the individual human being is such that I do not think you could expect aspirin, for example, to have identically the same effect on one person as it would have on another person.

Mr. SCHENCK. Will the chairman yield?

The CHAIRMAN. When you can discover the makeup of all 3 billion people in the world, then you will have this thing whipped.

Mr. SCHENCK. Some people are allergic to aspirin and to a lot of other drugs, so it does affect various individuals differently, and even the same people at different times.

The CHAIRMAN. A Member of Congress just told me only yesterday about a person that is very close to his family who developed a ringing in the ears, and, after a rather extensive examination, it was found that he had been taking too many aspirin.

I never heard of it before, but that is what I was told by a Member who seemed to know what he was talking about.

That is not going to keep me from taking aspirin if I think I need it sometime, but it does point up this problem.

In fact, I know the first time that I had penicillin administered to me, I had a violent reaction to it.

I did not know what was wrong with me.

But another doctor, in another town where I happened to be at that time, asked me if I had recently had penicillin, and I told him, yes, 3 days ago.

So he had to go back to find out from the same doctor what to do to treat it. That has been a good many years ago. Since then I have had any number of penicillin shots but no reaction.

Whether I became immune to it, I do not know.

But those are the things that do worry me about submitting to the final decision of any one individual, as was mentioned here yesterday, about the use of these drugs. I am old fashioned enough to believe that a doctor who has administered to a particular patient over the years probably knows more about what to do than anybody else.

Mr. Thomson, I have used all your time, I am afraid.

Mr. THOMSON. It has been very interesting. I have no questions.

The CHAIRMAN. Thank you very much.

Dr. FEENEY. Thank you, sir.

(The following information was submitted by Chas. Pfizer and Co., Inc.:)

EXTENSION OF CERTIFICATION TO ALL ANTIBIOTICS—SUGGESTED MODIFICATIONS

Extension of certification to include the many hundreds of human and veterinary dosage forms containing presently uncertified antibiotics will be productive of serious difficulties and confusion.

Requests for regulations permitting certification, or exemption from certification for all these dosage forms, will have to be submitted to FDA. This will need to be done even though virtually all of these drugs have previously been cleared by FDA under the new drug procedures.

In effect, FDA will rereview all of the clearances for these products which it has given over the last 13 years, and it will have the power to change its mind as to whether to permit the labeling for such products to bear any or all of the already accepted recommendations for use. If all antibiotics are to be subjected to certification, the following two modifications are proposed in an attempt to minimize the difficulties and inequities which will likely result:

First: Section 105 of H.R. 11581 should be amended to add the following new subsection to section 507 of the Food, Drug, and Cosmetic Act:

"As a requirement for issuance of a regulation providing for certification, or exemption from certification, for any drug as to which a new drug application, or supplement thereto, was in effect at any time prior to enactment of this Act, and has not been withdrawn or suspended pursuant to section 505(e) of the Act, the Secretary shall not require submission of efficacy data with respect to any indications for use contained in labeling which was a part of such new drug application, or supplement thereto."

Second: The extension should be confined to drugs for human use, and should not include veterinary drugs and drugs for use in animal feeds.

REASONS FOR THE "FIRST" SUGGESTED MODIFICATION

The vast majority of the hundreds of dosage forms which would become subject to certification as the result of enactment of H.R. 11581 have been, as beforementioned, already cleared by FDA under the new drug procedures. Unless a modification of the type proposed above is adopted, before FDA will issue regulations providing for the certification of each of these dosage forms, it will rereview the efficacy data bearing on each of the indications for use contained in their labeling.

This rereview will be made by a different division at FDA (and hence by different individuals) than the one which reviewed and cleared the new drug applications for these products. Since "efficacy" is a matter upon which equally competent authorities will frequently disagree, there is a real likelihood that, as a result of this rereview, some, or perhaps many previously accepted (by FDA and the medical and veterinary professions) uses for such drugs will be prohibited. At the very least, there will be prolonged delays while the Antibiotics Division rereviews the massive amounts of efficacy data available on these many hundreds of dosage forms, which data has already been reviewed and found acceptable by the New Drug Division.

The Senate has just considered the problems which "reclearance" by FDA would create for "new drugs" as the result of the "efficacy" provisions in S. 1552. Unfortunately, it did not consider the fact that the presently noncertified antibiotics would encounter the same problems as the result of extension of certification. To resolve such problems for "new drugs," the Senate bill (S. 1552) contains in section 8(g)(3) provisions which, in their essence, are the same as the "first" proposed modification set forth above.

The report of the Senate Judiciary Committee (on p. 7) contains the following explanation of section 8(g)(3):

"Under the amendment, a drug which is on the market and has gone through the new-drug procedure would not have to be resubmitted for clearance of existing label claims with respect to effectiveness of the drug unless approval of the new drug is withdrawn or suspended under the act or unless an amendment or supplement to the effective new-drug application is filed (in which event only the changed labeling would be reevaluated)."

The "first" proposed modification set forth above seeks to accomplish the same equitable result.

REASONS FOR THE "SECOND" SUGGESTED MODIFICATION

The main reason which has been advanced by the Government for extension of certification to all antibiotics is that this extreme form of governmental control is justified because these drugs are more often used against life-threatening infections in man than other drugs. While industry disputes the validity of this justification even as to infestious diseases of man, it is submitted that the fact that antibiotics are sometimes used against life-threatening infections of animals clearly is not of sufficient magnitude to justify such control over antibiotics for animal use.

The existing situation with respect to obtaining FDA clearance to market veterinary drugs or drugs for animal feeds is highly unsatisfactory because it is frequently necessary to obtain clearance for such drugs under both the food additives amendment and either the new drug or antibiotic certification procedures. This situation has become so burdensome and confusing that the Animal Health Institute has proposed legislation which would establish separate FDA clearance procedures for drugs for animal use. Extension of certification to all veterinary drugs and animal feeds containing presently uncertified antibiotics would compound the existing problems in this area.

The problems discussed above are particularly acute in the case of drugs used in feeds. To extend the antibiotic certification provisions to all antibiotics so used would accomplish no worthwhile purpose whatsoever since it is entirely impractical to certify each batch of such feeds. Three of the currently certifiable antibiotics are widely used in feeds, and FDA, so far as we are aware, has certified no batches of such feeds. Instead it has issued a maze of "exemptions" from certification. This means that the degree of governmental control over feeds containing certifiable antibiotics is no greater than in the case of feeds containing uncertifiable antibiotics (although in both cases the degree of control is more than adequate).

Because of practical considerations, moreover, if the certification procedures are extended to all other antibiotics used in feeds, it is virtually certain that such feeds will also be marketed under exemptions from certification. However, before such exemptions are granted a wholly unnecessary, wasteful, and time-consuming reclearance of each of the antibiotic feed uses will presumably be required in spite of the fact that virtually all of such uses were previously cleared under the new drug procedures.

No logical reason has been presented by the Government for extension of certification to antibiotics used in veterinary drugs and animal feeds. The degree of governmental control presently provided over such drugs by the Food, Drug, and Cosmetic Act (including the food additive and new drug provisions) exceeds the control provided over any other products subject to that act. Extension of certification to all antibiotics used in such products is totally unnecessary and would create extreme confusion, burdens, and delay.

CHAS. PFIZER & CO., INC.

The CHAIRMAN. Mr. Franklin M. Depew. We are glad to have with us, Mr. Depew, and we will be glad to have your statement.

STATEMENT OF FRANKLIN M. DEPEW, CHAIRMAN, FOOD, DRUG, COSMETIC SECTION, NEW YORK STATE BAR ASSOCIATION

Mr. DEPEW. Thank you very much.

Mr. Chairman and members of the committee, my name is Franklin M. Depew of 205 East 42d Street, New York City 17, N.Y. I am a member of the bar of the State of New York and chairman of the section of food, drug, and cosmetic law of the New York State Bar Association. This section was the first organization of lawyers practicing throughout the country in the food, drug, and cosmetic field, and its members represent most of the major companies engaged in the manufacture of food, drugs, and cosmetics.

The executive commitee of the section has authorized me to appear in support of the view that the inspection provisions of section 704 of the Food, Drug, and Cosmetic Act, should be retained without

change on the ground that no need has been demonstrated for the proposed expansion of authority as contained in section 201 of H.R. 11581.

This committee has approved the statement which I am about to make.

On March 15, 1962, President Kennedy in his special message to Congress on consumer protection stated that an uncooperative small minority can engage in a game of hide-and-seek with the Government in order to avoid inspection. The proposal is, therefore, apparently directed against an uncooperative small minority, yet, these are exactly the businesses that would be least likely to maintain adequate or accurate records. Thus, the privacy of the great majority of respectable businessmen is to be prejudicially invaded because of the misbehavior of a very small minority.

It cannot be too strongly stated that inspection of these factories as provided by this section, by outsiders, can expose to the world trade secrets, know-how, and other confidential information. This technology is, in the truest sense, the property of its owners. Frequently, it constitutes the element of greatest value—in economic and competitive terms in the manufacture of a product. To subject such technology to outside inspection exposes it to possible dedication to the public domain.

Of course, we are aware that FDA inspectors are subject to injunctions of secrecy. But that is no assurance to business corporations who guard their technology under the most elaborate security precautions. Yesterday's government official is tomorrow's private employee. Proof of unlawful disclosure is difficult. Surely these risks are not outweighted by the administrative inconvenience to which FDA may be put absent the powers granted in section 201 of H.R. 11581.

In concluding I would say that we in the section have the very highest regard for this great public agency, the Food and Drug Administration.

We do feel that, rather than a new law, they might possibly have endeavored to work out a better working relationship with industry with regard to these factory inspections.

Their inspectors, after all, are not administrative people or even trained in this field, and they have never attempted to demonstrate why disclosure would further the remedial purposes of the law.

We strongly urge your sympathetic consideration of this viewpoint.

Thank you.

The CHAIRMAN. Thank you, Mr. Depew, for your statement which the committee is glad to have.

Mr. Schenck observes from your statement, "yesterday's government official is tomorrow's private employee," that it might have some bearing on the election.

Mr. DEPEW. Well, it could have.

The CHAIRMAN. It is entirely possible.

Mr. DEPEW. That is very true.

The CHAIRMAN. Mr. Roberts, any questions?

Mr. ROBERTS. No questions.

The CHAIRMAN. Mr. Schenck, I will give you your chance.

Mr. SCHENCK. Mr. Chairman, I would like to commend Mr. Depew for his concise and well-developed statement.

Mr. DEPEW. Thank you.

Mr. SCHENCK. Expressing his point of view, and to also note that it may or not be significant, but your first name is Franklin rather than Chauncey.

That is all, Mr. Chairman.

The CHAIRMAN. Thank you very much, sir. We are delighted to have you with us.

Mr. DEPEW. Thank you. I appreciate the opportunity to be here.

The CHAIRMAN. The Chair would like to inquire if there is any other witness here who is scheduled to testify tomorrow, who would like to testify today.

This completes the witnesses scheduled for today. The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 2:45 p.m., the hearing was adjourned, to reconvene at 10 a.m., Wednesday, August 22, 1962.)

DRUG INDUSTRY ACT OF 1962

WEDNESDAY, AUGUST 22, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10: 15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

The first witness this morning, as we resume the hearings on H.R. 11581 to amend the Federal Food, Drug, and Cosmetic Act, will be the Honorable Daniel K. Inouye of Hawaii. We are happy to have you with us, Mr. Inouye.

STATEMENT OF HON. DANIEL K. INOUYE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF HAWAII

Mr. INOUYE. Mr. Chairman and members of the committee, I would like to express my appreciation for this opportunity to be heard on those provisions of title II of H.R. 11581 which would authorize Government inspectors to examine at will the files and records of all food product manufacturers.

As the committee well knows, Hawaii is the leading canned pineapple producer in the world, and is one of the major sugar producing areas. These two products, which are basic to the economy of Hawaii, along with other food products such as coffee, canned fish, and fresh fruits, accounted for an extremely large percentage of our exports in 1961. For the year 1960–61 the last for which complete statistics are available, almost 35 million cases of pineapple and pineapple juice were packed in Hawaii, and the great percentage of this production eventually found its way to the tables of consumers in every town and city in America.

Because of the importance of the pineapple and other food-producing industries to Hawaii, any proposed Government legislation that would seriously affect those industries is of primary concern to every citizen of Hawaii, and to those millions of consumers who rely upon the continuing flow of high-quality food products from the islands to the mainland. For this reason, I have asked to be permitted to testify in opposition to those portions of title II of H.R. 11581 that would amend section 704 of the Federal Food, Drug, and Cosmetic Act to permit FDA employees to enter any food manufacturing establishment and inspect—

all things therein (including records, files, papers, processes, controls, and facilities) bearing on * * * violations or potential violations of this Act.

In my view, this unprecedented grant of authority to a Government agency to pry into the files and records of private commercial enterprises on a regular and recurring basis is not only unwarranted and totally unnecessary, but it would conflict with the basic constitutional prohibition against unreasonable search and seizure, found in the fourth amendment. No evidence has been produced to establish the need for this drastic proposal. On the contrary, there is compelling evidence to establish that this unlimited authority in a Federal agency to enter food manufacturing establishments at will and rifle through their files may well seriously interfere with the efforts of reputable, progressive companies to produce high-quality, wholesome foods on a volume basis at a reasonable price to consumers.

During the course of my years here in Washington, I have come to respect, as has every other Member of Congress, the unceasing efforts of those in the Federal Food and Drug Administration on behalf of American consumers. It is possible that no other Federal agency carries out its assignments with the energy and dedication that are found in the FDA. Because of this well-earned reputation, the FDA has generally received a favorable reception here in Congress when it has requested new authority or amendments to old authority under the Federal Food, Drug and Cosmetic Act.

I sincerely believe, however, that that part of title II of this bill which would throw open the confidential files of all food manufacturers to every FDA inspector would be a grant of Federal power so at variance with fundamental concepts of democratic government and our basic views concerning the constitutional protection against unreasonable search and seizure, that no Congressman can afford in this instance to sit back and accept the proposal on the ground that it appears to be merely another FDA request for authority it claims is necessary to enforce the act.

It is my understanding that this bill is basically a drug proposal that has been broadened to include food manufacturing establishments, apparently on the assumption that what is thought to be necessary for drugs is also necessary for foods. It does not take an expert to realize that foods and drugs are by their nature entirely dissimilar, serving different purposes and subject to entirely different production and distribution techniques. Whether or not this greatly broadened factory inspection authority is necessary for drugs, and there is in my mind a great deal of doubt on that score, it seems clear that there has been no showing that this unprecedented invasion of the confidential and private records of commercial food enterprises is either necessary or desirable.

The record of the American food industry is unquestionable. Anyone who has been through a modern pineapple canning establishment would not question that these packers are taking the greatest conceivable pains to provide consumers with a high-quality, wholesome product that in every degree complies with all requirements of Federal and State laws. Certainly no question has been raised by the proponents of this measure concerning the wholesomeness of the American food supply, for it is recognized on all sides that American consumers enjoy the best food supply in the world.

Perhaps the most that can be said for title II of this bill, at least insofar as it applies to foods, is that it will simplify somewhat FDA's enforcement of the act. But in my mind this is a weak justification for a measure that would seriously threaten important constitutional rights, invade the privacy of every commercial food manufacturer in the country, subject food processors to expensive and delaying harassment, and create unfounded suspicions concerning their operations. I do not feel the time has yet come that administrative convenience or simplified law enforcement can be used to justify this kind of Government authority that runs counter to our basic beliefs concerning the Constitution and the rights of citizens to be free of unnecessary Government interference.

Other witnesses will doubtless cover in greater detail the basic objections to title II of H.R. 11581, at least insofar as it applies to food establishments. It is my understanding that no court has upheld authority such as here requested, and that serious questions under the search and seizure provisions of the fourth amendment would be raised if this part of the bill is enacted into law. As this committee well knows, that question was exhaustively and ably debated in 1953 when section 704 was enacted in its present form. In my mind the decision of this committee and Congress at that time was eminently wise. It was felt then that plant inspection by Federal agents in conjunction with the private efforts of all food manufacturers, would be ample to assure American consumers an unquestionably wholesome food supply. I know of nothing that would justify changing that conclusion.

I sincerely hope every Member of Congress will give his serious and close attention to this proposal. I cannot believe that Congress is yet ready to adopt legislation based on administrative convenience that would throw aside basic constitutional principles that have existed since the founding of this country.

For these reasons I urge upon this committee that they not recommend the adoption of title II of H.R. 11581 as it applies to foods.

The CHAIRMAN. Thank you for your statement, Mr. Inouye.

If there are no questions, we are now honored to have with us our colleague from New York, Seymour Halpern.

STATEMENT OF HON. SEYMOUR HALPERN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. HALPERN. Thank you, Mr. Chairman. I am here today to testify for H.R. 11581 which, in my estimation, is at the very least necessary if the public health of our Nation is to be safeguarded effectively. I have long been concerned with the needs of greater protection for our citizens in this area, and was an original cosponsor of the Kefauver bill.

Therefore, I would like to urge the committee to consider the need for amendments in two areas not embodied in the present bill—licensure and patents. Provisions in these areas were embodied in the bill I introduced several months ago, and while heartily supporting the great strides down the road to greater drug safety and efficacy embodied in H.R. 11581, I am convinced that licensure and patent requirements would push us even further ahead on this road.

Of course, I offer my complete support to the provisions of this bill which should not only provide the public with safer and more efficacious drugs but should also enable our doctors to receive the necessary information for more fully and effectively utilizing the many drugs made available by the progressive efforts of our pharmaceutical firms.

Though the U.S. drug regulations have been praised as the most comprehensive standards of any country in the world, the recent and highly regrettable thalidomide tragedy has left no doubt that the need for extending and revising the existing law is dire. The existing drug regulations, the conscientious efforts of the U.S. pharmaceutical firms, and the strong and knowledgeable stand taken by Dr. Kelsey enabled the United States to escape the magnitude of the thalidomide tragedy suffered in several European countries, but we cannot afford to disregard the warning implicit in the belated discovery of the deforming effects of this drug; we cannot ignore the fact that the drug was received for investigational use by some 1,073 U.S. doctors before the supposedly mild tranquilizer was known to be an abhorrent enemy to the public safety.

We must realistically evaluate existing regulations and, through comprehensive and perceptive legislation, offer greater safeguards to the health of the American people. I am thoroughly convinced that the additional safeguards provided by H.R. 11582 are essential to strengthen the existing legislation.

The bill, as introduced by Mr. Harris in the House of Representatives on May 3, 1962, aims at providing a safer and more effective drug supply for public use, more thorough and comprehensive drug information for the Federal Drug Administration, greater assistance to the drug industry in its efforts to improve the quality and safety of its products, and more honest drug advertisements to enable physicians to better utilize the large and continuously changing drug supply.

In the area of drug safety, section 101 of the bill grants the Secretary of Health, Education, and Welfare the authority to remove a drug from the market immediately if doubts arise as to its effectiveness or safety. The main difference in this provision and the existing one is that at the present the Government bears the burden of proving that a drug is unsafe or ineffective. The amendment places the burden of proof upon the manufacturer, so that drugs will not be marketed unless the sponsor has presented sufficient evidence that they are not only safe, but that they do what is claimed.

The extension of the Federal Drug Administration's approval time from 60 to 90 days or 180 days if an extension is desired, and the requirement of more detailed reports to the Federal Drug Administration on clinical investigations and findings by the manufacturer further augment the plan for more reliable drug approval and offers increased protection to the consumer.

The safety and efficacy of antibiotics will also be enhanced by the regulation requiring batch-by-batch certification of all antibiotics except those exempted by the Secretary. The complexity of the manufacturing process and the seriousness of cases treated with antibiotics make such regulations not only desirable, but necessary.

Section 112 of H.R. 11581, calling for the printing of the generic name in type equivalent to the brand name on drug labels, and a list-

ing of ingredients, promotes the interests of the medical profession and the consumers by simplifying drug terminology and classification.

We do, however, need additional provisions, as I stated at the outset, in the areas of licensure and patents. First, to prevent the use of license agreements as a means of fixing prices, establishing international cartels or otherwise restraining trade, license agreements under patent applications and issued patents should be filed with the Patent Office to be available for inspection and use by the antitrust agencies. Second, to bring about price reductions of those patented drugs whose prices are excessive, patents should be licensed after 3 years to qualified applicants upon a payment of a royalty of up to 8 percent where it is found that the price to druggists is 500 percent or more of the factory cost, including research.

The excessively high prices of drugs as revealed by the Kefauver investigations point out the pressing need of patent laws which do not allow drug production monopolies. Lifegiving drugs should not be prohibitive in price.

Finally, I feel that a program of licensure to insure the continued chemical structure, strength, quality, purity, safety, and efficacy of the products of drug companies and the revoking of licenses of companies not meeting the standards would be a more effective and efficient form of enforcement for maintaining the standards upheld by this bill than the method of seizure proposed in the present form.

I am hopeful that the committee will evaluate and consider the additional proposals I have presented. The above points are representative of the desirable and badly needed drug amendments embodied in H.R. 11581. I wholeheartedly support the passage of this bill created to insure greater protection to the health of America.

The CHAIRMAN. Thank you, Mr. Halpern. If the committee has no questions let us continue to our next witness, Mr. Benjamin G. Habberton, counsel for the Dairy Industry Committee, residing here in Washington.

Mr. Habberton?

STATEMENT OF BENJAMIN G. HABBERTON, ESQ. (FISTERE & HABBERTON, ESQS.), COUNSEL, DAIRY INDUSTRY COMMITTEE

Mr. HABBERTON. Mr. Chairman and members of the committee, my name is Benjamin G. Habberton, and I am a member of the law firm of Fistere & Habberton. I am appearing for the Dairy Industry Committee, for which organization our firm is counsel.

The Dairy Industry Committee is composed of official representatives of a number of national trade associations. These associations are as follows:

American Butter Institute.
American Dry Milk Institute.
Evaporated Milk Association.
International Association of Ice Cream Manufacturers.
National Cheese Institute.
National Creameries Association.
Milk Industry Foundation.

The members of the first six of these organizations are manufacturers of the products which their names suggest. The members of

the last—Milk Industry Foundation—are processors of fluid milk and other fresh fluid products. The members of these associations collectively come from every State in the Union and collectively they account for a majority of all the milk and other dairy products which are processed and delivered in the United States.

At its meeting held in Chicago on June 11, 1962, the Dairy Industry Committee expressed its strong disapproval of H.R. 11581 and authorized this appearance in opposition to the bill.

The opposition of the Dairy Industry Committee is based upon its conviction that title II of the bill, which has to do with factory inspection, is unnecessary and unwise. With title I of the bill, having to do with drugs, the Dairy Industry Committee is not concerned and takes no position.

DAIRY INDUSTRY COMMITTEE FAVORS FACTORY INSPECTION

Before discussing the reasons for its opposition to the factory inspection provisions of H.R. 11581, I wish to make it quite clear that the Dairy Industry Committee is not opposed to factory inspection but on the contrary is in favor of factory inspection and has supported factory inspection legislation.

In 1953 the Committee on Interstate and Foreign Commerce had before it for consideration a bill which proposed amending section 704 of the Federal Food, Drug, and Cosmetic Act. The Supreme Court of the United States, in the now historic *Cardiff* case, had ruled that a Food and Drug Administration inspector might enter a food establishment and make an inspection there only if the owner, operator, or custodian gave his consent. The Food and Drug Administration was thus left without compulsory inspection authority. Believing such authority essential to the discharge of its duties, the Administration caused to be introduced a bill which authorized entry and inspection as of right.

The Dairy Industry Committee agreed that the Food and Drug Administration should have this compulsory authority and my partner, Charles M. Fistere, acting for the committee, appeared before you on May 20, 1953, in support of the bill.

And so, I reiterate, the Dairy Industry Committee favors factory inspection and will continue to support factory inspection legislation.

But the Dairy Industry Committee cannot support the factory inspection amendments contained in H.R. 11581. In fact, it is our view that these amendments do not relate to factory inspection at all but to business records inspection. Under the existing inspection provisions of section 704 of the act, the Government agent is authorized to inspect every—

factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

This is certainly the language of factory inspection, and we believe that the inspection of these things constitutes factory inspection. But H.R. 11581, while retaining the denomination "Factory Inspection" for section 704, adds to the enumeration of things that may be inspected "records, files, papers, processes, controls, and facilities."

Now, the inspection of records, files, and papers is obviously something quite different from "factory" inspection as that term has here-

tofore been used and understood. It is not just an extension of factory inspection; it is a new kind of inspection. And so, I shall refer to this new inspection as "business records inspection" in order that this important distinction may not be minimized by the use of the original and quite unobjectionable name.

The Dairy Industry Committee is opposed to this new business records inspection which H.R. 11581 would authorize. It is opposed to it, first, because it is unnecessary.

BUSINESS RECORDS INSPECTING IS UNNECESSARY

The Federal Food, Drug, and Cosmetic Act is described as "An Act to prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes." It is the responsibility of the Food and Drug Administration to implement and enforce this prohibition, and to do so, it must have the authority to make reasonable inspections to determine whether foods moving in interstate commerce are in fact adulterated or misbranded. There can be no other legitimate purpose for inspection.

Let us consider the situation of a dairy products plant and see whether the inspector does not already have abundant authority.

The plant will be one in which the traditionally highest standards of sanitation are required and observed. The plant will be characterized by its use of equipment which has been designed and manufactured in conformity with Three A standards. These standards have been worked out over a long period of years through the closest possible cooperation of the manufacturers of the equipment, the users of the equipment, and Federal and State regulatory officials. A very high percentage of all of this equipment is fabricated of stainless steel.

The plant may be a milk plant, that is, a plant in which milk and cream are pasteurized, homogenized, and packaged for sale in fluid form. It may be a plant in which butter or ice cream or cheese is made. Or it may be a plant in which one or more of the various forms of dry, condensed, or evaporated milk are made.

The general formulations for all of these dairy products are well known to the Food and Drug Administration. In the case of some of them, standards of identity have been established by regulations promulgated by the Food and Drug Administration. These standards of identity specify the ingredients which the manufactured product must contain and, as well, the optional ingredients which they may contain. In the case of others of these dairy products, standards of identity have been prescribed by act of Congress itself.

Since we have thus far been speaking of only dairy products, it should be pointed out that under section 401 of the act, the Food and Drug Administration is not only authorized but directed to establish such standards of identity for any food whenever it finds it will "promote honesty and fair dealing in the interest of consumers" to do so.

The industries represented on the Dairy Industry Committee have at no time opposed the establishing of these Federal standards of identity, and with reference to certain products, it has been industry which has proposed that they be established.

With this brief recital of the facts concerning the nature of the "factories" to be inspected and the nature of the dairy products manufactured therein, let us now turn to the inspection itself.

Under existing law the inspector is authorized to see and examine the factory structure and all of the machinery and equipment. He will inspect all of these physical facilities in operation. He will examine them from the viewpoint of sanitation and from the viewpoint of effect of design and fabrication upon sanitation. But, as pointed out above, the highest possible standards for these things are traditional in the dairy products industries, and there is apt to be no problem. In any event, he is completely at liberty to see for himself.

And so the inspection proceeds to what section 704 refers to as "finished and unfinished materials," meaning, of course, the finished dairy product being manufactured and the ingredients being used in the product. This is not difficult. As pointed out above, the Food and Drug Administration already knows the permissible formulations for almost all of these dairy products. There is nothing esoteric about them. If the inspector wishes to determine whether the ingredients are for any reason objectionable, he may take samples and have them analyzed by FDA's laboratory scientists. And if he wishes to determine whether the composition of the finished product is within the permissible formulation established by the standard of identity, again he may take samples and have them subjected to laboratory analysis.

Dairy products, like practically all other food products except fresh fruits and vegetables, are packaged, and so the inspector will want to know about the containers. These may be either cartons, cans, drums, or glass bottles. Here again the subjects of the inspection are at hand and available for sampling and analysis. FDA has already made studies of the materials used in cartons and has not, so far as we know and believe, been hampered in any way by lack of inspection authority.

The inspection thus far has had to do with FDA's responsibility to insure that foods shipped in interstate commerce and not adulterated. But it is responsible also for insuring that goods shipped in interstate commerce are not misbranded. And so, the inspector will want to see all of the labeling materials used on these food products, and under the provisions of section 704 he is entitled to.

It may be added that the inspector is assisted in making his inspection of labeling by the fact that section 403 of the present act requires that the labels of foods for which there are Federal standards of identity shall bear the names of all those optional ingredients which FDA shall require in its standards and also requires that the labeling of all fabricated foods for which there are not Federal standards of identity shall bear the names of all ingredients.

Finally, if the inspector should find adulteration or misbranding, and if it becomes necessary for FDA to resort to compulsory action, there is existing authority for obtaining evidence of interstate shipment in order to establish Federal jurisdiction. We have in mind two kinds of authority. The first is the specific authority contained in section 703 of the act whereby FDA may demand shipping records, for use in civil proceedings, not only from carriers but also from persons receiving or holding the products in question. The second is the gen-

eral authority of orderly and time-honored court process whereby FDA may secure shipping records for use in criminal prosecutions.

We believe that a fair-minded assessment of the existing authority for factory inspection would result in the conclusion: The Food and Drug Administration needs and should have the authority it now has, but such authority is adequate for its needs and requires no "strengthening" or extension. We believe that the kind of factory inspection described above is at once reasonable and efficacious.

In expressing these convictions, we remind the chairman and members of the committee that we are speaking only of food establishments and of dairy products plants more particularly. The Dairy Industry Committee takes no position with reference to any alleged need for greater authority to inspect drugmaking establishments but wishes to point out that the two situations may not be identical or even necessarily parallel.

The convictions we have expressed are, we believe, in complete agreement with the conclusions reached by this committee in 1953. This committee was willing to report favorably on the compulsory inspection bill only because it stopped at factory inspection and did not authorize what we have called business records inspection. Yet the Food and Drug Administration now insists that it needs and must have authority to inspect the manufacturers' own files, papers, and records. The only limitation is that these files, papers, and records should be those bearing upon adulteration or misbranding "or otherwise bearing on violations or *potential* violations of this Act." [Emphasis supplied.]

The breathtaking sweep of this unprecedented request for power must assuredly impose a heavy burden of proof upon its proponents. It would be assumed that in order to feel justified in even presenting such a request, its proponents would point out either a shocking deterioration in the safety of our food supplies or else the happening since 1953 of events auguring the same for the future. Yet the proponents of title II have not even attempted to do the former and have not succeeded in doing the latter.

As to the present state of our food supplies, an official of the Food and Drug Administration has only recently reiterated the statement several times before made by others that they are the purest, safest, and most nutritious in the world. The lack of the additional authority which the Food and Drug Administration requests has not thus far caused any deterioration.

And so we look at the record made before this committee bearing upon the possible need for additional authority to prevent such deterioration from this time on.

Secretary Ribicoff stated on June 19:

> All too often inspectors are treated to a guided tour through the establishment. They are denied access to formula files, complaint files, shipping records, and a great deal more information that is absolutely essential for them to see in order to determine whether the products are being produced in compliance with law.

If it is true that as a result of their submitting to "guided tours" inspectors are failing to ascertain the required information concerning possible adulteration or misbranding, it would seem that they are not doing their duty. What is required in this situation is not more authority but more exercise of the authority which already exists.

Frankly we do not believe there are many inspectors who are submitting to "guided tours" as we understand that term to have been used.

As to the Secretary's statement that it is absolutely necessary for inspectors to see the manufacturer's formula files, complaint files, and shipping records in order to determine whether the products are being produced in compliance with law, we can only say that we are in respectful disagreement. We believe that the factory inspection which we have just delineated is quite adequate to make this determination, and there can be no doubt that for such an inspection there is ample existing authority every step of the way. The Food and Drug Administration is doing very well indeed with the inspection authority it already has, and we see not only no absolute necessity but no necessity at all for this requested authority to examine private business records.

But, says the Secretary, the times have changed, and recent enactments of the Congress have made it necessary that FDA have the authority to inspect business records if it is to discharge the responsibilities those enactments have imposed upon it. He says—

> We are required to establish and police safe tolerances for known poisons in our food supply * * *. Yet we are being denied access to the information in the manufacturing establishment to tell us whether our tolerances are being met.

The Secretary is here speaking primarily of the Food Additives Amendment of 1958.

This is indeed an important piece of legislation, though we are not sure that the use of the scare word "poisons" contributes to a dispassionate assessment of its purpose and effect. It is also legislation that adds to FDA's responsibilities, but we are unable to see that these are responsibilities which require that FDA be authorized to inspect private business records. In fact, insofar as any additional means are required to police this legislation, the food additives amendment itself supplies them.

The principal purpose of the food additives amendment, as this committee knows, is to require that these additives, before being used by the food manufacturer, shall be subjected to rigorous testing to ascertain whether there are levels at which they may be safely used and to require FDA to determine such levels. In enacting the amendment, which has now been incorporated into the act as section 409, Congress took precautionary measures.

For example, it prescribed that FDA shall not permit any use of the additive in question unless it finds—

> that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe.

Congress has prescribed also that no tolerance shall be fixed at a level higher than FDA—

> finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended.

Congress has further prescribed that FDA shall not only fix the maximum quantity of the additive that may safely be used or permitted to remain in or on the food, but also may determine the manner in which the additive may be added to or used in or on the food and may prescribe any directions or other labeling or packaging requirements for the additive as it deems necessary to assure safety of use.

Those are all excellent safeguards, but they go only to the fixing of safe tolerances, and Congress was concerned that those tolerances should not be exceeded in actual use. So it provided that every petition filed with FDA proposing the fixing of a tolerance and the issuance of a regulation must contain, in addition to many other kinds of information—

a description of practical methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use.

Here, then, is the way Congress, and presumably FDA itself in 1958 intended that FDA should ascertain whether tolerances are being observed. It required that practicable methods be supplied by which FDA can make these determinations. We think it is a good way. The FDA inspector can take his samples of the food in which the additive is used, and the FDA laboratory scientists, using these practicable methods or any others they may prefer, can subject them to analysis and easily ascertain the amount of the additive left in or on the food.

FDA itself, in enforcement regulations promulgated under section 409 of the act, has enlarged the statutory requirement that practicable methods be supplied by the petitioner. These regulations require that—

The test proposed shall be one that can be used for food control purposes and that can be applied with consistent results by any properly equipped and trained laboratory personnel (21 CFR, sec. 121.51(c)).

The statutory requirement is contained, along with other requirements for the petition, in section 409(b) of the act, and in this connection FDA's enforcement regulation states:

A petition shall be retained but shall not be filed if any of the data prescribed by section 409(b) of the act are lacking or are not set forth so as to be readily understood (21 CFR, sec. 121.51(g)).

FDA has enforced this requirement quite strictly and has in fact refused even to file a petition in which a practicable method of analysis, satisfactory to it, is not set out.

We believe and submit that analysis is the only method by which it can be determined whether tolerances are being complied with. This is true both as a practical matter and as a question of the rules of evidence. Existing law makes ample provision for such analysis, and the requested authority to inspect files and records for this purpose is wholly unnecessary.

It should not be overlooked that additives are components of foods and that the supplies of these substances in the food plant are readily available for inspection as such, as is also the process by which the additives are introduced.

In concluding this portion of our statement, having to do with the adequacy of existing factory inspection authority and the absence of any necessity for authority to inspect the manufacturers' private business papers and records, we should be remiss if we did not remind this committee that insofar as the responsibility for assuring the safety of our country' food supplies is a responsibility of government, it is one which the Federal Government shares with the governments of the several States and with municipal governments.

You may be sure that States and municipalities are not unmindful of their responsibilities in this area of the law. Pure food is the subject of legislation in every State and in hundreds of municipalities, and, as dairy products manufacturers may be more keenly aware than any other category of food manufacturers or processors, it is not only the Federal Government which knows about inspection as a means of enforcement.

PROPOSED BUSINESS RECORDS INSPECTION IS UNWISE

The second reason for the opposition of the Dairy Industry Committee to title II of H.R. 11581 is that the legislation it proposes would be not only unnecessary but also unwise.

This proposed legislation would affect a very large segment of our industrial economy, and your committee always desirous of avoiding unwise measures, would doubtless be especially desirous of avoiding the endorsement of unwise measures when they are of broad application.

We believe title II unwise, first, because we entertain grave doubts as to its constitutionality. Others who have preceded us in presenting their objections to title II have treated ably and elaborately of this most important one, and for this reason it is unnecessary for us to discuss it. We do request, however, that the chairman and members of this committe give their most earnest consideration to the question of how the provisions of title II can be reconciled with the prohibitions of unreasonable searches contained in the fourth amendment. In our view the inspection of the manufacturers' private files and records which title II would authorize is in fact a most thoroughly unreasonable search, and we should anticipate that title II, if enacted, would fall in its first judicial encounter.

But, aside from this hazard, and even if, contrary to our expectations, title II should survive constitutional attacks, it would still be unwise because it sanctions an erosion of rights which have been enjoyed since the founding of our country. Title II says to the thousands of foods establishments throughout our country to which it applies, your books, records, files, and papers are subject to search, without benefit of warrant, by the employees of an administrative agency of the Government, and this search is subject only to the limitation that it shall bear upon possible adulteration or misbranding or that it shall otherwise bear on violations or potential violations of this act. We can only say that constitutional or unconstitutional, this represents a shocking departure from what has heretofore been regarded as the proper function of Government as we know it.

We believe title II to be unwise, in the second place, because it is unworkable and will not accomplish its purpose.

Any realistic appraisal of the value of this proposal to authorize files and records inspection must take into account the fact that there are some dishonest food processors along with the great majority of honest ones. Cognizance must be taken, too, of the fact that, as the Secretary has pointed out, there are a few fly-by-night operators in food industries as well as a great multitude of established and responsible businessmen.

We respectfully submit that there is a relationship between these facts on the one hand and the facts surrounding food processing and recordkeeping on the other hand. We believe it may be asserted that as a general rule it will be only these very small minorities who would intentionally engage in adulteration, either by the use of impure ingredients or by the use of food additives in amounts excessive of established tolerances. We believe, also, that as a general rule those who would engage in intentional adulteration of their products would not hesitate to engage also, so to speak, in adulteration of their files and records. In short, it is almost inconceivable to us that the FDA inspector would ever find the actual facts reflected in the files and records of such manufacturers.

Correlatively, we respectfully submit that the consumer has nothing to fear from the great majority of honest and established manufacturers. We have pointed out above that the responsibility of the Federal Government for safe food supplies is shared with State and municipal governments. It is shared also with the foods manufacturing industry.

The stake of the foods industry in marketing pure and healthful products is a large one. Historically, the record of the foods industry is not only honorable but highly commendable, and pride exists in industry as in other activities of American life. The history of the dairy products industry, especially, has been quite outstanding. It has been a history characterized not only by a significant and long-continued contribution to the national health but also by a quite negligible incidence of illnesses caused by products that were in any way impure or contaminated.

But aside from such considerations as these, there are impelling factors of self-interest involved in the food industry's responsibility for a safe food supply. All food manufacturers know that the consumer is increasingly aware of product liability. And from the long-term viewpoint, no manufacturer can hope to stay in business if he gains a bad reputation. The authority of FDA under section 705 "Publicity" can, of course, have a great deal to do with this.

In summary, we submit that files and records inspection would not produce the kind of information which its endorsers say it would. It would not produce evidence of adulteration, actual or potential. It would not operate against the sharp dealer and the fly-by-night operator. It would not accomplish its purpose. We sincerely believe that better results would be obtained if the time and expense which files and records inspection would entail were applied to the reasonable factory inspection for which existing law provides.

In the third place, title II is unwise because it would increase the already great disparity between the control exercised by the Food and Drug Administration over foods manufactured in the United States and foods manufactured in foreign countries and imported into the United States. One has only to visit the supermarket to see that foods of foreign manufacture are being imported in large and increasing volume.

Section 801 of the act provides that with reference to any such food (or drug or cosmetic), the Secretary of Health, Education, and Welfare may, upon request to the Secretary of the Treasury, secure a sample of the same. If, from "examination" of this sample, it ap-

pears that the product is adulterated or misbranded, it may be excluded from the United States unless the consignee causes it to be brought into compliance with law.

But this "examination," if it occurs, and however it is performed, is the only means by which the Federal Government may exercise jurisdiction over this product. Obviously the FDA has no authority whatever to inspect the foreign establishment in which this food product was manufactured, and it would appear to be beyond the power of Congress to give it such authority. Accordingly, there is, and can be, no foreign factory inspection by FDA's inspectors.

This is quite different from the authority exercised over the manufacture of food products in the United States, where the FDA inspector is authorized to inspect plant, operations, processing, and ingredients, as well as the finished product. In short, FDA knows the conditions under which food products are manufactured in the United States. It does not know the conditions under which foods imported into the United States are manufactured.

Yet, title II of H.R. 11581 substantially broadens this conspicuous gap. It says that while foreign food products are admitted without even factory inspection, American food products must be subjected not only to factory inspection but also to private records and files inspection.

We reiterate: This is unwise.

We are not arguing against the import of food products into the United States. We know that it is necessary to import in order to export. But we do urge that this inequality of control over American and foreign food products has gone far enough. Let us not increase it by authorizing the inspection of the records and files of American businesses.

The CHAIRMAN. Does that conclude your statement, Mr. Habberton?

Mr. HABBERTON. It does, Mr. Chairman.

The CHAIRMAN. We appreciate having your views on behalf of the dairy industry.

I am also aware of the fact that the canners have expressed a great deal of concern over the extension of the factory inspection provision.

I had not realized that there would be so much concern among the dairy industry, because I did not think it was involved with formulas and things of that kind.

I do know that there are some very stringent local requirements insofar as the dairy industry is concerned. I imagine in certain types of dairy products there could be some great concern, such as butter, probably, but, generally, I cannot see how it would be of great concern, as it would with a lot of other food products.

I know the industry generally, and I can appreciate that it does not want the Government delving around in their records any more than they could help.

Mr. HABBERTON. Yes, sir.

The CHAIRMAN. That is a basic concept in this country, and I am wholeheartedly in favor of it.

But we do recognize that there are, as you said in the statement, certain areas in which it is necessary. Our society has grown to the

extent that when our needs are provided, certain protections must be also provided for.

What serious objection would your industry advance to keep those who are charged with this responsibility from looking at the complaint files?

Mr. HABBERTON. Well, sir, in the first place, let me say that the dairy industry has great confidence in its products. It has no apologies to make for its products. It has had a long and splendid history of producing healthful and pure products.

The CHAIRMAN. Well, we know all of that, and we agree with it.

Mr. HABBERTON. Yes, sir.

The CHAIRMAN. And if it were not for these few you spoke of a while ago, it would not be necessary to have any.

Mr. HABBERTON. Yes.

The CHAIRMAN. So now let us get down to the basic facts of what we are considering.

Why would there be any objection to it?

Mr. HABBERTON. Well, sir, complaint files generally consist of what is sometimes referred to as raw information.

It has to do with complaints which may concern any one of a large number of things. Some of them may have no connection whatever with the purity of the product or the sanitation of the plant or anything else.

Complaints are received many times from people referred to, correctly or incorrectly, as crackpots.

The CHAIRMAN. I am not talking about complaints generally or whether or not Sam Jones might be a good man or he wears one short-leg pants and a long-leg pants.

I am talking about complaints with reference to a dairy product as to whether or not it is adulterated or misbranded or in violation.

Mr. HABBERTON. Well, we think I would be unfair to the dairy industry for the inspectors to have these complaint files because they are not reliable information. It is unsifted information.

The CHAIRMAN. Well, they are the same kind of information that goes into the Food and Drug Administration, generally speaking, or that comes to a congressional office or some other place, is it not?

Mr. HABBERTON. I do not believe it is, sir; and I think, furthermore, that this is information which FDA can get by other means.

If they have reason to think that anything is wrong, there are certainly established means under the existing law by which they can get this information, without going into complaint files which have always been regarded as the private property of the manufacturer.

It would not produce reliable information for them.

The CHAIRMAN. It would seem to me, insofar as the industry is concerned, that you would want those kind of communications to be seen and then be able to show the inspectors where they are wrong, or, if there is any substance to it, where it has been corrected.

There seems to be a practical situation insofar as industry is concerned that must be met, instead of taking an absolutely negative position on everything.

Mr. Younger?

Mr. YOUNGER. If the complaint files are to be made available, then the complimentary files ought to be made available, also, should they not?

Mr. HABBERTON. I believe that is right, sir.

The CHAIRMAN. Will the gentleman yield?

Mr. YOUNGER. Yes, sir.

The CHAIRMAN. You do not hesitate to make those available, though, do you?

Mr. HABBERTON. Right.

Mr. YOUNGER. They are not called for in the bill.

On page 3, where you say "records, files, papers, controls, and facilities," do you interpret that to mean formulas also?

Mr. HABBERTON. Yes, sir, I certainly do. Undoubtedly, it would include formula files.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. HABBERTON. Formula files that are the principal source of trade secrets.

The CHAIRMAN. Mr. Glenn?

Mr. GLENN. Sir, I take it, then, that your only objection is to the inclusion in the bill on page 31 of the words "including records, files, papers, processes, controls, and facilities"?

Mr. HABBERTON. That is our principal objection, sir.

Mr. GLENN. And if that is deleted, you will be happy?

Mr. HABBERTON. Well, we object also to the extension of this inspection to laboratories which may be employed by food manufacturers to engage in research and experimentation for them.

We think that is a very vicious provision.

Mr. GLENN. Did you cover that in your statement?

Mr. HABBERTON. I had not said anything specifically on the subject, but we believe that there is certainly a highly confidential relationship between the food manufacturer and the scientific laboratory which it employs to engage in scientific research and experimentation for it.

This work has to do with the products which may be in the very beginning, products which are brandnew, products which are only in process and which have never been manufactured or marketed, and which may never actually be commercially marketed.

This is certainly highly confidential information between the food manufacturer and the scientific laboratory, and we think that it would be a great mistake and distinctly harmful to the food industry and to industry in general for this information to be made available to the FDA inspector.

Mr. GLENN. Thank you very much.

That is all, Mr. Chairman.

The CHAIRMAN. Mr. Hemphill?

Mr. HEMPHILL. Thank you.

I have one question here.

On page 4 you make a statement in the last paragraph:

> The general formulations for all of these dairy products are well known to the Food and Drug Administration.

Does that mean that any formula that you have or use in connection with the industry is known now?

Mr. HABBERTON. Mr. Congressman, those are formulations which are provided for in the Federal standards of identity. There are Federal standards of identity for practically all dairy products, and these are standards of identity which have been promulgated by FDA itself and, in the case of two dairy products, butter and nonfat dry

milk, standards of identity have actually been prescribed by the Congress in legislation.

So that for all of these food products, there are standards of identity, and obviously, they are well known to FDA, which has promulgated them.

Mr. HEMPHILL. But not necessarily standards telling the exact proportions?

Mr. HABBERTON. No, sir.

Mr. HEMPHILL. Or the manner in which they are put together?

Mr. HABBERTON. We think that would involve a great many trade secrets.

Mr. HEMPHILL. That is like Coca-Cola or Pepsi-Cola or something like that; you have the same problem?

Mr. HABBERTON. Yes, sir.

Mr. HEMPHILL. I would suspect, because I have such admiration for the dairy industry, that you people would want to make certain that your products continue to have the highest cleanliness and also food value, would you not?

Mr. HABBERTON. Indeed, we would, sir.

Mr. HEMPHILL. But your objection is to giving access to the books and records?

Mr. HABBERTON. Those, we believe, are the private property of the manufacturer, and in the case of the precise formulations, we think that those clearly involve trade secrets. They are valuable to the manufacturer.

It may be a formula which the manufacturer has developed over a long period of years. He probably thinks it is the very best product that can be manufactured, and he does not want other manufacturers, does not want the public, in general, nor does he want FDA, to know what the exact formulation is.

Mr. HEMPHILL. Suppose the language in the legislation were amended to protect the trade secrets except in those instances where there was some proof first that there was some injurious quality, not just a suspicion, but some fact of injury or harm.

You would not have any objection under those circumstances, would you?

Mr. HABBERTON. Well, sir, we think there is still a great deal of danger from inadvertent disclosure of information of this kind.

It seems to be very difficult to confine it to the manufacturer's files, once the files are open to anybody, whether it is a Government inspector or anyone else.

Mr. HEMPHILL. I understand that, but there are some people, of course, who see danger in everything the Government does, and, yet, those people who write us about the Government are willing to ride in the ships across the ocean on high-priced vacations or take advantage of the subsidies to airlines or write us to help out the railroads or anything else.

It sort of depends on whose ox is gored in this business of the Government being dangerous, is that not about the fact of it?

Mr. HABBERTON. Yes, sir.

Mr. HEMPHILL. Thank you so much.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Sibal?

Mr. SIBAL. Mr. Chairman.

I would like to get into the purpose of the request for the right to make the inspection of records.

Mr. HABBERTON. Of what, sir?

Mr. SIBAL. The purpose behind this request.

I do not think anybody can seriously argue with you that it is not proper for the Government to get involved in trade secrets and things of that nature, but it does not seem to me that you can use this as an excuse to brush aside some of the pertinent aspects of records.

Is it your position that if, for example, Mr. Habberton, some evidence, not conclusive perhaps, of impropriety in the production of a particular product cannot be developed further by checking a complaint file to see if there has been a history of complaints about this product, which perhaps might form a pattern, is it your position that this is not relevant and should not be made available to an inspector; not trying to intimidate the industry or to in any way impose himself upon your management, but to find out simply if the public needs some additional protection.

Mr. HABBERTON. Well, sir, we think that this is information which FDA can easily get under its present authority; its authority to take samples of all of these food products, to take samples of all of the ingredients, to analyze them at any time, to do so repeatedly, can go into that just as deeply as it wishes to, and, by doing that, it is getting reliable scientific information as to whether there is any basis for the complaint.

We think that since this information can be gotten by FDA under existing authority, that its authority should not be extended into the realm of the private property, the private files of the manufacturer.

Mr. SIBAL. I want to say that I am well aware of the danger of giving additional inspection rights, particularly in the record field.

Mr. HABBERTON. Yes.

Mr. SIBAL. There have been many pieces of legislation, not only before this committee but before the Judiciary Committee of this Congress, where constant request for additional power which go beyond the traditional scope of Government investigating agencies have been requested, and I certainly agree that we have to be careful and have to watch this very carefully in order to protect basic rights.

But where we have public health as our purpose, it is very difficult for me, as the chairman indicated in his question, to understand why, if a particular product is under investigation, the whole area of public expression, including complaints to the manufacturer, should not be made available to the investigating authorities.

Mr. HABBERTON. Oh, sir, if FDA is actually conducting an investigation of a particular product, in the course of that investigation it can get a warrant and get all of this information.

Mr. SIBAL. It has to go to court.

Mr. HABBERTON. It has that authority under existing law.

Mr. SIBAL. It has to get that warrant through a court process.

Mr. HABBERTON. Yes, sir.

Mr. SIBAL. Do you think it should be required to go to court for that?

Mr. HABBERTON. I think that it should when it is going into private files.

I may add to that that complaints, if they are a matter of interest to FDA, are certainly no less a matter of interest to industry itself.

Certainly the food industry does not want to have dissatisfied customers, whether there is some basis for their complaint or not.

Every complaint which is received, I am sure, by a dairy products manufacturer is considered.

An effort is made to try to determine whether there is some basis for it, and if it should develop that there were some basis for the complaint, naturally, the food industry itself would be the first to want to take any remedial action that might be necessary, because its own self-interest is so closely tied up with matters of that kind.

Mr. SIBAL. Are you not really saying that if you follow your statement through to its logical conclusion, you come to the conclusion there should be no Government inspection; that the food industry would take care of itself?

Mr. HABBERTON. Oh, no, sir, I do not take that position at all.

We think that FDA should have this broad authority which it has to inspect right now, this authority to come into the factory, to look at everything in the factory, to see the entire manufacturing process, to take samples of the food and all the ingredients, to make analyses.

That is a very broad inspection authority, we think, and we think FDA should have it.

We think it should have it by all means, because in the case of these people whom the Secretary referred to as fly-by-night operators, if they are using improper ingredients, certainly FDA ought to know it, and the way for them to learn it is by coming in and taking samples of the ingredients in the foods and conducting their own analyses.

That is the very kind of authority, it seems to us, which will result in FDA's getting the information that it needs and which it must have as a basis for prosecutions.

Mr. SIBAL. So it boils down to the fact, does it not, that if a given person makes a complaint to the FDA, then this complaint is a proper part of the investigation?

Mr. HABBERTON. I think it would be.

Mr. SIBAL. But if the complaint is made to the company, it is not?

Mr. HABBERTON. Well, I think that in either event it is a matter which ought to be pursued by court process rather than by broad, sweeping authority to a Federal inspector to come in and look at all of the plant's files and records.

Mr. SIBAL. Do you think it is possible perhaps to limit this right in some way to strengthen the requested authority of the FDA without opening this door, which I want to make clear I fully understand and am in sympathy with?

Mr. HABBERTON. Yes, I appreciate your position, but I frankly do not believe that it would. I do not believe that it would be possible to limit this additional authority in such a way that it would be satisfactory to FDA and still, in our opinion, still have a constitutional inspection statute.

Mr. SIBAL. Has any discussion been held between the industry and the Food and Drug Administration in this area?

Mr. HABBERTON. There has been discussion, yes, sir; there has.

It has not assumed any definite planning or anything of that kind. There has been incidental discussion. But we believe that if this in-

spection provision were to go beyond its present scope and purpose, that it would infringe upon constitutional guarantees.

Mr. SIBAL. Just one additional question.

Has Secretary Celebrezze expressed himself in this area since he has assumed office?

Mr. HABBERTON. I do not believe that he has made any public expression of his own views, on this. If so, it has not come to my attention.

Mr. SIBAL. So when you refer to the Secretary, you refer to his predecessor?

Mr. HABBERTON. Right, sir.

Mr. SIBAL. Thank you.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Yes, Mr. Chairman. I had a number of questions I wanted to ask the witness, if I might.

You referred to specific power in the Food and Drug Administration to secure information, books, records, and so forth.

You referred to section 703 whereby the FDA may demand shipping records for use in civil proceedings.

Now, does this section deal only with shipping records or is it more broad?

Mr. HABBERTON. It has to do primarily with shipping records.

Mr. DINGELL. I see, with shipping records.

Does it have to do with anything besides shipping records?

Mr. HABBERTON. Not so far as a specific grant of authority is concerned.

Mr. DINGELL. So it has authority to get shipping records only through civil proceedings.

Now, what kind of civil proceedings may it secure these shipping records it, in cases involving seizures, in cases involving misbranding, or in cases involving what?

Mr. HABBERTON. It can get this shipping information without there being any proceeding pending at all.

Mr. DINGELL. Just on shipping?

Mr. HABBERTON. That is right; yes, sir.

Mr. DINGELL. Shipping information as to what, volumes and quantities shipped?

Mr. HABBERTON. And who is the shipper.

Mr. DINGELL. And who is the recipient?

Mr. HABBERTON. Who is the recipient or consignee, and then FDA can take that information and institute a proceeding based upon the information gotten under 703.

Mr. DINGELL. These shipping records to which you refer are solely records of quantities shipped, persons doing the actual shipping and receiving, is that correct?

Mr. HABBERTON. Yes, sir; that is correct.

Mr. DINGELL. And they are no more broad, the shipping records provision is no more broad than that, am I correct?

Mr. HABBERTON. I think that is correct, sir.

Mr. DINGELL. So that, in a sense, then, is a very limited power that the Food and Drug Administration has, is that correct?

Mr. HABBERTON. We think it is a very broad power.

Mr. DINGELL. As a matter of fact, section 703 here says:

For purposes of enforcing provisions of this act carriers engaged in interstate commerce and persons receiving food and drugs—

and so forth—

food, drugs, devices or cosmetics in interstate commerce or holding such articles so received shall, upon the request of an officer or employee, duly designated by the Secretary, permit such officer or employee at reasonable times to have access to and to copy all records showing movement in interstate commerce of any food, drug, device or the holding thereof during shipment and the quantity, shipper, consignee thereof.

So this is the only power Food and Drug has to actually look at the bills of lading, is that not correct?

Mr. HABBERTON. That would be the thing they would look at first, I would think.

Mr. DINGELL. But that is actually all they really have the right to do, look at bills of lading, shipping documents and so forth?

Mr. HABBERTON. It enables FDA to make out a case in interstate commerce, and it has complete jurisdiction over the matter, so it is a broad power.

Mr. DINGELL. This only establishes jurisdiction. This section does not in any way apply to the contents of the goods, the food additives used, pesticide chemicals used, the manner of treatment of the commodity in transit, rather the amount of treatment of the commodity as it is manufactured; am I correct; or the way in which it is treated?

Mr. HABBERTON. After it gets this information under 703, it may then seize the food product, if it wishes to do so.

Mr. DINGELL. Now, on what basis can FDA seize, then, this particular commodity?

Mr. HABBERTON. Because it has a right to inspect all food products.

Mr. DINGELL. It has a right to inspect food products. This is exactly it.

Then on the basis of this the Food and Drug Administration has got to go in and has got to take samples; am I correct?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. This is the limit of their actual power to reach and to investigate the kinds of additives, whether the food or drug is contaminated, dangerous, or unsafe, whether it has claims made for it which are in excess of fact.

This is the limit of the powers of the Food and Drug to actually determine these things, is to go in and take samples and make laboratory analyses; am I correct?

This is the only power Food and Drug actually has concerning what goes into that food, the nature of the food, whether it is clean, wholesome, contaminated, whether it happens to have an excessive amount of chemical additives, whether it happens to have disallowed chemical additives, whether it happens to be unsafe or contaminated, dirty, filthy, or adulterated; is this not correct?

Mr. HABBERTON. You mean it is the authority that they have after it leaves the factory.

Of course, it can do all of these things while the process is going on.

Mr. DINGELL. While it is in the factory by going in and taking samples and then taking them off to have them analyzed; is that not correct?

All right; now, they have general authority to secure shipping records for use in criminal prosecutions; is that not correct?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. This authority in criminal prosecutions is limited solely to securing shipping records?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Am I correct?

So, in effect, the only real authority they have to determine what goes into the food, the nature of the food or the nature of the chemical or medicine is the power that they have to make a chemical analysis of the food; is that not correct?

Mr. HABBERTON. Well, sir, let me go back to——

Mr. DINGELL. The only authority they have, according to your testimony, is to make a chemical analysis of the food.

This is the only statutory authority the Food and Drug has is to actually make a chemical analysis of the food; is this not right?

Mr. HABBERTON. No, sir; it is not because many times no analysis at all is necessary.

It may be quite evident merely by visual inspection of the product that it is contaminated or deteriorated and analysis would not even be necessary.

Mr. DINGELL. Let us concede that this is true. But there are large numbers of additives present in minute amounts in food today which are very difficult to determine by other than very complicated chemical analysis?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Involving a great deal of time?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. Involving a great deal of skill.

In some instances on the order of a few parts per billion; is this not correct.

Mr. HABBERTON. I believe there are no tolerances expressed in terms of parts per billion. There are, of course, many expressed in terms of parts per million. And as pointed out in our prepared statement, FDA can enforce each of these tolerances by use of the practicable method of analysis approved by it at the time it established the tolerance.

Mr. DINGELL. So you propose to continue limiting the Food and Drug Administration to the power to analyze on the basis of a batch-by-batch and a sample-by-sample basis through very complicated, analytical, chemical procedures, and based on an investigation-by-investigation basis.

As a matter of fact, your objection lies to the fact that Food and Drug could, if this bill is passed, go in, look at laboratory records to determine what the company's own records say with regard to manufacturing practices, with regard to quantity and types of additives; is this not correct?

This is your objection to permitting the Food and Drug to go in and to do these?

Mr. HABBERTON. It is one of our objections.

Mr. DINGELL. This is your principal objection, as I read your statement.

Mr. HABBERTON. We object to it on many grounds, as pointed out in our prepared statement.

Mr. DINGELL. I see.

Well, what are your other grounds? What are your other grounds of objection?

Mr. HABBERTON. Well, sir, we object to the extension of this authority to all kinds of books and records, not just merely to formulations.

Mr. DINGELL. Supposing we were to limit it to books and records dealing with manufacturing. Would this eliminate your objection?

Mr. HABBERTON. Dealing with manufacturing?

Mr. DINGELL. Yes.

Manufacturing, the quantity, quality, and types of additives and dealing with the nature and the character of the foods. Am I correct? Would you object to this?

Mr. HABBERTON. I do not know just what would be included within the term "manufacturing."

Mr. DINGELL. I yield to my colleague from California.

Mr. MOSS. It just would seem to me at that point that formulas, controls, ingredients actually received and used certainly would be records bearing directly upon manufacture.

Mr. DINGELL. If we limit it to records bearing on manufacture, do you have any objection, then?

Mr. HABBERTON. We still think that it is an unwarranted and unnecessary extension.

Mr. DINGELL. Very well.

Let us take a look at this, then.

You tell us that this is an unwarranted extension. The present power of the Food and Drug entitles them to station an inspector upon the premises; is that not right?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. To conduct a continuing chemical analysis; is this not correct?

Mr. HABBERTON. He can stay here as long as he wishes to.

Mr. DINGELL. And to scrutinize the exact processes?

Mr. HABBERTON. Yes, sir.

Mr. DINGELL. But he has no power to determine what has taken place previous to the time he enters the scene or what is needed to protect the American people from contaminated and adulterated lots that may have proceeded through; is this not correct?

Mr. HABBERTON. No, sir, I do not think it is.

Mr. DINGELL. The only power he has is with reference to lots that have already gone through—interstate seizure—is that not correct?

Mr. HABBERTON. He is charged with the protection——

Mr. DINGELL. I know he is charged, but he does not have any power to do more than this.

Mr. HABBERTON. No, sir; that is not correct.

Mr. DINGELL. I recognize he is charged, but he does not have any more power than this.

Mr. HABBERTON. I think he does have the power; I think he has the authority.

Mr. DINGELL. You told me his power is limited to seizing of records to show that the shipments are in interstate commerce.

Mr. HABBERTON. That is what he has as a result of section 703.

Mr. DINGELL. Then he has the power of taking a batch-by-batch basis to make chemical analysis to determine residues that are present, chemical additives, amount of them, and so forth.

This may take a substantial period of time, may it not?

Mr. HABBERTON. Yes.

Mr. DINGELL. So, in effect, what you object to really is to workable factory inspection.

Mr. HABBERTON. Oh, well, we think they have workable factory inspection right now. We think that is exactly what FDA has under the present law.

Mr. DINGELL. As to the factory but not as to the records which would show what exactly goes into the food?

Mr. HABBERTON. Well, it can do better than that under the present law.

It can do better than have the records.

It can follow the food itself. The record would not, as one lawyer to another, sir—the record would not be the best evidence as to a violation. It would be the food product itself which would show the actual contamination or adulteration.

Mr. DINGELL. I recognize this, but the records would make it a great deal easier to prove contamination or to prove unsafe additives, would they not?

Mr. HABBERTON. I do not believe they would, sir.

Mr. DINGELL. It would make it a great deal easier for the Food and Drug Administration to determine whether or not there is an improper additive or contaminant present in the food, would it not?

Mr. HABBERTON. Mr. Dingell, I do not believe for a minute, I just do not believe for a minute that if a sharp operator, a fly-by-night operator, is going to exceed these tolerances, if he is going to adulterate, I do not believe he would ever in the world put those things in his records and files.

Mr. DINGELL. You do not think so?

Mr. HABBERTON. I do not think they would ever appear in his formula files.

Mr. DINGELL. But your opposition to factory inspection would make it a great deal easier for him to do so if he were inclined to, would it not?

Mr. HABBERTON. I think——

Mr. DINGELL. Your opposition to really worthwhile factory inspection would make it a great deal easier for him to have records involving contamination and unsafe manufacturing practices if he were of a mind to keep that kind of records, would it not?

Mr. HABBERTON. If he wanted to keep adulterated records?

Mr. DINGELL. I am not talking about adulterated records. I am talking about factual records of adulterated, unsafe foods, drugs, or cosmetics.

Mr. MOSS. Would you yield?

Mr. DINGELL. Let me finish this one question, and I would be happy to yield.

Is this not a fact?

Mr. HABBERTON. No, I do not think it is.

Mr. DINGELL. You do not think it is easier for him to do this?

The CHAIRMAN. I think you ought to let the witness answer, Mr. Dingell. And, furthermore, you have got 17 or 18 pages of his opposition.

Mr. DINGELL. I recognize this, Mr. Chairman.

The CHAIRMAN. If you want to set aside some half day to sit down and argue this, I will be glad to do that.

Mr. DINGELL. I do not want to do that, Mr. Chairman. I just want to scrutinize very carefully his position.

The CHAIRMAN. If you read the 17 pages, I think you will scrutinize his position.

Mr. DINGELL. I have done so, Mr. Chairman.

Mr. MOSS. In the press during this past week I have been interested in noting a case where it would appear that not fly-by-night operators, but an entire segment of the food industry is at least alleged to have, within the meaning of law, adulterated or misbranded its product, and I am referring to the macaroni or pastry.

Mr. FRIEDEL. A little louder, please.

Mr. MOSS. I am referring to the stories now currently being printed about the macaroni or pastry industry where, because of the price of certain ingredients normally used, there has been a substitution.

Now, that is alleged to have occurred.

I have no knowledge other than what I have read in the papers.

But on this product under these conditions I believe that the records of purchase would be the most reliable records on which to form a judgment as to whether or not the misbranding or adulteration has occurred. This is, as I point out, not alleged to have been the action of fly-by-night operators, but, rather, of a very large and responsible segment of the food industry.

So we cannot always, in looking at these provisions, say that they would only be used or it would only be necessary to use them in connection with the fly-by-night, the unstable in-and-outer of the industry.

It could occur. I recall reading in Washington a few years ago of a major processor being charged with certain somewhat similar practices in the manufacture of certain meat products.

It is not too many years ago that I have a recollection, and, again, I am not going to cite names, of a processor in your industry, in the manufacture of certain types of cheese spreads, being charged with the same sort of misconduct, and much of this would be readily ascertainable from pertinent records on manufacture or on acquisition of ingredients.

Mr. DINGELL. Which are not available under present practices.

Mr. MOSS. That is correct.

The only way they get it now is, as you say, by having the inspector there sampling the batches, and through analysis determining this, so that it is a discovery on the spot, but difficult to check on any prior action before the arrival of the inspector.

I would point out that you, as an attorney here, representing your clients, have your responsibility to them. I think we, as representatives of a broader based clientele, have a responsibility to be concerned with the safety, the cleanliness, and the efficacy of the things that they buy, and that we cannot just erect barriers and say we go not beyond this.

We have to carefully evaluate the public interest and the public concern.

But there is a real need in some instances for the access to more records than the shipping records, which really disclose nothing but the consignee and the shipper and the route they travel, minimal records at best, to help you track down something which has been regarded as sufficiently adulterated to cause it to be confiscated.

Mr. DINGELL. I have one more question I would like to ask.

Mr. HABBERTON. I—may I just say a word about this, sir?

Mr. MOSS. Certainly.

Mr. HABBERTON. I think the very kind of information which you say would be gotten from the sales records can also be gotten under section 703 from the records in the hands of the carrier or in the hands of the consignee or holder of the food.

Mr. DINGELL. All that shows is the designation of the commodity——

Mr. MOSS. Let me ask you how that is achieved.

Mr. HABBERTON. After it is found who the shipper is and it is found who the consignee is or the holder is, it can then take the product and do whatever it wants to with it.

If it thinks it is contaminated, it can seize it right there and subject it to analysis.

Mr. MOSS. It might sometimes be a good idea to audit the records of such a manufacturer to determine what his practices have been, whether when he has had a questionable batch, he has shipped it out and gambled with the public health or whether he has pulled it back responsibly and destroyed it or cleaned it up.

Mr. DINGELL. Over and above this, you say that section 703 gives power.

Now, listen to the language of this section:

> For the purpose of enforcing provisions of this Act, carriers engaged in interstate commerce and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such article so received shall, upon request of an officer or an employee.

This is the people to whom this act applies. It does not say anything about processors or manufacturers. It says "carriers and persons receiving."

Mr. HABBERTON. Certainly.

Mr. DINGELL. Now, if the Food and Drug does not have the authority to find out who at the factory site, at the manufacturing point, does not have authority to look at books and records and this section does not give them any authority to look at books and records, the only way they get authority to look at books and records of a person who is operating under their inspection is by initiating a criminal prosecution against the individual, according to the other section that you have cited to us this morning.

So, for all intents and purposes, what you are telling us this morning is that there is no effective inspection of books and records by the Food and Drug on the site.

The section you cite is limited to "carriers and persons receiving." It does not have a word to say about the sender, the manufacturer.

Mr. HABBERTON. Oh, well, certainly——

Mr. DINGELL. I challenge you to tell me where in the section that is.

Mr. HABBERTON. Well, sir, it isn't necessary to challenge me. The purpose of my entire appearance here today is to object to this very thing that you are talking about.

Of course they do not have the authority to inspect files and records.

These suggested amendments would give them that authority, and we are very much opposed to it, and that is why I am here.

Of course, they do not have the authority.

Mr. DINGELL. What you are here, then, to tell this committee is that you, on behalf of your industry, oppose any effective inspection of books and records of manufacturers under the Food, Drug, and Cosmetic Act?

Mr. HABBERTON. We certainly do.

We certainly do oppose the extension of this authority to inspect private files and records. We are very much opposed to that.

Mr. DINGELL. Obviously you must have some reason for this. Have you had a bad experience with the Food and Drug Administration?

Mr. HABBERTON. No.

We have had a very satisfactory experience.

Mr. DINGELL. You have had a very satisfactory experience.

Have you found that in any way they abused the due process clause in their inspections or in their conduct of their relations with your industry?

Mr. HABBERTON. We think that, in general, they have been very circumspect.

Mr. DINGELL. I see.

And there is no reason to think if they get this legislation, they will be other than circumspect, or to continue precisely the same pattern of conduct, am I correct?

Mr. HABBERTON. I think they can act entirely within the letter of the law if these amendments are enacted and still be going far beyond what there is any need for doing, and I think also that if we go beyond the present type of inspection in our inspection provisions, we are getting into fields of unconstitutional enactments.

Mr. DINGELL. I see.

In effect, you are a little bit like the old maid who looked under the bed and sort of hoped she would find somebody was there, am I correct?

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. HABBERTON. Mr. Chairman, may I just say one further sentence on the matter of complaints.

I want to make it clear that manufacturers are interested in complaints. Every complaint that is received by food manufacturers is considered.

If it should happen, as has been suggested by one of the members, that there might be a series of complaints coming from one person, a series of complaints concerning a particular aspect of a product, a particular product, the manufacturer would be the most interested person of all in trying to see that every step was taken that could possibly be taken in order to correct anything that needed correction.

So we think that that is largely a self-policing matter.

The CHAIRMAN. Thank you very much.

Mr. HABBERTON. Thank you very much, sir.

(The following letter was subsequently received for inclusion at this point in the record:)

WASHINGTON, D.C., *August 23, 1962.*

In re H.R. 11581.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House Office Building, Washington, D.C.

DEAR CONGRESSMAN: On behalf of the Dairy Industry Committee, I had the privilege of appearing before the House Committee on Interstate and Foreign Commerce on August 22 in opposition to title II—the factory inspection provisions—of H.R. 11581.

As chairman of the committee, you expressed some surprise that the dairy products industries would be opposed to these provisions. I did not at the time fully understand the significance of your comment, and I fear that the explanation which I gave was accordingly not responsive.

I have since that time realized that you were probably thinking more of milk than of other dairy products and felt that such an unsophisticated food could not involve any file or record information which industry would not be glad for FDA inspectors to have access to at all times. It is of course a fact that in addition to milk itself, there are the basic derivatives, namely cream and skim milk in fluid, dried, frozen, or concentrated form, to which no ingredient is added. With respect to such products there obviously would be no formula files.

On the other hand, there are a very large number of dairy products which are fabricated from two or more ingredients and there are Federal standards of identity for practically all of them. Ice cream, for example, does contain numerous ingredients including stabilizers to inhibit the formation of ice crystals, and other components in addition to the dairy ingredients, flavoring, sweetening, and possibly coloring. While conforming with the standard of identity, the individual ice cream manufacturer may very properly feel that his own precise formula makes a better and more popular ice cream than the products made under the slightly different formulas of his competitors.

What I have said about ice cream also applies in large measure to other manufactured dairy products. There are, for example, no less than 65 Federal standards of identity for cheeses, processed cheeses, cheese foods, and cheese spreads, and the manufacture of these foods may, and generally does, involve the use of numerous ingredients other than dairy ingredients.

Accordingly, the records and files of the dairy products manufacturer are as important to him and as much his own valuable property as are the records and files of the manufacturers of any other category of food products.

I shall appreciate your causing this letter to be added to my testimony as part of the record.

Sincerely yours,

BENJAMIN G. HABBERTON.

The CHAIRMAN. Mr. Andrew J. Biemillller.

STATEMENT OF ANDREW J. BIEMILLER, DIRECTOR, DEPARTMENT OF LEGISLATION, AFL–CIO; ACCOMPANIED BY ANNE DRAPER, RESEARCH ASSOCIATE, DEPARTMENT OF RESEARCH, AFL–CIO; AND KENNETH A. MEIKLEJOHN, LEGISLATION REPRESENTATIVE, AFL–CIO

Mr. BIEMILLER. Mr. Chairman, my name is Andrew J. Biemiller. I am director of the Department of Legislation of the American Federation of Labor and Congress of Industrial Organizations.

I am accompanied by Miss Anne Draper, an economist from the Research Department of the AFL–CIO, and Mr. Kenneth A. Meiklejohn, one of our legislative representatives.

I am happy to be here today to testify on H.R. 11581, the Drug and Factory Inspection Amendments of 1962.

The present hearings take on a special urgency because of the recent exposures concerning the drug industry. I refer to America's incredibly narrow escape from general distributions of the dangerous "tranquilizing" drug thalidomide, which had such tragic results in Europe and which, I am sure, is a matter of intense concern to the members of this committee. And I refer also the evidence of unconscionable profiteering in this industry.

Let me dwell for a moment on the recent narrow escape to which I referred. All of us who give drugs to our children or loved ones do so with faith in the doctor who prescribed them, the druggist who compounded the prescription and the industry that manufactured the basic ingredients.

We have to have this confidence. If we don't, then recovery from illness or retention of health are impossible. But how can we have this confidence without basic protective legislation?

Here we have an industry that tried its utmost to bulldoze a dedicated Government into giving a clearance on a drug that the employee suspected was dangerous. Here we have an industry proven to have inflated its prices beyond all bounds of comprehension.

All of us can imagine, I am sure, the uncertainty in the mind of a mother with a sick child. She wants her child to recover; she wants to be sure of the drug she is administering. She needs, and I submit she should have, that confidence and it is within the power of this Congress to give her that peace of mind.

I know that this committee does not have before it the price problem, but I would be derelict if I did not point out that we are urgently concerned over the high prices of many vitally important drugs, and that we consider H.R. 11581 seriously defective in failing to deal with this problem.

We have indicated in testimony before the House Judiciary Committee our strong support for H.R. 6245, the "Drug Industry Antitrust Act," presently pending before that committee, which would effectively deal with it. Here, I must reiterate our view that there is urgent need for legislation to bring down the high price of drugs, as well as to assure their safety and efficacy. Let me add this word about thalidomide. While we are very thankful that the drug was kept off the market, we are also concerned that the drug provisions of the Food, Drug and Cosmetic Act be substantially strengthened all along the line. We can't ever again run the risk of dangerous medicines getting to our population, and I say that on behalf of the 14 million wage-earning families who are members of AFL–CIO unions. The Dr. Kelseys deserve the backing of sound legislation.

We in the AFL–CIO have concerned ourselves with the Food and Drug Act for many years, supporting amendments to strengthen it and seeking adequate appropriations for the Food and Drug Administration to carry out its vital functions.

Our concern about these dual problems is not new, it was set forth in the most recent consumer protection resolution, passed by the

Fourth Constitutional Convention of the AFL–CIO on December 12, 1961. The pertinent portions read as follows:

The most glaring of the consumer interest issues arising over the past 2 years is that of the high price of prescription drugs, based on monopoly patent rights, restrictive licensing agreements, brand-name promotion and vast outlays for advertising. Drug industry profits, runnnig at 18 percent on stockholders' investment, outstrip those of all other manufacturing industries in the country. Further, the drive for profits has led to irresponsible advertiising claims, concealment of dangerous side effects of powerful drug agents, and the subordination of research on useful drug products to the development of inconsequential sales gimmicks of little value to the art of medicine or the ultimate welfare of sick patients. Reforms are clearly called for in behalf of the consuming public.

* * * * * * *

Now, therefore, be it resolved:

* * * * * * *

We call upon the National Congress to enact legislation that will bring down the high price of prescription drugs, combat misleading advertising by drug companies, and improve the safety and usefulness of drug products generally. To this end we endorse the provisions of S. 1552, and H.R. 6245, pending in the current Congress.

* * * * * * *

We urge new amendments to the Food, Drug and Cosmetic Act to strengthen the powers of the Food and Drug Administration in behalf of the consuming public, including these provided by S. 1552. In addition, power is needed to require manufacturers to pretest therapeutic devices and cosmetic products for safety before putting them on the market.

May I read also the text of a statement issued by the AFL–CIO executive council during its Chicago meeting August 13–16:

We join with the President of the United States and the entire American public in expressing our profoundest congratulations and gratitude to Dr. Frances O. Kelsey, of the U.S. Food and Drug Administration, for her courageous persistence in withholding approval of the dangerous drug thalidomide from the general prescription market. Her action, in the face of strong pressure for its release, is in the finest traditions of public service.

It is a sad commentary, nonetheless, that our present food and drug laws are so inadequate that it takes heroism to administer them properly in behalf of the consuming public. Hopefully the story of the thalidomide tragedies will spur the Congress to enact much needed drug reform legislation in full and undiluted form, such as the AFL–CIO has supported ever since the facts about drug industry practices became apparent from the exhaustive investigations undertaken by the Senate Antitrust and Monopoly Subcommittee, under the chairmanship of Senator Estes Kefauver.

The thalidomide episode has served to highlight one of the very important series of complex and vital issues involved in the legislative proposals growing out of the Kefauver investigations. The safety of drugs is paramount and every effort should be made to see that unsafe and new drugs do not reach the public. Fully adequate animal tests should be required, as a matter of course, before drugs are used even in limited experimental amounts on human beings, and the Food and Drug Administration should be safeguarded from undue industry pressures for hasty approval of inadequately tested drugs.

Additional safety measures needed include more adequate factory inspection powers, for the Food and Drug Administration, the enforcement of manufacturing standards, licensing of drug manufacturers, the addition of tests for efficacy of new drugs as well as for safety, provisions for prompt reporting of adverse side effects of drugs to the Food and Drug Administration, stronger authority to remove hazardous drugs from the market and provisions for seeing that prescribing doctors are fully and truthfully informed as to the efficacy and side effects of drugs.

Further, the general concern for drug efficacy and safety should not be allowed to sidetrack the issue of the high price of drugs. The prescription drug industry is still reaping enormous profits from its patent and brand name monopolies, and charging excessive prices to the public for drug preparations. S. 1552, as

reported out by the Senate Judiciary Committee has been completely stripped of its original patent amendment provisions, which are the key to price reform in this industry. The bill offered by the administration in the House of Representatives, H.R. 11581, is silent on this issue. We strongly urge the prompt adoption of adequate measures not only to insure the safety and efficacy of drugs, but also to bring down the high price of drugs.

The only provisions in H.R. 11581 touching on the price problem are sections 111 and 112 providing for the standardization of drug names and setting out specifications for the printing of the "established name" on drug labels. We fully support the intent of these provisions. Standardization of drug names and the specific requirements for their conspicuous placement on drug labels will aid both the physician and the consumer.

Hopefully, more general usage of the generic name by prescribing physicians will be encouraged so that the consumer will not always have to pay the exorbitant prices commanded by the heavily advertised brand names. We believe, however, that the bill's provisions on labeling should be further strengthened by extending them to advertisements as well, as is now being proposed in the Senate, rather than confining them to drug labels alone.

Very little really can be done, however, to bring down drug prices unless action is taken to deal with the patent monopolies which have been estimated to encompass about two-thirds of all prescription drugs on the market.

Most of the amendments to the Food, Drugs, and Cosmetics Act made by H.R. 11581 relate to health and safety issues. We are naturally in accord with measures which will increase the effectiveness of the protection afforded to the public by the act.

Certain of the proposed provisions have been highlighted by the current thalidomide episode and also recent particular instances where new prescription drugs were actually released to the public without any real knowledge of their dangerous side effects and later recalled from the market only after considerable delay. MER 29 is a clear example. We are aware of the steps taken by the Food and Drug Administration to install more adequate controls over the testing and distribution of such drugs, but we strongly support legislative measures to buttress these regulations and to supply added authority where needed.

The main amendments in H.R. 11581 that relate to proper controls over the release of new drugs appear to be as follows:

1. Greater procedural flexibility for the Secretary of Health, Education, and Welfare in acting on new drug applications;

2. A requirement that new drug applicants keep records and furnish reports on experience with new drugs both in the investigational stage and after approval for the general prescription market;

3. Strengthened authority for the Secretary to remove approved drugs immediately from the market if they present an imminent hazard to the public health.

We believe these amendments are fully justified. We are not prepared to comment on the specific language in which they are drawn, but we hope that they will have the effect of freeing the Food and Drug Administration from undue pressure in approving applications and of enabling the agency to make a thorough evaluation of the evidence in behalf of each new drug. We fully subscribe to the need for

a reporting system on experience with new drugs and to the proposal to enable the agency to withdraw unsafe drugs promptly from the market.

We suggest further that the new regulations recently announced by the Secretary of Health, Education, and Welfare, relating to the investigational distribution of drugs, be fully reviewed by this committee for possible additional legislative authority that may be needed to make them effective. We understand, for example, that there is some question as to whether the Food and Drug Administration has authority to require animal tests before a drug is tried out on human beings. We think that such animal testing should be required and that the Food and Drug Administration should clearly have whatever authority it needs to enforce such a requirement as well as other requirements relating to clinical testing.

Several other amendments in H.R. 11581 also bear significantly on the safety and effectiveness of drugs for human use. These amendments include the following:

(1) Authority for the Secretary of Health, Education, and Welfare to issue regulations establishing standards for manufacturing procedures and controls;

(2) Clarification and strengthening of factory inspection authority;

(3) Requirement that drugs be pretested for efficacy;

(4) Certification of all antibiotics;

(5) Requirements for truthful statements in advertising;

(6) Special controls for barbiturate and stimulant drugs.

In general we support these amendments and have only a few general observations to make on them.

1. MANUFACTURING STANDARDS

We believe that the authority for establishing standards for manufacturing procedures and quality should be strengthened by a provision for licensing drug manufacturing establishments.

2. FACTORY INSPECTION

We understand that the proposed factory inspection amendments, which would apply to all establishments under the Food and Drug Act, have been criticized as giving overly broad and vague authority for inspection. We think that the authority should be broad enough to allow for adequate inspections, but that it would be wise to make the authority appropriately specific, so that it will stand up in court if challenged.

3. EFFICACY TESTS

We strongly support the proposal that new drugs be pretested for efficacy in addition to meeting existing tests for safety. In effect, this will mean that the manufacturer must back up his claims as to what the drug will do. This is an essential measure to protect the user of medicines against wasting his money and delaying adequate treatment of his illness. Ineffective drugs are worse than useless; they are actually dangerous.

It is important that the self-dosage, "over the counter drugs," should be covered, as well as prescription drugs, and we support provisions

of the bill that would do so. These provisions should deal a virtual deathblow to the vicious quack medicine industry which robs the American public of hundreds of millions of dollars a year. The ordinary person is in no position to evaluate such claims, and many are easily led by distress to "try anything," no matter how fantastic. Our Government is nearly helpless in its battle to stamp out this dangerous thievery. We cannot emphasize too strongly the need for these provisions.

As we understand it, however, efficacy will have to be shown only if the drug is introduced or a new claim is made for it after the enactment of the law. This leaves many worthless drugs now on the market subject only to the much weaker controls of the present law which puts the burden of proof on the Food and Drug Administration in a court of law to establish that a drug is not effective. We think the Food and Drug Administration should be allowed to challenge the efficacy of an existing drug under the new suspension and withdrawal procedures and to require proof of efficacy to be shown, at such time. Possibly this is contemplated by the language of the effective dates section, but it is not clear, and we think it should be made clear. Otherwise, it may be many years before we have a genuinely effective law that will actually keep worthless drugs off the market.

4. CERTIFICATION OF ANTIBIOTICS

We support the proposed provision giving the Secretary power to require certification of batches of all antibiotics in addition to the five antibiotics presently listed in the law. As we understand it, many of the newer antibiotics stand in greater need of the certification procedure than the ones already covered by the law, some of which, in fact, might safely be decertified. Omission of the newer antibiotics, however, is a loophole which should be closed.

The provisions relating to records and reports on antibiotics parallel the proposed amendments relating to records and reports on experience with new drugs and should be enacted for the same reasons.

5. ADVERTISING

The need for legislation to control drug advertising grows to some degree out of the breakdown of the machinery for voluntary policing of such advertising, which at one time was exercised by the American Medical Association. Prior to 1955, drug advertisements in the Journal of the American Medical Association were scrutinized for accuracy by the association's drug council. In 1955, however, a change in policy took place and supervision of advertising in the Journal was taken over by an advertising committee. The result was a tremendous increase in drug advertising in the Journal and other professional publications which followed the lead of the Journal. There also resulted a complete breakdown in the system of voluntary controls over drug advertising theretofore relied upon by the American Medical Association and the medical profession generally to make sure that such advertising was fair and truthful.

We strongly favor appropriate measures to enforce truth in advertising by the drug industry. We have been greatly impressed with the harm done by costly and misleading advertising by the drug indus-

try. Here, we have a real safety issue. Essentially the problem boils down to (1) concealment of dangerous side effects of certain powerful drug agents, and (2) exaggereated or unfounded claims for effectiveness of the drug.

The AFL–CIO takes the position that doctors should receive copies of drug package inserts along with promotional material mailed to them. In the case of new drugs, doctors should get a full statement of all relevant findings required to be made under the new drug section of the Food, Drug and Cosmetics Act. We understand that regulations to this effect have been issued by the Food and Drug Administration, but the requirement should also be written into the law.

We believe drug advertisements should include a proper warning as to side effects, accomplished in whatever way is most feasible, under the supervision of the Department of Health, Education, and Welfare, and a full and accurate statement of the efficacy of advertised drugs.

These measures should do much to remedy the low estate into which prescription drug advertising has fallen and to increase the protection of the public against errors inadvertently made by doctors on the basis of inadequate information. In view of the intense personal stake that any sick patient has in the matter, the general public has the right to demand that information going to doctors be truthful and complete. We cannot be satisfied with anything less.

Under H.R. 11581, the advertising amendments would be administered by the Federal Trade Commission through a broadening of its present authority for policing misleading advertising. We think your committee should give serious consideration to transferring this authority, insofar as drugs are concerned, to the Food and Drug Administration, as the more appropriate agency for this purpose.

We have no special comments on the proposed controls for barbiturate and stimulant drugs other than to express our general position in favor of such controls. We note, however, that while stimulant drugs are quite broadly covered, the sedative drugs are limited to barbiturates. We believe that controls over sedative drugs should be of similarly broad character, in order to prevent the bootleg market from simply shifting over from barbiturates to some other type of sedative.

Mr. Chairman, I would like to say, in behalf of our organization, that we hope the present Congress will move rapidly to enact necessary legislation on drugs, which in our view includes price reform as well as health and safety measures. The drug issue has been in the forefront of public concern for over 2½ years, and rightly so. There are those who may urge that legislation not be passed in the present atmosphere of an aroused public concern in the wake of the disclosures as to the tragic effects of the drug thalidomide. But I suggest that that opinion will be even more aroused if nothing is done or if token, halfway measures are adopted. The usual atmosphere in which food and drug measures come under consideration is monumental public apathy, and perhaps the present interest seems remarkable only by contrast.

The drug issue has been exhaustively explored. The passage of time and the occurrence of new incidents serve only to confirm the

need for action. We hope that action will be taken promptly. It would be cruel and inhuman to delay this action any longer.

Thank you, Mr. Chairman, for the opportunity to be heard.

The CHAIRMAN. Thank you, Mr. Biemiller, for your statement on behalf of the AFL–CIO.

I do not know if you are aware of it or not, but these hearings developed a fact which many are aware of. There seems to be a great deal of emphasis placed on the unfortunate incident of thalidomide, and it was pointed out here a couple of days ago that under present law this situation could have been adequately dealt with.

Now, no one has pointed out anything in the proposed amendments how the arm of the Federal Government would be strengthened insofar as that unfortunate experience is concerned.

So I think that at these hearings we must keep in mind what the actual problem is in dealing with it.

I agree that the tragic and unfortunate incident of the worldwide publicity and particularly the results in Europe from the use of thalidomide has emphasized the general need for strengthening our food and drug laws. I think also we should keep in mind that because of this highly publicized incident, it appears that it is not affected by this bill at all.

Mr. BIEMILLER. Quite obviously, Mr. Chairman, the law in this instance did keep the drug off the market, but it kept it off the market because Dr. Kelsey simply refused to cave in under the pressures exerted.

The CHAIRMAN. Because the agency and the ones responsible in the agency did not approve it.

Mr. BIEMILLER. That is correct.

Mr. DINGELL. As a matter of fact, Mr. Chairman, I understand that the history of this is simply that Dr. Kelsey was able to keep thalidomide off the market solely by technicality, and that is by sending back for additional information and by failing to approve the claim, and that she actually had no basis other than her suspicions which required her to keep sending the application back for additional information.

And it was only by this technicality that she was able to prevent certification of this drug.

The CHAIRMAN. The gentleman is rather familiar with the provisions of law with respect to foods and drugs, as has been demonstrated during the course of these and many other hearings.

But everyone knows, if the Food and Drug Administration had failed to prove it, they could have gone to hearing on the subject.

I just point that out. I do not think we should go into something that is foreign to this particular emotional problem to settle some other question.

Mr. Roberts?

Mr. ROBERTS. Mr. Biemiller, I agree with you on this matter of truth in advertising.

I am not too sure that I agree with you that this authority ought to be transferred. It would seem to me that the Federal Trade Commission has the authority—perhaps they are not using it.

Mr. BIEMILLER. There have been a couple of cases in recent years, as you know, Congressman; Doan's pills, if I remember correctly, is a

case that went through several years of litigation before an order was finally issued.

You may be correct, and this is certainly not a major point that we would be stressing.

What is in the back of our minds is the fact that an awful lot of technical information is needed in judging the truth in advertising in this area.

I would agree that if the Federal Trade Commission was functioning in a determined manner, it could draw upon the knowledge of FDA. We simply throw out a suggestion that it might be preferable to let an agency that is expert in the drug field—the specific field of efficacy and the other problems relating to drugs and the side effects that have been developed—pass judgment rather than one that is primarily expert in the advertising field.

Mr. ROBERTS. I observe some of the TV advertising and it seems to me that they make very great claims as to the cure and relief of certain matters that I have certainly a lot of concern about as to one of the products that is being advertised, because I happen to know it is a new field, and it is a field where, in taking the wrong thing, it can irreparably damage the person who takes it.

I certainly agree with you that whether we put anything in this bill or whether we simply stress in the report that attention should be given to this matter and perhaps the two agencies could very well work together, one supply the technical information and the other supply support where it is needed, but I certainly agree with you that there is a dangerous situation in that field.

Now, to go back to your statement as to over-the-counter drugs, I am one interested in what we can do about items such as aspirin, turpentine, Vick's salve, and a lot of these things that I suppose may not effect a cure, but perhaps they do afford some type of relief.

I am wondering if there is very much we could do.

Now, if we were to require prescriptions for this type of item, we are simply driving the price very high. There are some types of maladies or discomforts that aspirin does relieve.

Mr. BIEMILLER. That is right.

Mr. ROBERTS. And that are used many times by people without the services of a physician.

I am wondering if you do not think we ought to leave that as is.

Mr. BIEMILLER. Well, let me raise a question there. Certainly I would agree that most of the aspirin advertising generally adds that if a headache persists, you should see your physician, and so on, which is all to the good.

But it happened that within the last week or so I took a couple of pills of a so-called superaspirin—I will not name it because it would not be fair. I mentioned this to my doctor, whom I visited only yesterday on a couple of matters, and he said: "You should not be taking that. That is going to have an adverse effect on you."

Now, this is another preparation that is sold right over the counter. You can buy it in any drugstore in America.

I just raise this as the kind of thing that bothers us. I am not saying that it is an easy, simple problem. I know what is bothering you.

I have, in one way or another, been connected with attempts to pass legislation in this field for about 25 years, and I am reasonably familiar with the problems involved.

But this is what bothers us. I am sure you are aware of the absolutely worthless medicines that have been, and in some cases are still being, sold. I remember in my youth a preparation that was sold rather widely and became a quite desirable medicine during prohibition days called Peruna, which was prune juice and alcohol. It probably did not do anybody harm, but it did not do them any good, except that it was a way of getting a little alcohol during prohibition days.

This is the kind of problem that concerns us here, and I think that at a minimum the proprietaries ought to be required to show the efficacy of their drugs before being allowed to proceed as widely as they have been.

I mean, in the case of aspirin you have proven facts that for certain kinds of things aspirin is very valuable. Of course, if we got into the price of aspirin, I might have something to say on that, but I realize that is not a subject before this committee.

Mr. Chairman, may I say, parenthetically, that I am sure you understand our attitude on this. We are expressing our concern about the high prices of many drugs, but we realize that this committee cannot have a direct effect upon that problem.

Mr. ROBERTS. I appreciate your statement, Mr. Biemiller.

Mr. Chairman, that is all I have.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Thank you, Mr. Chairman.

I have been very deeply interested in Mr. Biemiller's statement, because I know he has had such a longtime interest and close connection with this problem.

Now, on the first page of your statement, Mr. Biemiller, you say:

> Here we have an industry that tried its utmost to bulldoze a dedicated Government employee into giving a clearance on a drug that the employee suspected was dangerous.

Do you feel that it is fair to indict the whole industry? I mean in your own field of labor relations, would you want to indict the entire labor field because of some action by a given group?

Mr. BIEMILLER. I think possibly your point is well taken, and if we had said the pressure came from one drug company, it would have been a more accurate statement.

I have in mind, as I am sure you know, Congressman, the long factual statement put into the Congressional Record by Senator Kefauver of the attempts to pry this drug loose which Dr. Kelsey resisted.

I think your criticism has merit, and you are right: that we probably should have referred to the company rather than to the industry as a whole, although I think you will find other instances that have not been made public in the way that the thalidomide situation has been.

Mr. SCHENCK. I appreciate that statement.

Now, Mr. Biemiller, speaking only for myself, as a member of this committee, I am deeply desirous that safer drugs, medicine, and medi-

cal preparations are made available to everyone who needs such help, at a price that they can afford to pay, and from which they have every right to expect they will receive this help.

So we here in our hearings this week have been trying to develop the necessary information on which to make a legislative judgment.

Now, I am sure you know, for example, the Eli Lilly Co., which is highly regarded as a pharmaceutical manufacturer. Its President, Mr. Beesley, testified that they would this year spend from $20 to $21 million in research alone, and in further questioning Mr. Beesley, I asked him if the improved manufacturing methods which they developed through their research and so on, if this is not also reflected in a lower price of their products, and he said very definitely it is; that they have had a considerable number of downward revisions in prices.

He mentioned one drug that I mentioned to him, the drug insulin, which has been extremely important to many, many people.

Mr. Beesley and the Eli Lilly Co. manufacture that drug, have been one of the leading manufacturers of that drug.

He said this: That in about 40 years, since they first introduced insulin—

> We have had 13 price reductions during that period and that the current price is about 6 percent of the price that prevailed in 1922.

Now, I would think that this indicates that the industry is trying to bring the costs down even though they have got to recapture their research costs, would you not agree?

Mr. BIEMILLER. Certainly they have to recapture their research costs, but the fact does remain—and I think the evidence has been produced—that this industry, as an industry, is still showing the highest return of any industry.

There have been specific cases shown of drug prices that have not dropped to any appreciable extent.

You were referring, of course, just a moment ago, to a drug that has been on the market for a good length of time, as to which it has been possible to learn new methods of mass production.

I realize that our concern with the high price of drugs is a problem that this committee itself cannot handle; I am fully aware of this because of my experience as a member of this committee and my knowledge of the care that members have always exercised in these matters. I believe this committee is doing its best to find a solution to the drug problem; hence, I regret you cannot really attack this price question.

I think that you will find, if you look into it on your own, from the evidence that you can pick up from the Kefauver hearings, from just good, basic, standard reporting services like Standard & Poor's, that the industry as a whole is still getting the highest return of any industry in the country. This is something that I think you ought to take into consideration.

Now, if cross-licensing, which the Kefauver original proposal called for and which the Celler bill calls for, were provided for, I think we could immediately drop the prices of some of these drugs.

Mr. SCHENCK. I appreciate the gentleman's point of view on that.

We had a gentleman here, a professor in business administration, who tried to draw some parallels between what has happened in this

country, for example, and what is happening in Russia, and apparently there is a pretty strict control and planned economy in Russia.

We have also had other witnesses who stated unequivocably that the advanced and scientific medical treatment, the kind of drugs and so on that we have developed and are receiving in this country is far superior to any other country in the world.

It would seem to me that our committee must do everything it can to insure safety and effectiveness of drugs, ample drug laws, inspections and all that, to protect the public interest and health and we are already receiving in this country the very best medical attention and drugs of anywhere in the world, and life has been prolonged quite a span as a result of many of these discoveries.

So we must also, somehow or other, leave enough leeway here to encourage research and encourage incentive and encourage an opportunity to develop new drugs and new methods and new medical ways of doing things.

Now, again, we had Mr. George Cain, who is president of the Abbott Laboratories in north Chicago, and Mr. Cain testified, I believe, that his company will spend some $11 million in research this year, and that their advertising budget for this year is about $2,275,000.

So it would seem to me that they are not going clear overboard in their advertising.

I wonder if you cared to comment on that, Mr. Biemiller, because you indicated in your statement you thought a disproportionate amount is being used in advertising.

Mr. BIEMILLER. This is still our opinion.

On the research question, certainly we want research done.

I would just like to point out, however, that some of the most important drugs of modern times have not come out of the research done by the drug companies; they have been financed by funds supplied either by the Government or by public subscription, the various foundation type of operations. I hate to think what the prices charged for some of the drugs that have come out of governmental or foundation research would have been if they had been developed by private industry.

You have to weigh all of these matters, I think, one against the other.

Mr. SCHENCK. Mr. Biemiller, I could not agree with you more as to the outstanding scientific contributions made by National Institutes of Health and other portions of the Public Health Service. They have contributed tremendously to the knowledge, growth, and ability of the science of medicine and the treatment of people who are ill.

We have a chart here presented to us by the Proprietary Association, which states the source of the information is the U.S. Bureau of Labor Statistics. This chart shows that between 1940 and 1960 packaged medications have gone up 30 percent; housing has gone up 72 percent; services, 111 percent; foods, 150 percent; wearing apparel, 166 percent.

So, on the basis of that information from the Bureau of Labor Statistics, it would seem that the drug industry as a whole is making a rather good comparison with other living costs, would you not agree?

Mr. BIEMILLER. May I ask our economist to comment on this matter?

Mr. SCHENCK. Surely.

Miss DRAPER. I have not been studying particularly the prices of proprietary drugs; I have been more concerned about the prices of prescription drugs. I think however, you would have to take into account the level from which the prices start.

In other words, you have the situation where prices fail to fall when they ought to. Maybe they do not go up much, but they are very high to begin with. It is a little misleading to rely wholly on the percentage of increase over a given period, unless you take into account the level at which the prices start and whether those prices may be unreasonable in themselves.

I think this was the point that was made in the case of prescription drugs. You have an enormous spread between cost and price, and the price does not drop; maybe the price does not go up either, but it would not be altogether a disproof of excessive prices to use this type of chart.

Mr. SCHENCK. Miss Draper, I think you have a very definite point there, but, again, and I am not defending any exorbitant price that is charged for any drug by any manufacturer, I think these safe and effective drugs ought to be made available to people who need them at a price they can afford to pay.

My doctor recently told me, for example, that he could prescribe a drug which would be expensive in a given instance, but which would save a 4-week, ordinarily 4-week, stint in the hospital and consequent loss of time from work.

So, while the price of the drug may seem to have been high, the overall cost of health may have been reduced by the use of that drug.

Mr. Biemiller, you dwelled at some length on advertising, and that is one that concerns me also a good bit because of the question of printing all of the so-called contraindications and side effects and so on in medical journal advertising or any other type of advertising.

The testimony we have received here from the pharmaceutical manufacturers is to the effect that the doctors are given full information by extensive brochures on the medicine that is being proposed, the compound, and I think you also indicated, Mr. Biemiller, that sometimes one compound will react one way on one person, and the same compound will react another way on another.

Therefore, it is a medical judgment of the doctor as to whether he should use X, Y, or Z brand, where perhaps the same active ingredient in the compound, with perhaps different inert material, binding material, or whatever you might want to call it, is in there and this may affect individuals differently.

What is your feeling on that?

Do you still think that they ought to publish all of these contraindications and the side effects and so on in all the medical journals?

Do you think that would be in the public interest?

Mr. BIEMILLER. May I again call on Miss Draper, who has been researching this matter rather thoroughly.

Miss DRAPER. I do not know that we would want to testify as to exactly what should appear in a drug advertisement.

We would think that the Food and Drug Administration should work this out in some practical manner.

I think that, in substance, what is proposed is to have proper warnings in advertisements, as to side effects and contraindications.

We would certainly want them in there if it is at all feasible and practical.

It is a matter of working out, it seems to us, exactly how you do it.

Mr. SCHENCK. I appreciate that.

I just want to point out, and I hold them in my hand, for instance, these are printed exhibits which were given to the committee for the committee record. These are reported to be—these booklets are provided by Abbott, for example—these are purported to contain complete information for the doctor, scientific information, showing all of the side effects, the dosages, and the chemical makeup and molecular construction and everything else of these various remedies.

It is my understanding that all of the pharmaceutical companies do this same procedure with the doctor prior to the so-called detail man or salesman calling on the doctor.

Do you feel that this is a sufficient type of information, or do you think this or additional information ought to be included as a full-page-or-more ad?

For instance, I saw yesterday in a doctor's book two-thirds of a page on one drug in order to describe that drug.

Now, should that be included in advertising?

Mr. DRAPER. I guess the problem is that an advertisement generally just stresses how good the drug is and so forth and so on, without any warnings at all, and it would be a matter of some practical method of getting across due cautions.

Some of these descriptions of drug effects, and so forth, I understand, run to 40 pages, and this is obviously not practicable.

We think there should be an offset, shall we say, to the psychlogical effect of an advertisement that is all about a whiz-bang new drug, but which gives no inkling as to cautions to be observed.

You might win somebody over with an advertisement so thoroughly that he will not look at the brochures quite the way he ought to.

Mr. SCHENCK. I can well appreciate that position, Miss Draper, because my mother, bless her heart, would listen to the radio programs and read newspaper advertisements and say, "Now, that sounds exactly like I feel and that is what I ought to get."

So I know that that is very important.

Mr. Chairman, I think Mr. Biemiller and his associates have made a very fine contribution to these hearings.

The question of using generic or chemical names on drugs is quite a difficult problem for the reason that many generic and chemical names are very long and involved, and also the packages are relatively small, and there is some question whether or not an abbreviation of some sort that is agreed upon in the medical profession would not do just as well.

And there is some question in the minds of many of us as to whether or not that would actually produce a lower cost in the drug.

Now, do you have any evidence to the contrary, Mr. Biemiller?

I have read Senator Kefauver's statements and have followed that quite closely.

Mr. BIEMILLER. In the semitherapeutic field, for example, I have recently run into a situation where a rather high-powered vitamin, in

exactly the same structure, is advertised under three different names and at three different prices. All three products consist of exactly the same compound.

Now, the question is—each one has a name, X, Y, Z—if the doctor prescribes X, which is the most expensive one, it is pure happenstance if the person finds out he can get exactly the same thing as Y or Z, which are much cheaper.

This is the kind of thing that is bothering us here, sir.

Mr. SCHENCK. Mr. Biemiller, how would you reach, legislatively, the problem of asking the doctor to prescribe any certain drug?

The doctor does not get a commission, I do not believe, does he?

Mr. BIEMILLER. I hope not, not if he is an ethical doctor, and I think most doctors, practically every doctor, is an ethical doctor.

Mr. SCHENCK. I would think so.

A doctor, as I understand it in my discussions with some of them, has developed a certain degree of confidence, faith, and assurance with a given company because of his acquaintance with the quality control and scientific ability of that company, and so they gravitate to the idea of prescribing X-named drug.

Perhaps you buy an Arrow shirt instead of another shirt, and perhaps the other shirt is made exactly the same with a different label on it.

How would you get at that, legislatively, to require the doctor to say: "I want this or that"?

Miss DRAPER. I do not think you could require the doctor to do this.

I think that if this bill is enacted, the doctor might feel safer in prescribing by generic name. Many doctors are conscientious about taking their patient's pocketbook into account, if they can, and this bill would certainly make it easier for them to do so.

You would have a much more uniform quality of drugs assured, with efficacy assured and procedural controls established over manufacturing operations all of which are provided by this bill.

So I think the bill would encourage more general usage of generic names.

I do not think you would cure the problem entirely, sir.

Mr. SCHENCK. Just this one question, Mr. Chairman.

There would be nothing for the doctor to use the generic name and right after it say Abbott, Parke Davis, what have you, would there?

Miss DRAPER. If he felt strongly about it, I suppose he could still do so; yes.

Mr. SCHENCK. That is all, Mr. Chairman.

Thank you very much, and thank you, Mr. Biemiller and Miss Draper, for your fine help.

The CHAIRMAN. Of course, the problem there is that the doctor writes in a way that nobody can read it anyway.

Mr. SCHENCK. May I just make a little comment there. A friend that I met yesterday thought that we should develop a regulation requiring doctors to make typewritten prescriptions.

Mr. DINGELL. Or teach them to write.

The CHAIRMAN. Sometimes you do not know whether that is the reason or whether they are using Latin terms or Greek terms, and then,

of course, if you get into that field, everybody has to take Latin or Greek.

Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I listened to every word Mr. Biemiller said in his statement, and I was very much impressed.

I am not going to get into the price end of it because another committee has that jurisdiction, but I am impressed about this statement on page 3:

> The safety of drugs is paramount, and every effort should be made to see that unsafe new drugs do not reach the public, and fully adequate animal tests should be required.

I hope the committee will pursue that further. Before any experimental drug is marketed, that it will have been adequately tested on animals, and that when experimental drugs are used on humans, they will get permission from the patient before they are used.

It can be done in a lot of ways.

I imagine the doctor can say:

"I have tried everything else, and it has not worked. There is a new experimental drug that might help. I would like to have your permission before I give you this drug."

I hope that will be included in this bill.

You have been very patient, but it is 12:30, so I will cut my statement short by saying that I wholeheartedly agree with that part of your statement.

Mr. BIEMILLER. Thank you, Congressman.

The CHAIRMAN. Mr. Thomson?

Mr. THOMSON. Mr. Chairman, I would like to ask Mr. Biemiller a question that I think is related to this price problem.

You have said very little really can be done, however, to bring down drug prices unless action is taken to deal with the patent monopolies which have been estimated to encompass about two-thirds of the prescription drugs on the market.

Now, this committee has before it and will consider next week at this time a bill known as the quality stabilization bill, which will deal directly with the price that is paid for drug products as well as others.

I would like to inquire whether you appeared before the subcommittee of this committee either for or against the quality stabilization bill.

Mr. BIEMILLER. The AFL–CIO is opposed to the quality stabilization bill.

Mr. THOMSON. You think that bill should not be enacted?

Mr. BIEMILLER. This has been a longstanding position of the labor movement.

Mr. THOMSON. Could you prepare a set of standards that would be used or might be suggested to determine the term "efficacy" or "efficacious"?

Mr. BIEMILLER. We think that the Food and Drug Administration could do so.

Mr. THOMSON. You have none to suggest yourself?

Mr. BIEMILLER. I would not presume, as a layman in this field, to try to lay out standards or definitions in this area.

I know what the phrase means to me as a layman, but that is an entirely different matter than the point you are raising.

Mr. THOMSON. Is it not the problem that it means something different to everybody?

Mr. BIEMILLER. But I think somewhere there has to be a standard created, and I think the Food and Drug Administration would be the proper agency to do that.

Mr. THOMSON. You would like to have them determine whether a drug is efficacious or whether it is not?

Mr. BIEMILLER. Quite so.

Mr. THOMSON. Did you read all the advertising on those pills you took the other day?

Mr. BIEMILLER. Yes.

Mr. THOMSON. You did?

Mr. BIEMILLER. I did.

The CHAIRMAN. Is that the reason you took them?

Mr. BIEMILLER. No.

I took them, Mr. Chairman, on the same basis that so many people take pills. Somebody said, "This will take care of the bad headache you have got."

I had a sinus headache, and I pray you do not have them, but if you do, you know you feel the top of your head is going to blow off.

I have a prescription drug for this problem which I, unfortunately, had left in Washington. I was in Chicago when this happened.

I read the advertising. All the advertising said was it was better than aspirin, as a practical matter; the advertisement was a little longer than that, but that was the basic statement on the little box.

Mr. THOMSON. I have no further questions, Mr. Chairman.

It disturbed me to hear in the testimony this morning that Mr. Biemiller was still, after all of these many years, in the need of some pills occasionally.

I have known him for a long time, and I had hoped that he had outgrown this need.

Mr. BIEMILLER. Unfortunately, Mr. Chairman, I am afraid statistics show that the older we get, the more likely we are to have to take pills.

The CHAIRMAN. You mean the more likely we are to come to a full realization in our own minds that a pill will do us good.

I thought Mr. Schenck would ask you further about the information presented by one of the witnesses with reference to prices, since you did get into that, and which interested me.

It showed how prices rose from 1940 to 1960, packaged medications up 30 percent; housing up 72 percent; all goods and services up 111 percent; foods up 150 percent.

Do you agree with that?

Miss DRAPER. We have no way of disputing the figures at this point.

I think we did respond on this point. I said that I did not know about the proprietary medicines.

The CHAIRMAN. On behalf of the committee let me thank each of you for your appearance here and the contribution you have made to this hearing.

Mr. BIEMILLER. Thank you, Mr. Chairman.

We appreciate the opportunity to appear.

The CHAIRMAN. Our former colleague, Harry L. Towe, advised me that he will be unable to be here tomorrow, when he is scheduled to appear. He would like to include a statement in the record.

STATEMENT OF HARRY L. TOWE, GENERAL COUNSEL, MEDICAL ECONOMICS, INC.

Mr. TOWE. Yes, Mr. Chairman.

It is a statement of Mr. William L. Chapman, Jr., who is the chairman of the board of Medical Economics, Inc., publishers of medical journals and books. I would appreciate having permission to insert that statement in the record.

The CHAIRMAN. Very well, we will be glad to receive it. It may be included in the record at this point.

(The statement referred to is as follows:)

STATEMENT OF WILLIAM L. CHAPMAN, JR., ON SECTION 131 OF H.R. 11581

My name is William L. Chapman, Jr., I am chairman of the board of Medical Economics, Inc., publishers of the following medical publications:

Medical Economics: A medical journal which circulates to all active practicing physicians and osteopaths in the United States. This is a biweekly journal which has been published for 39 years and the circulation is approximately 193,000.

Physicians' Desk Reference: An annual reference book with quarterly supplements which makes available essential prescription information on major pharmaceutical properties, biologicals, and antibiotics in convenient reference form, and has been published for 16 years. The 1962 edition of "Physicians' Desk Reference" has the following approximate distribution and circulation:

MD's and DO's in active private practice	192,000
MD's in U.S. military hospitals (U.S. and abroad)	7,000
Hospitals	23,000
Residents and interns	42,000
Senior medical students	7,200
Druggists	14,000
Miscellaneous (including Federal and State food and drug officials, State health officers, medical and pharmacy schools, nurses, dentists, industrial clinics, hospital staff physicians, pharmaceutical manufacturers, and foreign)	74,800
Total	360,000

Riss: A monthly medical journal circulating to over 51,000 residents, interns, and senior medical students.

RN: A monthly journal circulating on a subscription basis to approximately 165,000 registered nurses in active practice throughout the United States.

On behalf of "Medical Economics" and its affiliated publications I would like to present our position on Section 131 of H.R. 11581.

This section proposes to amend the Federal Trade Commission Act to require that all advertisements of prescription drugs contain a conspicuous, full, and accurate statement of the efficacy of the drug, as well as a conspicuous and truthful disclosure of the drug's formula, side effects, and contraindications. In addition, section 131 authorizes and directs the Federal Trade Commission to prescribe such rules and regulations as may be necessary to administer the new provisions.

A fair conclusion to be drawn from the proposals in section 131 is that the sponsors of the legislation are under the impression that physicians in prescribing for their patients rely almost entirely upon information provided in medical journal advertisements. This is an inaccurate assumption.

While all of us will agree that before a physician prescribes any drug he should have as much information as is available including the composition, action and uses, administration and dosage, the side effects and precautions, and the contraindications, it should be emphasized that this information is provided to the physician in many different ways other than through journal advertising.

The physician received a wide range of information directly and indirectly from the pharmaceutical manufacturer which enables him to intelligently prescribe a drug. In addition to that source of information, there are over 400 medical journals published in the United States for approximately 235,000

physicians. These publications range from the small county medical bulletins and specialty journals to the larger therapeutic publications. The vast majority of medical journals are supported mainly by advertising of pharmaceutical products and a large portion of this income is used to support editorial staffs which either prepare original therapeutic, scientific articles, or review and publish submitted material from clinical researchers. These articles are of great value to the practicing physician in bringing to his attention the latest developments in drug therapy.

In addition to the information provided by the manufacturer and the information contained in therapeutic articles published in medical journals, the physician has available to him many sources of accurate information with respect to the specific use of prescription drugs. Among the recognized drug directories which surveys show are in constant use and relied upon by active practitioners are "Merck Manual," "Physicians' Desk Reference" and "New Modern Drug Encyclopedia." These reference books substantially provide detailed information which section 131 proposes should be included in all journal advertising and these books are available to all physicians and are actually used by a very high percentage of practicing physicians throughout the United States.

As a result of our experience as publishers of medical journals, we are certain that the purpose and function of advertising prescription drugs in medical journals are as follows:

(1) To announce the availability of a new drug indicating the disease or diseases for which the company has been given Federal Food and Drug Administration approval to market the drug;

(2) To inform physicians of any additional usages of a drug discovered after the product has been on the market for some time;

(3) To remind physicians of the availability and merits of a drug about which they already possess detailed written information. Thus, the primary function of medical journal advertising is designed to announce, to inform, and to remind.

We should like to emphasize that we agree fully with the view that before a physician prescribes a drug, he should have all of the information which he needs readily available to him. We think, however, that after the committee has fully explored the subject, it should conclude that medical journal advertising is not the proper medium through which to attempt to provide this information, and we think that the committee can also conclude that all of the information which section 131 requires to be in journal advertising is now readily available to all physicians through the various other media which we have referred to in this statement.

In the final analysis, the physician is the one who prescribes and the one upon whom a patient relies, and we are firmly of the opinion that the physician discharges his obligation to properly inform himself before prescribing for a patient.

We are opposed to the proposals contained in section 131 because we do not think they are necessary nor do we think that they will actually serve their intended purpose. We think, however, that the present law could be amended to require all advertising of prescription drugs to include a statement advising the physician that "Before prescribing you should secure full and complete information by referring either to the manufacturer's literature, the officially approved product brochure, or package insert."

Mr. TOWE. I would also like, if I may, to make available for the committee files a publication of ours which is known as "Physicians' Desk Reference," which is in the hands of every practicing physician in this country and also circulates to hospitals and others. It is referred to in the statement.

It is a book that contains over 2,000 descriptions of pharmaceutical products, those which must be obtained through prescription, and is of great value to physicians.

It might be of some help to the committee determining whether or not, on this question of advertising, complete information is presently in the hands of doctors.

If I may make that available as a part of the committee's files, not the record.

The CHAIRMAN. We will be glad to receive it for the files for information of the committee.

Mr. TOWE. Thank you, sir.

The CHAIRMAN. A few days ago I received a communication from our colleague, Mr. Bolling, of Missouri, who brought to the attention of the committee the statement from Dr. Rudolph Seiden, vice president of Pharmaceutical Research and Control, Haver-Lockhart Laboratories in Kansas City.

I would like for the statement to be included in the record at this point and for a copy of it to be forwarded to the Secretary of HEW with the request that he give us his comments on it at an early date.

(The documents referred to follow:)

PROPOSED AMENDMENT TO THE FOOD, DRUG, AND COSMETIC ACT'S NDA SECTION 505

"From the provisions of section 505(a) are exempted compounders of drugs, provided the manufacturer of a basic drug possesses an effective NDA which includes formulations of this drug such as tablets, solutions, ointments, or powders, plain or mixed with other drugs.

"The manufacturer is obligated to sell the basic raw material only to drug compounders who are equipped to follow all requirements of production, control, and labeling contained in the NDA with respect to the various dosage forms.

"The NDA holder and his customers, who must sign an agreement stating that they will observe the requirements stipulated by the FDA, are both responsible for observing them."

Such an amendment would (1) save the FDA many thousands of working hours a year by making it unnecessary for it to repeatedly review NDA's or supplemental NDA's for the very same drug; (2) save industry the often high cost of (repetitiously) gathering data needed for an NDA and avoid the sometimes tremendous loss of time necessary to clear an NDA; and (3) make it possible that the public obtains better, newer drugs faster and at lower prices since the compounder would be able to omit from his cost calculations the often high expenses for obtaining an NDA.

Even if, in addition, a public rulemaking procedure would have to be devised that would give the FDA authority to prescribe manufacturing standards and labeling for the finished products—similar to the like regulations concerning antibiotics and (particularly veterinary) insecticides and disinfectants, it would still be a great advantage over the current slow procedures which waste time, money, and energy of a multitude of firms compounding the very same (or very similar) drugs.

RUDOLPH SEIDEN, CH. E., D. SC.,
HAVER-LOCKHART LABORATORIES,
Vice President, Pharmaceutical Research and Control.

PROPOSAL FOR CHANGE IN NDA PROCEDURES

I am speaking for Haver-Lockhart Laboratories, for 42 years one of the leading manufacturers of veterinary pharmaceuticals and biologics, and for many of my colleagues in this industry when I state that we have found it increasingly difficult throughout recent years to develop new products to be marketed economically. In fact, it often becomes prohibitive for us to spend the amounts of money currently needed for testing new veterinary drug preparations since the cost may run into four and five figures. Thus, progress is being hindered and it becomes more and more probable that effective and safe new drugs will become available sooner in foreign countries than in the United States of America.

Not only the high costs of determining tissue and milk residues in large farm animals are the cause of exhorbitant expenditures, necessary for preparing new drug applications (NDA's), but—even more important—the repetitious testing and (supplemental) NDA submission requested by the FDA from each com-

pounder who intends to use the new, already NDA-approved, drug in the manufacture of an identical pharmaceutical product.

Registration of antibiotic preparations and of insecticides, once approved by the FDA and the USDA, respectively, can be obtained easily from any (legitimate) compounder. Why, then, the great difficulties and great costs and time losses with respect to pharmaceuticals?

No doubt a tremendous saving of money, time, and efforts for both the FDA and industry is possible by changing the NDA regulations so that only the manufacturer of the basic drug (raw materials) has to obtain it. He should be informed by the FDA, once and for all, of any conditions the compounders of pharmaceuticals have to fulfill when they wish to add the item to their lines, be it as is or with minor changes as to color, taste, and maybe in combination with other simple, old-established and compatible drugs or inert materials. If the compounder does not follow through, the basic manufacturer (and NDA holder) has to stop selling the raw material to the offender and the FDA can act in accordance with the provisions of the law.

What does this proposed change amount to?

To give an example, such a change would make it necessary for Merck or Cyanamid or a firm X to supply all the information needed to prove the safety and efficiency of a new basic drug, say the sulfonamide S. The hundreds of large and small (human and veterinary) compounders of pharmaceuticals who may wish to add S tablets to their lines could do so without each one having to first submit lengthy NDA's which require each one of them to undertake much unnecessary experimental work and even more unnecessary paper work. All that these compounders should have to do is to sign a form supplied by X in which they declare that they will follow the FDA's specified provisions concerning label text and production and control procedures. Any major variation the compounders might wish to make in formulations or indications, naturally, would have to be cleared with the FDA; but those who want to bring out a simple S tablet could do so without having to lose months of time waiting for a decision from the FDA.

The saving of time and money by dozens, if not hundreds, of firms would benefit the public which, thus could get new drugs much faster and probably at lower costs, without sacrifice of their safety and efficiency. And the FDA would not be overworked, but would have more time for work other than studying countless supplemental NDA's and exchanging much correspondence with the individual compounders. Most if not all of them are reputable firms; to those few which are not reputable, X would not sell, especially if he is made responsible for the compliance by his customers with the FDA's provisions regarding S.

RUDOLPH SEIDEN, Ch.E., D.Sc.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., August 27, 1962.

Hon. OREN HARRIS,
House of Representatives,
Washington, D.C.

DEAR MR. HARRIS: This is in reply to your letter of August 11, 1962, regarding a proposal of Dr. Rudolph Seiden to change the new drug application procedures.

The present new drug procedures were designed in part to prevent drug residues in man's food. It is well established that the improper use of drugs in food-producing animals may leave hazardous residues in meat, milk, or eggs to be consumed by man.

If there were a change in the new drug provisions with respect to veterinary drugs, the same degree of control would have to be exercised. The same scientific groups in the Food and Drug Administration that now consider requests for approval of the use of drugs in veterinary products—the veterinary medical officers, the medical officers, the pharmacologists, the chemists, and others upon occasion—would need to review the request.

We are continually striving to simplify the administrative procedures involved in handling veterinary new drug applications, and believe we have been making worthwhile improvements.

If Dr. Seiden wishes a relaxation of present substantive requirements for clearing new drugs for safety, we would have to oppose the change. We doubt

that an amendment of the law is needed to permit administrative improvements as the need for them becomes apparent.

With best regards.

Sincerely yours,

JOHN L. HARVEY, *Deputy Commissioner.*

The CHAIRMAN. The committee will recess until 2:15. We have gone longer than we intended, but we will be back at that time.

(Whereupon, at 12:40 p.m., the hearing was recessed, to reconvene at 2:15 p.m., of the same day.)

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

The first witness this afternoon will be Dr. Lloyd Miller.

Dr. Miller.

STATEMENT OF LLOYD C. MILLER, DIRECTOR OF REVISION, THE UNITED STATES PHARMACOPEIA

Mr. MILLER. Mr. Chairman and members of the committee, my name is Lloyd C. Miller and I reside in Westchester County, N.Y. My academic training leading to a Ph. D. in 1933 from the University of Rochester has been in biochemistry and in pharmacology. My experience has included 8 years with the headquarters laboratory staff of the Food and Drug Administration, and 9 years in industrial pharmaceutical research.

Since 1950 I have served as director of revision of the U.S. Pharmacopeial Convention, an independent, nonprofit scientific oranization devoted to providing standards of strength and purity for drugs.

A published booklet on our organization giving the officers, the board of trustees, and other pertinent information is available here for the committee's use.

The United States Pharmacopoeia is a book of drug standards, as I have indicated, and it is published at 5-year intervals in bound form, and is actually the main product of our endeavors.

A rather comprehensive statement of the nature and aims of the United States Pharmcopeial Convention, Inc., was presented in 1960 to the Senate Subcommittee on Antitrust and Monopoly. If reference to the record of the hearings of that committee does not suffice for the purposes of this hearing, I should like to ask that the statement that I prepared for that committee be included in this record.

The CHAIRMAN. Let it be included.

(The statement referred to follows:)

STATEMENT OF LLOYD C. MILLER, PH. D., DIRECTOR OF REVISION, THE PHARMACOPOEIA OF THE UNITED STATES OF AMERICA, PREPARED FOR PRESENTATION BEFORE SENATE SUBCOMMITTEE ON ANTITRUST AND MONOPOLY

KANSAS STATE UNIVERSITY LIBRARY OCT 1 1962 MANHATTAN, KANSAS

INTRODUCTION

The United States sets up its standards of quality and purity for drugs in a unique way. In this, a large measure of reliance is placed upon the United States Pharmacopoeia, which is a relatively concise compendium that has appeared regularly at intervals since 1820. The Pharmacopoeia, or U.S.P., as it is commonly called, provides definitions and specifications of strength, quality, and purity for drugs, including the necessary test procedures. It is prepared and published by a private scientific nonprofit institution that exists for the sole

purpose of providing drug standards. The U.S.P. is revised entirely every 5 years, and the latest edition, the 16th revision, appeared in March of this year. Interim revision of the standards is effected by means of supplements.

PURPOSE OF THE PHARMACOPOEIA

The object of a pharmacopoeia was set forth in the preface of the 1820 Pharmacopoeia, and remains the same today. In short, the Pharmacopoeia over the years has provided a list of those therapeutic substances that reflect the best practice and teaching of the healing arts and has endowed them, in published form, with standards of identity, strength, and purity that are creditable and firmly grounded on scientific fact. The fulfilling of this objective ever more completely in successive revisions has steadily increased the service rendered to the public and the health professions.

THE U.S.P. ORGANIZATION

The convention is virtually re-created for each decennial meeting, although the rather unusual title "The United States Pharmacopeial Convention, Inc." The corporation meets regularly every 10 years according to a plan adopted in 1820. The latest meeting, the 15th such decennial session, was held on March 29 and 30, 1960.

The convention is virtually recreated for each decennial meeting, although the organizations entitled to membership remain substantially the same. These include the 79 accredited colleges of medicine, the 76 colleges of pharmacy, 7 agencies of the Federal Government, the State medical and pharmaceutical associations, and 12 national professional associations and societies in the fields of medicine and pharmacy. Thus a total of 277 were entitled to representation in the 1960 meeting held recently; of this number, 194 exercised their franchise by sending delegates.

The proceedings of the 1960 meeting have not been prepared but copies of the printed proceedings of the 1950 meeting are being submitted for the use of the subcommittee.

The delegates are appointed to serve not only for the decennial meeting, which usually last only 2 days, but for the entire 10-year period until the next meeting. The convention confers its authority upon an elected board of trustees and the elected officers of the convention, who function very actively during the 10 years between meetings.

It is scarcely possible to emphasize too much how completely independent the convention is in performing its service to medicine and pharmacy in the interest of the public welfare.

THE BOARD OF TRUSTEES AND THE OFFICERS OF THE CONVENTION

The board of trustees consists of six elected members, two of whom represent medicine and two the field of pharmacy, and the remaining two of whom are elected at large from among the convention delegates. The four officers of the convention, the president, vice president, secretary, and treasurer, likewise elected from and by the convention, all sit with the board of trustees.

The members of the board and the officers have always been outstanding leaders in medicine and pharmacy, distinguished for their statesmanship and public-spirited contributions.

THE U.S.P. COMMITTEE OF REVISION

At its decennial meetings, the convention, in addition to selecting the board of trustees and the officers for the ensuing decade and in addition to receiving reports on the pharmacopoeial program for the decade just ended, elects a committee of revision comprising 60 experts, 20 from medicine and 40 from pharmacy and the allied sciences. This 1:2 ratio of representation between medicine and pharmacy has its origin in the changing character of the respective roles played by medicine and pharmacy in the first 100 years of the U.S.P.'s existence.

The 60 members of the committee of revision are elected by ballot from 120 nominees, who need not necessarily be delegates to the convention, who are selected to provide every type of skill and knowledge required in the U.S.P. revision program. Thus, the committee includes specialists in anesthesiology, cardiology, surgery, and other branches of medicine, and pharmacists, bacteriologists,

analytical chemists, and other specialists in various branches of the actual practice of pharmacy. The committee is organized into subcommittees, each charged with definite responsibility for some phase of the revision program.

The committee of revision is drawn from the entire breadth of medicine and pharmacy. The members serve as individual experts and not as "representatives" of their respective institutions.

Advisory boards of experts outside the committee of revision may be appointed to consider special policy matters. Similarly, ad hoc panels of special consultants are appointed from time to time for highly technical advice on matters of more restricted interest.

The U.S.P. Committee of Revision is responsible for drafting and revising the Pharmacopoeia, while the U.S.P. board of trustees is mainly concerned with maintaining the legal and financial standing of the Pharmacopoeia. The board has broad jurisdiction over general U.S.P. policy, relationship of the U.S.P. with other scientific and professional organizations, and matters having a bearing on the prestige of the Pharmacopoeia.

THE REVISION PROCESS

It is literally true that the Pharmacopoeia is under continuous revision to keep pace with medical progress. The revision process consists of three phases. The first is concerned mainly with the selection of the drugs to be recognized in the next revision; the second phase deals with developing the appropriate standards of strength, quality, and purity and the tests that they require; and, finally, the third major effort is directed toward processing the manuscript and guiding it through the various stages of printing to ultimate publication in bound form.

Since the value of the Pharmacopoeia lies in large measure in the selective list of drugs that it presents, the first phase of the revision receives most painstaking attention. It is mainly in the hands of the 20 physicians elected to the revision committee, who are assisted by pharmacists fully familiar with the pharmaceutical forms of the drugs under consideration. The resulting list consists of those drugs and their dosage forms that are believed to represent the best practice and teaching of medicine. This selection process continues right up to press time. Obviously, U.S.P. status is not accorded to every new drug developed.

We come now to the second phase. While the selection phase is still proceeding, the U.S.P. subcommittees concerned with drafting the standards begin their work. Proposed or provisional standards are put to actual laboratory test under the supervision of a member of the U.S.P. Committee of Revision and the final standards are set accordingly.

The work of the third phase, that of the actual publication, is shared as widely as possible by distributing proof copy to the entire revision committee and, in addition, to a large number of other scientific and technical experts. The comments thus received are taken into account in settling on the final text. The task of guiding the text through the various stages of printing is handled from U.S.P. headquarters.

KEEPING THE UNITED STATES PHARMACOPOEIA UP TO DATE

The revision committee is alert to any need for new standards or revision of existing standards during the 5-year period during which each U.S.P. is effective. Interim revisions take one of two forms. For changes of relatively limited application and interest, interim revision announcements, in the form of releases to the pharmaceutical press, are issued, especially if prompt effectiveness is a consideration. For more extensive changes and for the publication of new monographs on drugs, supplements are issued; and each supplement includes also the entire content of all interim revision announcements released since publication of the main volume or of the previous supplement. Supplements are distributed without additional charge to each purchaser of a copy of the current Pharmacopoeia.

APPLICATIONS OF U.S.P. STANDARDS

It often suffices, in explaining the U.S.P. revision program to laymen, to say simply that its object is to insure that the three letters "U.S.P." will continue to be a mark of distinction, something like the letters designating an academic degree.

Of the several roles filled by the Pharmacopoeia, that of providing regulatory agencies with enforceable standards of purity and strength often obscures the other essential functions.

It is important that the U.S.P. possess the character of a legal document. As an official compendium under the terms of the Federal Food, Drug and Cosmetic Act and the counterpart statutes of the States, all of its provisions must lend themselves to the unrestricted use of the regulatory agencies. This creates demands for clarity of context and freedom from ambiguity which frequently preclude conciseness.

The Pharmacopeia serves medicine in two ways. First, it gives the practicing physician his most effective voice in determining the quality of the drugs he prescribes. Second, it assists him by listing those drugs that constitute, in the words of the first Pharmacopeia, therapeutic agents "the utility of which is most fully established." To fulfill these functions, the Pharmacopeia must reflect with fidelity the best practices of medicine and pharmacy in providing standards of purity and potency for drugs of established merit and necessity. To this extent, the U.S.P. is a therapeutic guide the soundness of which is tempered only by that of the judgment of those who select the articles recognized. Yet, by its nature, the process of selection can scarcely be perfect, for no means has been found to insure, at least by the time of publication, that all drugs included are of equal merit and that no other equally meritorious are omitted. In view of today's rapid progress in medical sciences, a varying degree of lag is inevitable.

It is equally important to recognize some of the things that U.S.P. status does not affect. For example, numerous U.S.P. articles are subject to patent rights.

The board of trustees long ago decided that the existence of such rights constituted no bar to U.S.P. recognition. In fact, the U.S.P. would be quite incomplete if patented drugs were left out. The U.S.P. listing does not modify patent coverage in any way, either here or abroad. The Pharmacopeia does give notice, however, on the back of the title page that the inclusion in the Pharmacopeia of standards for a patented or trademarked article does not convey any right or privilege protected by the patent or trademark.

WHAT "U.S.P." SIGNIFIES

The term "U.S.P." acquires its greatest significance from the prestige of the organization behind it. This is doubtless enhanced immensely by the knowledge that the U.S.P. standards are enforced by the Food and Drug Administration.

U.S.P. purity standards are minimums, or floors beneath which the level of purity may not fall. Thus, U.S.P. aspirin must be not less than 99.5 percent pure by actual assay.

Not infrequently, advertising claims are made to the effect that an article "is better than U.S.P." What is meant, of course, is that it assays above the U.S.P. minimum. Because of such claims, the general notices pertaining to all U.S.P. standards specifically state that the minimum purity tolerances specified for pharmacopeial articles other than dosage forms are established with a view to the use of the articles as drugs. Such limits do not bar the use of lots of an article which more nearly approach 100 percent purity nor do they constitute a basis for a claim that such lots exceed the pharmacopeial quality.

Some U.S.P. limits are maximums, as, for example, the limit on the time required for a tablet to disintegrate under specified test conditions. For instance, the maximum disintegration time permitted under the present U.S.P. standards for aspirin tablets is 15 minutes. The important point, nevertheless, is that aspirin tablets that disintegrate in as little as 2 to 3 seconds are still U.S.P. tablets.

THE LEGAL STATUS OF THE U.S.P.

Since 1906, the U.S.P. has been recognized by Federal statute as an "official compendium." As such, it provides the standards of strength, quality, and purity for the articles that it describes and defines. These standards constitute the basis for enforcement of the Food, Drug and Cosmetic Act in respect to drugs moving in interstate commerce. The U.S.P. serves the same purpose for enforcement of the counterpart legislation at the State level.

This role of the U.S.P. in providing a base for law enforcement is not generally regarded as a delegation of legislative power by the Congress. This view was most recently upheld in 1953 by the Supreme Court of the State of Wisconsin. The role, however, is obviously in keeping with the separation of legislative, executive, and judicial functions that it so firmly established in our form of

government. Because the U.S.P. is available, the Food and Drug Administration, for example, is not obliged to make regulations which later it must enforce.

It is essential to point out a very important limitation on the authority given the U.S.P. under this arrangement. This is that the U.S.P. standards apply only to articles intended for use as drugs. The use of a U.S.P. title or synonym brings an article squarely within the scope of the standards.

THE NATURE OF U.S.P. TITLES

Drugs selected for recognition in the U.S.P. are described under their respective nonproprietary or generic names. With rare exception, these names have been in use for months to years, so that the U.S.P. revision committee has the rather restricted option of taking, as the U.S.P. title, the name already in use or else changing it. The latter alternative is scarcely attractive in view of the confusion that is bound to result even if the name seems to be quite unsuitable for any one of a variety of reasons.

Actually, the United States lacks any very specific official procedure for assigning nonproprietary names to drugs.

THE U.S.P. HEADQUARTERS AND STAFF

The U.S.P. maintains permanent headquarters in the Pharmacopeia Building, at 46 Park Avenue, in the Grand Central area of New York City. The heaquarters property was purchased in 1949, largely through generous response to a once-in-a-lifetime appeal for financial contributions, and is now maintained out of current income. The Pharmacopeia Building houses the small permanent staff that directs the U.S.P. program and provides space for the numerous conferences necessary to working out problems of drug standardization.

The U.S.P. staff consists of three persons who have scientific training in pharmacy or the allied sciences and a secretarial staff of three to four persons.

FINANCIAL SUPPORT OF THE PHARMACOPEIA

The funds required to finance the pharmacopeial program are derived mainly from the proceeds of sale of the Pharmacopeia. The price per copy has always been set to return only enough to meet conservative estimates of the expenses of the revision program.

It has been possible to keep the price low because a substantial part of the true cost of the program is contributed voluntarily by physicians and other scientists located over the entire country. The physicians include both private practitioners and physicians engaged mainly in teaching or research. The other specialists are engaged variously in teaching, retail or hospital pharmacy, or in one or more phases of producing drugs. Finally, a considerable amount of welcome help is received from Government scientists, both here in the United States and in Canada. Yet, no tax money has ever been earmarked for U.S.P. revision.

It will be clear from these brief comments on the financial structure of the U.S.P. revision program that careful stewardship is obligatory. Nevertheless, the U.S.P. Convention is proud of what it accomplishes through the cooperative efforts of the professions of medicine and pharmacy and the Government in behalf of the public health and welfare.

Mr. MILLER. Some comment is needed in addition to that for present purposes because of the unique character of the U.S.P. Convention. As an institution, it dates back to 1820 and actually was organized in the Senate Chamber of our Capitol. Regularly, at 10-year intervals since then, the medical and pharmaceutical colleges and the State and National societies of these professions have been asked to send delegates to it. They and delegates from seven Federal agencies, including the Departments of Defense, and Health, Education, and Welfare, have but one duty, namely, to provide for revision of the United States Pharmacopeia during the ensuing decade. For this purpose, a revision committee of 60 members is elected and is charged with selecting those drugs that reflect the best teaching and practice of medicine and ultimately seeing that standards of potency and pur-

ity are developed and published for those drugs in what is better known among pharmacists and physicians the world over as simply the "U.S.P."

In 1906, and again in 1938, the Congress recognized the U.S.P. as an "official compendium" for the purpose of enforcement of Federal food and drug laws; and H.R. 11581 continues this recognition.

A board of trustees, also elected by the convention, is mainly concerned with maintaining the legal and financial standing of the pharmacopeia.

The 60-member committee of revision which I mentioned earlier is drawn from the entire breadth of medicine and pharmacy. The members, 20 from medicine and 40 from pharmacy and the allied sciences, serve as individual experts and not as "representatives" of their respective institutions. Advisory boards of experts outside the committee of revision may be appointed to consider special problems.

The convention undertakes to revise the U.S.P. completely every 5 years, and to issue interim supplements as needed; it is so highly respected that in doing so it can draw freely upon the knowledge of experts in medicine and pharmacy throughout the Nation, including experts employed by the Government. The convention is able thereby to overcome such handicaps as are imposed by limited financial resources. Indeed, the U.S.P. program is conducted on a very modest budget, inasmuch as its sole support is the net income from the sale of the book and of standard samples of drugs made available for reference purposes. No grants or subsidies are received from either State or Federal tax revenues.

From a vantage point of nearly 150 years' experience with drug standards, our board of trustees has studied the various legislative proposals for drug law revision now before the Congress, including H.R. 11581. The board is especially interested in those sections of the proposals that deal with extension of presale certification to all antibiotics and with choosing common names for drugs. The board wishes to record its opposition to additional certification, and puts forward an alternative to what H.R. 11581 would do in respect to drug nomenclature. The purpose of the remainder of my statement will be to make clear the reasons for our position.

OPPOSITION TO EXTENSION OF ANTIBIOTIC CERTIFICATION

Our opposition to the extension of certification of the antibiotics as proposed in H.R. 11581 rests in large measure on the fact that the concept of certification violates the basic principle upon which regulatory enforcement of drug standards has stood since the first Federal law in this field was enacted in 1906. The principle was reaffirmed in 1938, but in 1940 it was breached for insulin-containing drugs and again more extensively shortly thereafter as a wartime measure to expedite the volume production of penicillin.

The point involved here is essentially legal in character and I should feel most reluctant to touch upon it were it not for the fact that it is too important to be overlooked.

We are indebted to Mr. Walter G. Campbell, who headed the Food and Drug Administration from 1927 to 1944, for perhaps the clearest exposition of the underlying philosophy of this aspect of the food

and drug law. Mr. Campbell was trained as an attorney and devoted his entire career to public service in food and drug law enforcement. It was his view that to be able to depend upon standards for drugs provided independently was a source of great strength to the FDA since thereby the Administration avoided being placed in the position of having to police regulations it had itself created. He regarded this division of authority as simply a manifestation of the basic separation of powers so fundamental to our form of government. The development of standards of purity for drugs is a simple extension of the legislative process by which the Food, Drug, and Cosmetic Act was enacted. The enforcement of these standards is an executive function entrusted to FDA, an agency of the executive branch of the Government. The batch certification of insulin preparations and the antibiotics, under standards of strength and purity which the Administration promulgates and subsequently applies in conducting its tests, places upon this highly respected Government agency the responsibility for serving at once as legislator, tester, and judge. We hold that if certification is not needed for the host of drugs whose quality is maintained through the development and application of U.S.P. standards it should be equally unnecessary for the antibiotics.

It is a fact, of course, that several antibiotics are distributed without presale certification. Indeed, of the 12 basic antibiotics recognized in the present edition of the U.S.P., only 4 are subject to certification. A fifth, chlortetracycline, was once so recognized but is no longer; standards for it are provided by the National Formulary.

Antibiotic certification requires duplication of costly testing. Persons or firms introducing an antibiotic drug into interstate commerce do so under the general provisions of the Food, Drug, and Cosmetic Act. This means taking full responsibility for having complied with certain basic requirements which apply to all drugs regardless of how much or how little they affect the course of a life-threatening disease.

Antibiotic producers pay the Food and Drug Administration fees totaling nearly $1 million a year to reproduce tests they have already conducted to demonstrate the satisfactory character of the lots of antibiotics in question. These fees must of course show up in the final selling price of the antibiotic, regardless of how dubious is the value of the doublecheck that the certification program provides. It is the position of the U.S.P. Board of Trustees that there is no longer a need for treating antibotics as a class any differently from other classes of drugs.

While it may be shown that the cost of certification is spread rather widely so that perhaps it amounts to about one-twentieth of a cent per dose, this figure is misleading, because it is equivalent to averaging the costs of a mouse and a mink; that is, payment for certification of antibiotics is based on fees per batch, and a large batch means a great many doses, and for a large manufacturer the cost per dose is very little.

However, the same fee is charged for a small batch, and for a small manufacturer the amount per dose may be very substantial.

If the expenditure of $1 million annually is largely wasted, then surely the public interest would be better served if the money were otherwise used. Indeed, this was the tenor of a report [1] to the Con-

[1] See "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education, and Welfare, September 1960."

gress by the Comptroller General of the United States, wherein it was held that the Federal funds and manpower required for antibiotic certification might better be put to other uses.

No need for extending or even continuing antibiotics certification has been demonstrated. In support of this position, we should like to direct the committee's attention to the contrast between the nature of penicillin that was being produced in 1943 when certification was first conceived and the quality of the penicillin that is being produced now. In 1943, pencillin was being turned out practically by hand in batches produced using 1-gallon bottles. Now it comes out in huge batches that are started in vats holding as much as 18,000 gallons of fermentation mixture. The standards for 1943 penicillin were actually so rudimentary that they should not be compared at all with those of today, which fill over 3½ pages of fine print in the U.S. Pharmacopeia.

A more telling comparison comes from putting a vial of the 1943 product alongside a vial of today's pencillin. I happen to have here an unopened vial of 1943 commercial pencillin. Having had a part in its production, it is a memento of those days. This penicillin was produced by the methods best known at that time. The contents of this vial are amorphous. That means that they are not crystalline. You can see that they are a deep orange in color, and if I were to open the vial you would notice a strong, almost pungent odor. When produced, the contents had a potency of barely 100 units per milligram; but the stability was so poor that doubtless all therapeutic activity has now vanished. Although intended for intravenous use, this product would not meet today's requirements for freedom from "pyrogens" (substances that produce febrile reactions in man and animals) and potentially toxic impurities. Quite possibly it would fail the present more rigid test for sterility. In contrast, 1962 pencillin is as colorless as fresh-fallen snow. I have several samples here, and all are odorless, and indefinitely stable. Their potency is about 1,660 units per milligram.

In 1943, pencillin was scarce and costly (the price of this vial was $20) so that only 100,000 units were put into each vial. Today, this is considered to be a small dose so that the 1962 vial contains 500,000 units. Yet the actual weight of this five-times-larger quantity of purer penicillin is substantially less than the 1943 vial contents and sells for less than a dollar.

The purpose of making this comparison is to point out that under the conditions prevailing in 1943, the certification program served admirably to expedite the production of a product desperately needed by our Armed Forces, impure though it was. However, for the past 15 years our American pharmaceutical industry has been turning out penicillin of almost unvarying purity. The duplicate testing conducted by FDA has contributed nothing that would not have been achieved just as well under the provisions of the Food, Drug, and Cosmetic Act that require all drugs to be tested to demonstrate compliance with their label claims.

Finally, in the opinion of the U.S.P. Board of Trustees, the continued use of antibiotics certification appears to imply a failure of the system of providing purity standards through the official compendia. The argument for special handling of all antibiotics, including those forms used to treat mild skin disorders, for example, on the

grounds that they are used to a greater degree in life-threatening illnesses simply does not stand up on scrutiny when drugs such as digitoxin, the heart stimulant, are among those not subject to presale, batch certification.

The U.S.P. Board of Trustees, therefore, respectfully urges that H.R. 11581 be revised to eliminate the reference to certification of antibiotics, as now defined in the Food, Drug, and Cosmetic Act. At least, it would be a progressive step to limit certification to new antibiotics of uncertain purity and stability and, furthermore, to provide a positive means of dispensing with certification when it can be shown that the output is of uniformly high purity and stability.

STANDARDIZATION OF DRUG NAMES

Section 111 of H.R. 11581 proposes to authorize the Secretary of the Department of Health, Education, and Welfare to establish, under specified circumstances and through promulgation of regulations, "a single standard name" for each drug. Section 112 deals with how these names are to be used. This concerns, of course, only the nonproprietary names, not the trademarked brand names for drugs. This class of names is variously called generic, common, or public names. The term "nonproprietary name" is gradually coming into more widespread use because it is more specific and because it is used internationally.

As one of its basic objectives, the U.S. Pharmacopeia has been providing standardized nomenclature for drugs since 1820, more than 85 years prior to the passage of the first Federal regulatory drug law. This long experience emboldens us now to suggest a close examination of the reasons for proposing in H.R. 11581 that Congress make the Secretary of the Department of Health, Education, and Welfare responsible, either wholly or partially, for the names of drugs. We ask whether the goal is greater safety in the use of drugs, or whether it is economic in nature. If the objective is purely a matter of safety, then the adequacy of the present law, the Food, Drug, and Cosmetic Act, should be looked at more closely; if the objective is economic, relief should be sought otherwise than by amending a law dealing mainly with public health.

Confusion over drug names can jeopardize public health. That the identity of drugs has been uncertain in the past because of a multiplicity of names has been demonstrated amply in medical writing, public outcry, and the hearings on S. 1552. However, those who thoroughly understand the problem agree that its nature is such that there is no simple solution. Only a radical change in our trademark laws can bring about marked improvement, and there has been no substantial suggestion that this is wanted. Almost any change of this kind would involve the whole structure of drug distribution.

While the situation does not lend itself to genuine simplification, some improvement is possible. One witness who testified on S. 1552, Dr. Louis Goodman, professor of pharmacology, University of Utah College of Medicine, a most distinguished teacher and scientist, spoke from firsthand experience with naming drugs, as follows—and I quote from the record of the hearings:

> This nomenclature problem is sticky. I once believed that drug companies, on occasion, deliberately and gleefully proposed generic names so polysyllabic and

so unpronounceable that even a simon-pure pharmacologist would gladly settle for a short euphonious trade name in his teaching of medical students and in his lectures to practicing physicians. Upon becoming a member of the AMA Council on Drugs, I learned that I was wrong.

By the very nature of a generic name, it must give some indication of the chemical class of the drug concerned, it must include the full name of the salt (if the drug is marketed as the salt), it must give some hint as to the chemical relation to any prototype agent already in the field, and it must avoid any therapeutic connotations. Furthermore, conflict and confusion with existing names often limit the choice of a generic name, and, in addition, there are certain international conventions which must be observed. By virtue of these severe but necessary restrictions, I doubt very much whether generic names are ever going to be as attractive as trade names. The days of such short, agreeable, official names as ether, morphine, atropine, and digitalis are gone.

Dr. Goodman's well-stated comments extend for several paragraphs more and include a highly complimentary reference to an article of mine that is entitled "Doctors, Drugs and Names" that appeared in the July 8, 1961, issue of the Journal of the American Medical Association, and which is reproduced on pages 483–490 of part 2 of the hearing record on S. 1552.

By way of adding emphasis to Dr. Goodman's appraisal of the problem, we may say that, fundamentally, physicians and pharmacists seek what is practically, if not absolutely, beyond attainment. It is utterly unrealistic to hope that drug names can be as familiar as those of common foods, for example. Seldom are we confronted with the scientific counterparts of the names of well-known fruits like the apple, pear, peach, and so forth. Nor does commerce in fruits require each grower to identify his produce so exclusively by a brand name that anyone risks mistaking an apple for an orange; moreover, if that happened, little harm would result.

With drugs, the situation is far more complicated. Chemists who synthesize and manufacture drugs use chemical terminology which must be complex to be precise, for the molecules of today's drugs are generally quite complex. But even chemists tend to abbreviate these long chemical names so that we hear such terms as DDT for dichlorodiphenyltrichloroethane, which, as an insecticide, is also a drug for use in ridding surroundings, clothing, and even one's person of disease-bearing insects.

This human tendency to abbreviate cannot be legislated out of existence, so we must be resigned to seeing more and more of jargon consisting of combinations like DDT or for that matter, FDA, AEC, and so forth. But there is great danger in using such terms for drugs because of the risk of confusion. DDT, as a drug, is quite safe if used prudently to dust clothing and the skin, but it can be toxic if misused.

Quite a different drug has come to be well known by the initials DFP, short for diisopropyl flurophosphate. It is extremely toxic and always must be used with utmost caution. If DFP were written for DDT on a doctor's prescription or on orders to a nurse and the error was not caught by the pharmacist, tragedy could result. These two drugs are listed in the U.S. Pharmacopeia under the titles Chlorophenothane and Isoflurophate, respectively, nonproprietary names which we feel differ enough from each other and from other titles to rule out confusion.

Fortunately, trivial designations consisting of letter or letter-and-number combinations are comparatively uncommon and only as rare exceptions do U.S.P. titles include letters or numbers.

Until quite recently, nonproprietary names were chosen haphazardly in the United States despite earnest efforts on the part of the American Medical Association that were aimed mainly toward encouraging early selection and toward avoiding therapeutic implications. There was no real stimulus to brevity or to showing interrelationships between similar drugs.

In 1961, the America Medical Association and the United States Pharmacopeia joined forces in this area and in the past year what are now called U.S. adopted names have been given to about 170 compounds. Less than one-third of these compounds will eventually be marketed as drugs, but the selection committee is much less concerned over this "waste" of names than with making certain that the names that do come into use are suitable. The names adopted for compounds that do not prove out as drugs will serve a useful purpose in identifying the compounds in reporting test results in the scientific literature.

The secretarial expense of this program is borne wholly by the AMA as a public service, although the U.S.P. shares other costs incurred. The program makes no call upon public funds. We feel that it is gaining steadily in general acceptance and that all that it now needs is formal recognition of the same sort that is accorded the U.S.P. standards of purity for drugs.

Toward that end, we propose the following change in H.R. 11581: Delete the reference to section 508 at line 12 on page 17 of H.R. 11581 and substitute a new section:

> For the purposes of this Act, each drug shall be known by one and only one nonproprietary or common name. If it is an article recognized in an official compendium as defined in section 201(j) or is an article that was once so recognized, the common name shall be the principal title for the drug used in that compendium, provided that if it is an article that has not been recognized in an official compendium or if it is a mixture of two or more drugs in established proportions, the common name shall be the name selected for it by the body charged with the revision of the United States Pharmacopeia: *Provided*, That if no such name has been selected, the Secretary shall inform the body charged with the revision of the United States Pharmacopeia of the need for a name, and if that body fails within a reasonable time to provide a name which, in the judgment of the Secretary, is suitable, then the Secretary may promulgate regulations establishing a single, common name for such drug (or for such identical drugs), and shall publish the name together with any related or additional information which, in the judgment of the Secretary, is desirable to facilitate the correct and effective use of such name?

We believe that our proposed alternative would achieve the following purposes:

(1) Provide unequivocally that each drug have but one standard nonproprietary name;

(2) Establish that the titles used in the official compendia shall be the required nonproprietary names;

(3) Make the United States Pharmacopeia responsible for providing names for drugs not recognized in the official compendia; and

(4) Give the Secretary of Health, Education, and Welfare standby authority to see that the U.S.P. fulfills its obligations in respect to names.

We offer this proposal in the belief that it will meet all current and future needs and that it will answer all valid criticism against nonproprietary names.

However, there are two criticisms that our program cannot possibly answer. One criticism is that confusion results from having numerous trademarked names for a single drug. Obviously, those who object to a multiplicity of trademarks for drugs are, in effect, criticizing our trademark laws. A second criticism is that the Food and Drug Administration has neglected this area. With respect to this complaint, it is our view that more might be done under existing authority.

It may suffice simply to point out that the very first subsection of section 502 of the Food, Drug, and Cosmetic Act defines as misbranded any drug having labeling that is "misleading in any particular." Further on, subsection (e) requires that the labeling of drugs not recognized in an official compendium bear "the usual or common name of the drug, if such there be." It would seem to be a matter of simple logic that ordinarily only one name for a drug can be regarded as "the common or usual name" and where two or more names appear to be competing for this distinction, the FDA may readily assert which name is to be used, to avoid having labels become misleading in this respect at least. Thus, the problem of multiple nonproprietary names really should not require amending the Food, Drug, and Cosmetic Act. This act, however, does fail to chart a course of action for the case in which a drug has no common or usual name. Our proposal covers this situation and we feel that FDA needs only to make known that it will require use of U.S. adopted names. It also confers standby authority upon the Secretary of Health, Education, and Welfare of the same sort he now has under section 501(b) of the Food, Drug, and Cosmetic Act, that permits him to correct inadequacies in the tests and standards for drugs that appear in the official compendia.

We trust that we may continue to conduct our name-selection program, in such a way that the standby authority would never be invoked. We will welcome such assistance as the Secretary may give us. As grounds for optimism on that score, we may point out that the Secretary has not yet been obliged to promulgate a regulation to supplant a U.S.P. assay which he has adjudged inadequate for regulatory purposes.

To recapitulate, we feel that it provides a reasonable basis for opposing the intent and effect of section 105 of H.R. 11581 with respect to extension of presale batch certification of antibiotics. Furthermore, we hope that we have paved the way for consideration of such changes in H.R. 11581 as will end the certification of all antibiotics that are produced in substantially pure form. Finally, we hope that our suggestions on drug nomenclature will be acceptable and will result in some changes in H.R. 11581 to bring about recognition of the existing and effective system for the selection of nonproprietary names for drugs.

I want to thank you very much for the privilege of appearing here.

The CHAIRMAN. Thank you very much, Doctor, for your interesting and helpful statement.

Any questions, Mr. Roberts?

Mr. ROBERTS. Doctor, with reference to the convention, I believe you stated you undertake to revise the United States Pharmacopoeia every 5 years, a complete revision.

Mr. MILLER. Yes.

Mr. ROBERTS. And you issue supplements as needed. How do you determine when you need an interim supplement?

Mr. MILLER. We have the tests and standards under study at all times. We receive complaints that this or that may be inadequate—suggestions more often than complaints—from several sources, the Food and Drug Administration being perhaps our most fruitful source, because the FDA is applying these tests itself every day in its laboratories.

We find the producers of drugs themselves are helpful and fruitful sources of suggestions. Our own committee members are conducting the tests that are specified in the Pharmacopoeia. And they occasionally find shortcomings. Or, as frequently happens, new methods are developed by scientists to apply to the existing drugs, and we endeavor to work them into the official tests just as soon as we can perfect them.

Mr. ROBERTS. How long have you been in your present position?

Mr. MILLER. Since 1950, 12½ years.

Mr. ROBERTS. You have had quite a bit of experience in this matter of designation of drugs. Now, are new drugs entering the field more rapidly now than they were when you first came to this work?

Mr. MILLER. Yes and no. Up until a year or so ago they were. There has been some slacking off within the last year and a half, but certainly the records show that the number of new drugs is increasing with the passage of time.

In 1960 there were nearly 50 new drugs, whereas in 1950 the number was between 30 and 35. I am speaking of new drug entities, not the dosage forms or combinations.

Mr. ROBERTS. You mentioned the fact that you received complaints sometimes. In what form or forms do these complaints take?

Mr. MILLER. Various forms.

Mr. ROBERTS. A description of the drug and its properties, or what?

Mr. MILLER. Yes. These pertain exclusively to the technical aspects. The melting point of the drug as we set it forth may be slightly different than that which is correct. Without getting too technical, the assay may be giving a slightly low result because of such a thing as increased solubility which we didn't recognize, so that we change the assay to correct that slight deficiency, and the result then is more nearly correct. That is the sort of thing, if I make my point clear.

Mr. ROBERTS. In your example of penicillin I take it that you mean by that that since its introduction during the war, I believe it was 1943, it has now reached the point where it is very stable, and as you pointed out the pyrogens and impurities are not prevalent as they were in the first experiences that we had with it.

Mr. MILLER. Yes, sir.

Mr. ROBERTS. Do you indicate by that line of reasoning that you think there should be a grandfather clause written into 11581 for these drugs that we have seen and used and experimented with over the period of years?

Mr. MILLER. Rather the reverse, I should think, if I interpret correctly your use of the grandfather clause. By grandfather clause I would understand you to mean we should blanket into a new regula-

tion something that has been exempt theretofore. I would rather put it the other way around.

Mr. ROBERTS. Here is the thing that gave me that impression, and maybe we can straighten it out. You say, "At least it would be a progressive step"—after you were talking about the provision to eliminate the reference to the antibiotics—you don't have the number.

Mr. MILLER. Page 7.

Mr. ROBERTS (reading):

> At least, it would be a progressive step to limit certification to new antibiotics of uncertain purity and stability and, furthermore, to provide a positive means of dispensing with certification when it can be shown that the output is of uniformly high purity and stability.

Mr. MILLER. May I make that clear?

Mr. ROBERTS. Yes, sir.

Mr. MILLER. What I mean to say is that all five of the present antibiotics that are now required to be certified are being produced in a state of high purity and stability. Certification really isn't needed for them any longer. It once was, but isn't now.

New antibiotics are coming along, however, which are in a state of purity that these others were 15 to 20 years ago, and if certification is to be continued, it would make sense, it seems to me, to restrict it to these new antibiotics but only for such period as they are being produced in an impure and possibly less stable state.

And when the technology improves so that these new ones are being produced in pure state, then let's get away from certification as being unnecessary and a duplication of testing effort.

Mr. ROBERTS. Can you name some of the new antibiotics that you think have not reached the point of stability and purity that penicillin has?

Mr. MILLER. Yes; I can. I could do better if I had access to the list of the 30 that——

Mr. ROBERTS. Would you like to supply that for the record?

Mr. MILLER. I would hate to put the finger on two or three of the new ones that might be less deserving of mention than some of the less pure ones.

Mr. ROBERTS. Let me suggest that you supply that for the record.

Mr. MILLER. I would be glad to do that; yes.

Mr. ROBERTS. Now, this theory of one name or generic name for drugs, who first promulgated that idea, do you know?

Mr. MILLER. Of having a single name?

Mr. ROBERTS. Yes, sir.

Mr. MILLER. I couldn't say. I would suppose that it probably originated from frustrated teachers of pharmacology, as I was once myself, when they were obliged to use several names in order to make sure that students understood what was being taught. More recently—in trying to get at the origin of the suggestion—more recently, the idea has grown up with an economic aspect, that is, if the so-called generic or nonproprietary name were given more prominence, at the expense of trade names, the thought is that that would result in lowered costs of drugs.

I think it is a fallacy, but I don't believe that we need to go into that particular aspect. The idea, I think, is perfectly obvious and sound, to have only one name for a compound, in general, is a good thing.

Mr. ROBERTS. Don't you think it would be very difficult to do in view of the many complex chemical combinations that make up some of these compounds?

Mr. MILLER. No. I must not have made my point. I think it is quite feasible to have one nonproprietary name for each compound. We must also have a chemical name which will be long and complex and precise. And that is all right. That will be in the chemical literature. And it will identify this nonproprietary name when properly used. But for the physician and for the pharmacist, we can very well have one single nonproprietary name for each drug.

Mr. ROBERTS. And you believe the Food and Drug Administration has that authority under the present law?

Mr. MILLER. I think they do. I think that they could long ago have said, when a new drug application came in, that used a strange and new and contrived name, they might very well have said, "Well, this drug has been in numerous combinations for which new drug applications have become effective, and in those it was called, let's say, ABC. But here you propose to call it XYZ. We believe that to avoid confusion and protect the public health that you should call it in your labeling just like everyone has done earlier." But FDA have not done that; in fact, they seem to have gone out of their way to have avoided doing it.

Mr. ROBERTS. You were with Food and Drug for 9 or 10 years, I believe?

Mr. MILLER. That is right. I wasn't in the new-drug branch. I was in the Pharmacology Division.

Mr. ROBERTS. And you had a good relationship, I mean your committee with the Food and Drug?

Mr. MILLER. The closest and most cordial; yes.

Mr. ROBERTS. That is all I have, Mr. Chairman.

The CHAIRMAN. Mr. Glenn.

Mr. GLENN. Doctor, after the USP sets these standards do you or any allied organization take it upon yourselves to see whether the industry is complying with using these standards?

Mr. MILLER. Not in the police sense. We do from a technical standpoint, to see if the standards are feasible and practical, but it is the responsibility of the Food and Drug Administration to police them as a part of the executive branch of the Government. If we were a part of the Government, we would belong to the legislative branch. In fact, it is not infrequently said that our function is an extension of the legislative effort of the Congress. Indeed, it was alleged in court one time that Congress must have exceeded its authority in having delegated to the USP this function back in 1906. But the Supreme Court of the State of Wisconsin ruled otherwise.

Mr. GLENN. You have said that you do exercise name selecting.

Mr. MILLER. Yes.

Mr. GLENN. And if this bill is enacted into law, is it your contention that the Secretary will then take over the jurisdiction which you are now exercising?

Mr. MILLER. He certainly will be authorized to do so. Because the words are "may promulgate regulations." I think it is not obligatory, but he is given the right to do so. And furthermore, the terms of the bill before the Senate are such now—I haven't had a legal expert inter-

pret them for us, but the terms are such that he is required to do certain things. He is required to review the titles of the U.S.P., and he may change them if he feels that they could be simplified and made more useful.

And I think boiling it down, a page and a half of this bill to two sentences, that seems to be the intent of the present form of H.R. 11581.

Mr. GLENN. Thank you very much. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Curtin.

Mr. CURTIN. I take it from your statement, Doctor, that you would rather see all drugs designated by the full technical name rather than initials; is that correct?

Mr. MILLER. If you will permit me to use the term "nonproprietary name" instead of "full technical name," yes. But if you mean the chemical name, the complex chemical name, no. We think the use of initials is abominable and dangerous. But this is a terribly complex subject. For complex molecule that has a long and difficult-to-pronounce name, that is, the full chemical name, we try to give a name of three, four, six syllables which will be the nonproprietary name that will be assigned to that compound and that alone.

Mr. CURTIN. The so-called generic name?

Mr. MILLER. The so-called generic name; yes.

Mr. CURTIN. When a doctor is writing a prescription to be filled by a druggist, doesn't he normally use these initials rather than the full generic name?

Mr. MILLER. Too frequently the pharmacist has to exercise his powers of guessing what the doctor meant. If he is uncertain in any respect he will check back with the physician, and you can guess at what that gives rise to, because the physician thinks that the pharmacist ought to know, be smart enough to guess what he meant, and so on.

But the physician should be more specific, if I were to be allowed to criticize him.

Mr. CURTIN. You call attention in your statement to the distinction, for example, between DDT and DFP.

Mr. MILLER. Yes.

Mr. CURTIN. Human nature being what it is, don't you think that doctors are still going to use those initials when they write prescriptions, regardless of what you people recommend or what the law may say?

Mr. MILLER. If he persists in disregarding what he is taught, he may. But doctors are generally pretty careful to be specific. But there are areas in which they abbreviate, particularly in prescribing the biologicals, which have terribly long names.

Mr. CURTIN. And that is going to continue?

Mr. MILLER. That is going to continue.

Mr. CURTIN. This practice is going to continue in doctors' prescriptions, regardless of what we say or do here; isn't that true?

Mr. MILLER. Yes. The U.S.P. was once asked to set up a standard set of abbreviations, as is done in England. The British Pharmacopeia has a standard set of abbreviations where such would be appropriate. And this was one of the suggestions that we received one time.

We went to the Council on Drugs of the American Medical Association, and you could hardly imagine anything being denounced more roundly than that suggestion was. We went to the NIH—the National Institutes of Health—which licenses producers of the biologicals. They were unalterably opposed to the idea that the U.S.P. should set up standard abbreviations for the biologicals.

Mr. CURTIN. What do you think about it? Don't you think it is a practical suggestion?

Mr. MILLER. If I had not, I wouldn't have taken time to consider it. I felt as you have indicated a moment ago, doctors are human, and tend to be a trifle lazy in writing prescriptions. So I felt that it might help to have standard abbreviations.

Mr. CURTIN. It would seem to me that the greatest need for being very clear in what drug is being described is in the field of writing a prescription rather than in an article on the drug or public mention of it in an advertisement, because there the danger from a mistake is much less than it is when a doctor is saying to a druggist, "This is what I want the patient to have."

Mr. MILLER. And he is more likely to be short of time when he is writing prescriptions than when he is writing an article for a medical journal.

Mr. CURTIN. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Moss.

Mr. Moss. Dr. Miller, you have apparently two major objections to the legislation now before us. The first, the batch-by-batch certification?

Mr. MILLER. Yes.

Mr. Moss. And then the matter of name designations?

Mr. MILLER. Yes. I wouldn't go so far as to put the two in the same degree of opposition.

Mr. Moss. No, I understand one you are flatly opposed to certification.

Mr. MILLER. Yes.

Mr. Moss. And the other you suggest a modification to which would ultimately reach the same result.

Mr. MILLER. I think so, yes.

Mr. Moss. I can thoroughly understand the latter objection. The first one is more difficult. You have no function in your role with the U.S. Pharmacopeia of checking any of these products once there has been an agreed upon standardization?

Mr. MILLER. Our function is that of providing purity tests and standards.

Mr. Moss. Are you familiar with Dr. John L. Harvey?

Mr. MILLER. Yes.

Mr. Moss. In a speech given by him on August 8 in San Francisco, to the American Bar Association, discussing this question of certification, he stated that—

Batch-by-batch certification of all antibiotic drugs is needed because: (*a*) more than any other drugs, antibiotics are the first choice in treating life-threatening infectious conditions.

I think it has been frequently charged that they are too readily resorted to in many instances without proper evaluation of the effect which might arise when they would be more critically needed.

(*b*) Most antibiotics are produced by complex processes in which both the desirable antibiotics and quantities of undesirable byproducts are manufactured.
(*c*) The potency of antibiotics must be determined by biological assay procedures, the interpretation of which requires unusual competence.

Do you disagree with any of those statements?

Mr. MILLER. I would not disagree with them, but I would hold that the antibiotics are not at all unique in that respect.

Mr. Moss. They said "despite the manufacturer's check." Well, unique in one respect in that more than any other drugs—if you agree with his statement——

Mr. MILLER. No; I do not think so.

Mr. Moss. You do not think they are resorted to more frequently than any other?

So if you accept that statement as being accurate——

Mr. MILLER. On a quantity basis, of course, because about one-third of the drugs used in terms of volume are antibiotics, so that you cannot deny that.

Mr. Moss. He said:

Despite the manufacturer's check of each batch of antibiotics before submitting it for certification, in fiscal year 1961 samples from over 100 batches offered for certification—

we are dealing now with only the five?

Mr. MILLER. Yes.

Mr. Moss. Not the other 25?

Mr. MILLER. No.

Mr. Moss (continuing):

failed to meet the standards set forth in the regulations.

Mr. MILLER. What was the percentage?

Mr. Moss. It does not relate it to percentage.

Mr. MILLER. I see.

Mr. Moss. He said samples from over 100 batches offered for certification failed to meet the standards set forth in the regulations.

Mr. MILLER. Mr. Harvey has the records. I would not challenge that figure at all, but I would offer this, knowing some of the circumstances.

Whether this pertains to the year that he is speaking of, but this used to be the practice among the antibiotic producers:

That when a batch has been finished and their tests had reached a stage that they felt reasonably sure that the material was satisfactory, they dispatched the FDA sample to Washington, so that Washington might start its testing in order that they both might get done sooner.

In many cases, and it used to be prior to—not long ago—I should not say "many"; occasionally, let us say—the producers would find in completing their tests that in some respects that the batch did not live up to the requirements.

It used to be that they could withdraw that sample and say, "We wish to withdraw the application for certification."

For some time now, Food and Drug has refused to permit them to withdraw, but has been counting that sample as a rejection.

As a result, I understand within the industry that they are now completing all of their tests, such as they would do, in any case, before they put the drug on the market, before sending a sample to the Administration.

Mr. Moss. This would be very current practice?

Mr. MILLER. Yes.

Mr. Moss. Because it is for the 1961 fiscal year?

Mr. MILLER. Yes.

With respect to how much there has been, it would be very relevant to inquirie in just what respect these 100 samples failed. I would be greatly surprised if these were very significant deficiencies.

Mr. Moss. Of course, the question is as to the currency of your own experience as contrasted to the material developed within the Food and Drug Administration.

Mr. MILLER. I am quoting this experience——

Mr. Moss. If we accept the fact that Dr. Harvey is a reliable and informed source of information, he cites this as an illustration of the need for not only a continuing of the existing practice, but an extension of it.

Mr. MILLER. Yes.

Mr. Moss. I would assume that he is competent to make such a determination.

Mr. MILLER. He certainly has access to the record.

What he has not said and indicated, in citing 100 instances, whether those were material deficiencies, whether they were very serious or they simply had a misspelling on a label or something of that kind.

Mr. Moss. Do you think, if they were not material instances, that from them he would conclude that a need existed for a continuation of this practice?

What motivation might be anticipated?

Mr. MILLER. Mr. Congressman, the Food and Drug Administration carries out a very substantial part of its testing program on the basis of fees collected from manufacturers, fees which are determined by them as being essential.

Therefore, it somewhat relieves the Food and Drug Administration of coming to Congress for appropriations.

Mr. Moss. Well, now, let us examine that carefully.

Do you know this as a fact: That it relieves them from coming to the Congress for the appropriation? There are many agencies, such as the Post Office Department, that collect a lot of fees.

Mr. MILLER. Yes.

Mr. Moss. But, Doctor, believe me, they come to us for the authorization for every dollar they expend.

Mr. MILLER. I realize that.

Mr. Moss. And I doubt very much that this money collected in fees goes into some fund exempt from reappropriation by the Congress.

Mr. MILLER. May I ask that you check into that before the latter part of this week.

Mr. Moss. I will check, certainly, but I would hate to think that we are dealing with an agency so unreliable that fees approximating $1 million a year, and that, related to its total budget, is rather an insignificant portion of it—that this bait influences their judgment to give misleading advice and unfounded advice to this Congress.

If that were true, Doctor, then I think we should make a most searching inquiry of this operation, because it would not be at all responsible.

I do not like to see that sort of motivation attributed unless you have some basis for so intimating.

Mr. MILLER. I would be the last one in the world, because I have so many good friends in Food and Drug Administration, to attribute any motives but the best to them, but it is my understanding and it is the understanding of the industry——

Mr. MOSS. You just indicated a rather base motivation.

Mr. MILLER. I am indicating that Mr. Harvey wants to make a good case for maintaining certification.

Mr. MOSS. In order to get the the fees?

Mr. MILLER. In order to get the fees.

Mr. MOSS. Mr. Chairman, I might observe that is a most amazing statement, and does no service to Dr. Harvey.

Mr. MILLER. If it is a disservice, I want to apologize publicly to him and to the committee.

Mr. MOSS. On that basis, then, sir, I note that the Pharmacopoeia is supported by two sources of revenue. I was not going to mention it, but if we must be so suspect of those who appear before us as to their motives, what are yours in this, and what do you derive from the sale of sample drugs?

Mr. MILLER. These are reference standards that are required for the carrying out of the assays.

Mr. MOSS. Yes.

Mr. MILLER. And it might be said that we write into our assays the need for standards that one would have to have, but I can assure you that it is so much trouble for us to put these out that that is certainly not the reason they go into these tests.

Mr. MOSS. You state here that inasmuch as its sole support is the net income from the sale of the USP and from standard samples of drugs made available for reference purposes, that I assume that the revenue derived from this activity contributes to the support of your shop?

Mr. MILLER. Yes.

Mr. MOSS. And does this influence, in any way, any of the judgments you make here or the advice you give this committee?

Mr. MILLER. I assure you that it does not.

Mr. MOSS. But you think that the personnel of Food and Drug is just a little less pure in motive than you?

Mr. MILLER. No, I would not, Mr. Congressman, wish to impugn——

Mr. MOSS. I am concerned because you are a former employee.

Mr. MILLER. Yes.

Mr. MOSS. And you are talking about former associates, and it is an amazing statement and a disturbing one to me to hear you make it.

Mr. MILLER. And, if I am not wrong, it should be disturbing.

I have the recollection one time of Mr. Larrick having been explaining this system before the Appropriations Committee of either the Senate or the House—I suppose it would be the House—where it was suggested that all drug testing be put on a fee basis, and Mr. Larrick indicated that that would put him in a very embarrassing position.

Mr. Moss. Doctor, I think this matter of whether an industry being policed should pay the cost of the administering of the program is one that is not related solely to Food and Drug.

This committee, as you know, has rather a broad jurisdiction, having all of the regulatory agencies of the Government, the independent regulatory commissions.

Mr. MILLER. Yes.

Mr. Moss. You are probably aware that it costs a lot of money to regulate television and radio.

Mr. MILLER. I am sure it must.

Mr. Moss. There are many who feel that we should impose fees to recover all of this cost and perhaps it would be good business, but I think that whether or not you show a fine record on fees when you only produce a piddling $1 million a year in a budget of the size of the one Food and Drug has is really unworthy——

Mr. MILLER. At one time their budget, when this $1 million was substantially what it is now, their budget was in the neighborhood of $12 to $14 million.

Mr. Moss. It is not too many years ago that the budget of the United States was less than the cost of the interest on the debt at the present time, sir.

They all grow.

You would not want me to conclude in this vein of suspicion of motives that the objective in the proposed amendment to the section 508 or substitution of 508 is in order to continue your very excellent and well-reputed publication in business, would you?

Mr. MILLER. You certainly might assume that.

Mr. Moss. I do not.

I think you feel you render a service and that you are competent to render it and there would be no need to duplicate.

Mr. MILLER. I do no like to attribute that sort of motivation to people.

Mr. Moss. I hope you will not sincerely.

Mr. MILLER. I would not want to.

Mr. Moss. I might add that in your statement you appear to have an error here.

I think you are not wanting to delete but rather to substitute language on page 17.

Mr. MILLER. That perhaps is a better word.

Mr. Moss. What you are seeking here in this proposed amendment, then, is to have the Secretary first exhaust the resources of existing, recognized sources before, on his own, designating a name for any drug. But you feel that there is sufficient justification for arriving at simplification of terminology that it should be achieved ultimately?

Mr. MILLER. We think, yes, that he should use the existing system which costs the Government nothing; a voluntary and, I hope we can say, democratic process for arriving at names which is working, and we think working real well, should be used, instead of burdening the Food and Drug Administration with this business of selecting names.

Mr. Moss. Of course, I had assumed that this would probably be the sort of rule or regulation the Secretary would adopt under the language as it is in the bill, in order to achieve the final objective of the simplification of name or terminology.

That is all the questions I have, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Mr. MILLER. Thank you, again.

The CHAIRMAN. I might advise the committee that we have four other witnesses this afternoon.

Mr. Fred L. Van Aalst?

We are very glad to have you with us, and we will be glad to have your statement.

STATEMENT OF FRED L. VAN AALST, CONTROLLER, FLEUROMA, INC.

Mr. VAN AALST. Mr. Chairman, my name is Fred L. Van Aalst. I am the controller of Fleuroma, Inc., New York. We are members of the Essential Oil Association of the U.S.A., and fully support the statement which will be made before this committee by its president, Mr. Frank F. Dittrich.

I appear on behalf of my company, in opposition to section 201 of H.R. 11581, the factory inspection authority, which is the only provision in this bill that concerns my company directly.

Fleuroma, Inc., is in the business of creating, manufacturing, and selling perfume bases, and we have limited ourselves to this highly specialized field. We do not make or sell any finished cosmetics or other consumer product; nothing we make is sold, as such, to the public. Our perfume bases are sold to the manufacturers of finished cosmetics; they are our customers.

My company was started in 1946 by two partners who invested not only all of their savings and money borrowed from friends, but also unique craftsmanship, excellence, and experience into this venture. When we started in 1946, in a small garage-type building, we had a staff of three. When I joined the company, we had 12 people. Today we are still small, employing about 80 people; but our sales are now in the millions of dollars, and we have carved a niche for ourselves in this industry. We are highly regarded for our creative ability, and count most of the largest and best known cosmetic companies among our customers.

Permit me to emphasize that our work requires creative ability, unique talents, and true artistic qualities—rather than the application of a skill or trade. By selecting and blending scores and often hundreds of ingredients from among the thousands available, each one of which we must know intimately, and after carrying out countless experiments which often stretch over periods of years, we finally produce the fragrance that will be the heart of a new perfume, cologne, or cosmetic preparation. This blend, when finally established as a result of this long and painstaking procedure, is recorded as a formula which goes into our files.

Obviously, this formula represents all of the talent, all of the artistic creativity, and all of the accumulated experience of which we are possessed.

Like every responsible citizen, I want to see the welfare and safety of the public protected. I have spent most of my working life in the business of perfume bases, and naturally am in close contact with the manufacturers of finished perfumes and cosmetics. My company alone, during its existence, has sold perfume bases that must have

been used in the production of billions of bottles and jars and tubes of perfume, cologne, creams, and powders. I know of no cases of injury or harm of any kind as the result of the use of perfume bases.

The factory inspection provision of H.R. 11581, if applied—as this bill now proposes—to the creators and manufacturers of perfume bases, would add nothing to the safety of the public. However, the inevitable losses which would result from the inspection and the consequent violation of the secrecy of our formulas would be a tragic blow to my company and other companies in our field.

If we believe that a man is entitled to the fruits of his labor; if we believe that he is entitled to safeguard his most precious possession; and if we believe that the laws should protect these rights, then the manufacturers of perfume bases should be exempt from the factory inspection provisions of H.R. 11581. For the sake of what is just and right, I appeal to you to do just that.

Thank you for the opportunity to make this statement.

The CHAIRMAN. Thank you, Mr. Van Aalst, for your statement, and certainly your plea will be given most careful consideration.

We are glad to have your statement.

Mr. VAN AALST. Thank you.

The CHAIRMAN. Dr. Bernard L. Oser?

STATEMENT OF BERNARD L. OSER, PH. D., PRESIDENT AND DIRECTOR, FOOD & DRUG RESEARCH LABORATORIES, AND CHAIRMAN OF THE FOOD AND DRUG ADMINISTRATION LIAISON COMMITTEE OF THE AMERICAN COUNCIL OF INDEPENDENT LABORATORIES, INC.

Mr. OSER. Mr. Chairman and members of the committee, my name is Bernard L. Oser. I am president and director of the Food & Drug Research Laboratories, Inc., Maspeth, N.Y., an independent consulting, research, and testing organization. I have the honor to address your committee in my capacity as chairman of the Food and Drug Administration Liaison Committee of the American Council of Independent Laboratories, Inc., an association of which our laboratories are a charter member and of which I was formerly president. The council was founded in 1937 and consists of 74 member laboratories with 171 headquarters and branch laboratories throughout the Nation.

Of special interest to our members is the proposal to include consulting laboratories in the factory inspection provisions of H.R. 11581. It is widely held in our profession, and by many in the industries we serve, that such unrestricted inspection as is contemplated would seriously compromise the confidential relationship existing between us and our clients. It would furthermore place laboratory administrators in a difficult and embarrassing position with respect to their obligation to guard the property and rights of their clients.

Independent consulting laboratories are not engaged in the manufacture or sale of foods, drugs, cosmetics, or devices; they are not factories in any commonly accepted sense of the term; their stock-in-trade is information or advice, and such laboratory services as they may render incidental thereto include basic and applied research and product and process development as well as analyses and assays.

These analytical services may be related to identity, purity, quality, or potency and may provide information for labeling purposes, but such services are only a part, and in many cases a minor part, of a consulting laboratory's activities.

It is pertinent to this discussion to contrast the Food and Drug Administration definition of a consulting laboratory with that of the American Council of Independent Laboratories for an independent laboratory which is a—

> proprietorship, partnership, or corporation which is not affiliated in any manner with either a governmental agency or a tax-favored academic or research institution; or with an outside proprietorship, partnership, corporation, or trade association in any manner which may jeopardize its capacity to conduct investigations, render reports, or give professional council objectively and without bias.

In the FDA definition a consulting laboratory is—

> a laboratory which for a fee or other remuneration, performs assays or other laboratory services for a manufacturer, processor, or compounder who owns or has under his control an establishment which (other than as a consulting laboratory) is subject to inspection under this section.

Bearing in mind that many universities, medical schools, hospitals, et cetera, regularly or occasionally perform such services under grants from industrial sponsors, it is apparent that the proposed regulation can readily be construed to encompass inspection of these institutions as well as of commercially operated laboratories. We cite this not to suggest that they should be excluded if they render such services, but to indicate the extremely broad scope of the proposed extension of authority.

To the best of our knowledge, no member of the American Council of Independent Laboratories, nor any other consulting laboratory, has ever denied a request on the part of a representative of the Food and Drug Administration to inspect its facilities. We have, in fact, urged such visitations and have welcomed the opportunity to display our physical facilities and equipment. It is regrettable that such invitations are not more frequently accepted since this would help acquaint responsible officials with the availability of our services to both Government and industry, for implementing the technical requirements of the Food, Drug, and Cosmetic Act.

In testimony before the Kefauver committee former Secretary of Health, Education, and Welfare Ribicoff stated that in the 32 months ending August 1961, 122 firms had refused to permit 1 or more phases of inspection "needed to make a complete determination of the legality of some phase of the drug business." I might add that he also said: "Most of the firms we inspect voluntarily permit such inspections today."

No elaboration of the nature or source of these refusals was given to permit a conclusion as to whether or not any consulting laboratories were involved. However, Commissioner Larrick has acknowledged that "the desirability of mentioning independent laboratories in connection with any new legislation is not, so far, occasioned by refusals of such laboratories to permit inspection." An extremely rare situation has been cited where a laboratory, suspected of rendering dishonest reports, was subsequently inspected by FDA and found to be unequipped to perform the pharmaceutical testing services it purported to render. In this instance a conviction was obtained by the

Food and Drug Administration under the present law. We seriously question the generalization implied in testimony before this committee that false reports given to clients by "some" laboratories make it necessary to broaden the existing inspection powers of FDA.

Thus, insofar as the inspection of facilities of consulting laboratories is concerned, the need for amended legislation does not appear to have been established, nor is it believed to exist. In saying this, however, a distinction must be made between inspection of physical plant and equipment, on the one hand, and records and files, on the other.

To the extent that the contemplated inspection is unrestricted and includes the examination of correspondence files, laboratory notebooks, and similar records and reports, or any inquiry into the scientific or technical qualifications of laboratory personnel, the American Council of Independent Laboratories wishes to register its unalterable opposition to this proposal. Our objection is predicated not merely on the possibility of fishing expeditions, to which reference has been made by other witnesses, but is based on the facts that much of the work of a consulting laboratory—and, hence, its files, records, and so forth—has no direct relationship to pending or proposed administrative matters; that services rendered for a specific client may relate to research projects or to the development and improvement of products which may not come within the scope of the Food, Drug, and Cosmetic Act; that such services, and hence records, may relate to products or processes not yet subject to patent protection, or may involve independently obtained data concerning competitive products, or they may relate to pending or proposed litigation to which a competitor or the Government itself may be a party. These are but examples of the highly confidential nature of the relationship between consultants and clients, a relationship no different from that which exists between lawyers and their clients, or between physicians and their patients.

A consulting laboratory having custody of secret formulas or other confidential information belonging to a client is not in the same position as the client with property rights in such information. The consultant should not be expected to assume the responsibility of deciding what and how much of his client's information may properly and legally be released; this should be the prerogative of the client, rather than of the service laboratory. The responsibility for withholding what he may legally be entitled to withhold should rest on the client's shoulders. Under the proposed amendment a manufacturer would be exposed to compulsory disclosure of confidential matters under circumstances beyond his control and a consulting laboratory entrusted with such confidential data might be criminally liable for guarding too zealously its client's interests.

The ultimate objective of scientific investigations which a consulting laboratory is asked to undertake is sometimes not disclosed even to the investigator. Under these circumstances it is difficult to decide what is pertinent to a food and drug matter and what is not, or what is control testing as distinguished from research. The line of demarcation between research and control testing is not so sharply drawn as to distinguish one type of record from the other. This is not to deny that where a clear distinction does exist, and a request is made for specific analytical control data, they should be made avail-

able for inspection. But for this purpose it seems unnecessary to expend present inspection powers to the degree that irrelevant confidential information might also be disclosed.

It has been contended that any information made available to a food and drug inspector is treated confidentially and that trade secrets have never been known to be revealed except when necessary in administrative or judicial proceedings. In such statements, the qualification must be recognized that no such instances are "known." This does not mean they do not exist or may not occur. Without questioning the claim of the Food and Drug Administration for a good record in this respect, it must be acknowledged that proof of a breach of confidence or misuse of private information is extremely difficult to establish. To say that no known violations have occurred is tantamount to claiming a drug to be safe simply because no adverse effects are known. Scientific or technological information once impressed on a prepared mind cannot readily be erased. The application of such information, either directly or perhaps subconsciously under appropriate circumstances, is hardly avoidable. Furthermore, it is well known that Government agencies, like industrial organizations, are experiencing a constant turnover of personnel. What opportunity has the FDA or any other agency to check on the misuse of confidentially gotten information, once an individual has left its employ?

It has been claimed that adequate administration of the food additive regulations is hampered by the inability of FDA inspectors to look into production and control records in plants. It is certainly not news to this committee that practicable analytical methods are required for detecting the presence and amounts of additives to food, as well as for controlling the purity and potency of drugs. These methods are more definitive and unequivocal than self-serving production records. To the extent that inspectors might rely upon production or control records in lieu of independent analyses, it would tend to encourage the maintenance of duplicate or ex post facto records.

It has been proposed that FDA inspection be extended to include inquiry into the qualifications of technical personnel. The problem of certifying laboratories has been considered for many years and progress in this direction, particularly as applied to clinical laboratories, has been made in many States. However, the setting of standards of competence for scientific or technical personnel at different professional levels is fraught with many difficulties and has been the subject of concern among professional societies representing various scientific disciplines.

Under these circumstances it would seem logical that a prerequisite to any attempt to inquire into the qualifications of laboratory personnel should be the adoption of criteria, not unilaterally by FDA, but in collaboration with the appropriate technical and professional organizations. The complexity of this problem would seem to militate against the advisability of granting authority to inspectors to pass upon the qualifications of technical personnel. This should be the responsibility of the operating management of any organization engaged in scientific activities.

In summary, we respectfully submit that the inclusion of consulting laboratories with manufacturing establishments subject to the broad

inspection powers contemplated under the proposed amendment, is neither necessary nor desirable because (i) adequate authority for such laboratory inspection as is appropriate to the purpose of the act already exists; (ii) no evidence has been established that inspection under present law has been refused by a consulting laboratory; (iii) reasonable limitations have not been defined which would restrict inspection to specified analytical control data; (iv) no standards or criteria for the qualifications of personnel have been established by the pertinent scientific or technical professions; (v) no protection is afforded the consulting laboratory against disclosure of irrelevant or confidential information belonging to a client; and (vi) unrestricted inspection would impair the confidential relationship between scientific consultants and their clients to the extent of seriously jeopardizing their professional activities.

The CHAIRMAN. Doctor, thank you very much for your discussion of this particular problem, which I think is the first one we have had on the question of consulting laboratories.

Any questions by members of the committee?

Thank you very much.

Mr. OSER. Thank you.

Mr. MOSS. Mr. Chairman, I have no questions, but I wanted to have the record reflect the fact that the fees received by the Food and Drug Administration are, as I suspected, paid into the Treasury and subject to the annual appropriation by the appropriate committees of the Congress.

I think that the doubt raised by Dr. Miller's statement as to whether or not that was the procedure should be clearly resolved, and I had the matter checked with the agency in order to ascertain the truth.

The CHAIRMAN. Very well.

We think the record should speak what the facts are.

Dr. Miles H. Robinson?

Dr. Robinson, you may proceed.

STATEMENT OF MILES H. ROBINSON, M.D.

DR. ROBINSON. Mr. Chairman and members of the committee, I am Miles H. Robinson, a graduate of the University of Pennsylvania Medical School in Philadelphia, and for the last 20 years I have been in the practice of internal medicine in Washington State and in Maryland, with the exception of 4 years teaching and doing research in physiology and pharmacology at Vanderbilt Medical School in Nashville, Tenn., and at the University of Pennsylvania Medical School.

I am an independent, practicing physician, not connected in any way with the drug industry, and I have some facts with documentation to give the committee, which I believe are good reasons, among others, for passing H.R. 11581.

The fact that large numbers of children have been born without arms in Europe as a result of taking a tranquilizer drug also approved in this country for testing by the Food and Drug Administration seems reason enough to pass legislation to strengthen the safety provisions of the FDA.

Yet, there is a deeper significance to this tragedy which should be laid before this committee. It is that the people of this Nation are

being steadily educated by doctors and the drug industry to take a drug whenever they feel anxious about anything. They are thus diverted and distracted from really constructive actions to preserve health, and the moral fiber of the country is seriously weakened.

As Dr. Herbert Ratner, director of public health for Oak Park, Ill., says:

> * * * we must not forget that, with the barbiturates and stimulants, the tranquilizers are the most misused drugs in the United States. We consume fantastic quantities of these drugs. For many they are used as a panacea to solve personal problems; they are practically replacing the *function of the virtues* in striving for a sane and well ordered life.

The emphasis is mine. This quotation is from an interview printed in pamphlet form by the Fund for the Republic, Inc., Santa Barbara, Calif., 1962, page 34.

Dr. Ratner is making the point that the more tranquilizers, the less people are resorting, let us say, to the Bible and the Ten Commandments.

What is our consumption of tranquilizers? I have not heard that given in testimony before the committee. I was able to get yesterday the dollar volume for 1958 and the tonnage for 1961. In 1958, $200 million was spent on them; one-fifth of all Americans had taken them; 1 out of 3 prescriptions were for tranquilizers; and 20 million Americans were taking them regularly.

This is from a clipping from the Baltimore Sun in 1958, reporting a speech by the assistant professor of pharmacology at the University of Maryland Medical School.

In 1961, I have not got similar figures, but 7,200 tons were produced, which was 119 tons more than in 1960. This is just in the United States, and that reference is from Drug Trade News, August 6, 1962, page 55.

The thalidomide catastrophe is just the part of this iceberg, so to speak, which shows above the surface. Underneath the surface lie the potential consequences of continued intemperate ingestion of drugs, tranquilizers, and others. We have now had a strong warning and it may be a fortunate thing that we did not have to wait 20 years as in the case of cancer from painting radium on watch dials before we got this warning.

Who is promoting the widespread consumption of tranquilizers, and how do they do it? I would like to read very brief excerpts from typical misleading advertisements which the drug industry displays to doctors and which urge a fantastic use for drugs. I picked almost all of these advertisements out of my mail which came in the last few days.

This is a full-page advertisement on the back cover of the Maryland State Medical Journal for July 1962, in which a drug called Librium, "the successor to the tranquilizers," is recommended for a pregnant mother with her first baby, who imagines that she is having birth pains 6 months ahead of time.

You will recall that thalidomide was given in just about this period, early in the pregnancy.

This drug is also recommended for "the surgical patient who sees doom in the frown of a nurse."

Here is another full-page advertisement for Librium in another free medical magazine.

May I interpolate a remark in connection with what has been said here about the generic name for drugs. The remark was made that doctors would not like the generic name; that they would prefer to stay with the trade name of some drug company they trust.

I would dispute that.

I think that every conscientious doctor will be definitely affected by this new law, if it goes into effect; that he will then use the short generic name.

As Mr. Miller, of the United States Pharmacopeia, told you, there are three names. There is a brand name, for example, Thorazine, which I am looking at here on another tranquilizer advertisement; then there is the generic name, which happens to be chlorpromazine, three or four letters more in the word; then there is the long chemical formula, which takes 2 or 3 inches on a page.

The new law, which you are considering here, will give the Food and Drug Administration, at least under Mr. Miller's amendment, standby power, if the U.S.P. does not do it first, to standardize on the short generic name, and I want to say with emphasis that any doctor who will not write three or four more letters on a prescription is not a very good doctor.

He has to be careful that his prescriptions mean what they say. He can be sued for malpractice if they do not. Both he and the druggist have been, and will be, sued for malpractice, if anything goes wrong.

And, finally, it is a very good thing for the doctor to get acquainted with a standard name for these drugs which have so many duplicate trade names.

Here is another tranquilizer advertised in another free medical magazine, which comes out in a newspaper format, the Medical Tribune for August 20, 1962. Here we have a drug called Mellaril, recommended also for women with emotional symptoms in connection with childbirth. It is also for—

tense, nervous patients seen in everyday practice * * * for chronic fatigue, insomia, anxiety, and apprehension, vague digestive disorders, etc.

This is all stated on the advertisement.

I am impressed with that "etc." It just tapers off into the wide, blue yonder where tranquilizers are claimed to be good for everything.

Here is another tranquilizer advertisement, also full page, in the same Maryland State Medical Journal for July 1962. It has a beautiful picture of a happy family, with the caption—

Emotional control regained * * * a family restored * * * thanks to a doctor and "Thorazine" * * * Experience in over 14 million Americans * * * A fundamental drug in both office and hospital practice.

Down at the bottom it also says: "Posed by professional models." They do not want to give the doctor the idea that these handsome people were ever sick, perhaps, or took a tranquilizer.

Let us stop for a minute and take note that many of these advertisements appear in the official journal put out by the State medical society, which is really the local branch of the AMA, and this gives the advertisement a definite degree of official sanction. But the connection lies deeper than that. The facts are that in practically every State in the Union, it is the big drug advertisements which constitute the major financial support for each State medical society journal.

For example, the Maryland State Medical Journal has 54 pages of advertisements in it this month, and they are almost all of them big drug advertisements.

Furthermore, about half the income of the AMA itself comes from drug advertisements in AMA-controlled journals. This has been true for years.

The reference I can give you on that is from the Journal of the American Medical Association itself, volume 140, page 614.

A similar reference in the same magazine, in the same volume, page 979.

A similar reference supporting this statement I have made, volume 147, page 1246, in 1951.

Will organized medicine ever stop its narrow-minded preoccupation with drugs, far too many of them used precipitantly, displacing sensible procedures, maintaining the patient in a weak and ignorant condition? Does a dog bite the hand that feeds it? There is, of course, a monopoly here, a collusion between organized medicine and the drug industry which strongly suppresses any nonsurgical healing which does not depend on drugs.

Perhaps I may quote to you a statement by Oliver Wendell Holmes, Sr., the physician father of the Justice Holmes who was quoted by one of the pharmaceutical witnesses present before you last Monday.

The father of the great jurist was an equally famous man. He was the codiscoverer of the cause of childbed fever, along with Semmelweiss in Europe, a very great man.

At the time when he was professor of anatomy at Harvard, he made this statement before the Massachusetts Medical Society in 1860.

He said:

> I firmly believe that if the whole materia medica [that is, our drugs] as now used could be sunk to the bottom of the sea, it would be all the better for mankind—and all the worse for the fishes.

I do not mean to say I am a therapeutic nihilist, but I would mention to this committee that our greatest doctors in the past, Hippocrates, who began first with diet and regimen of daily living, then secondly with drugs, and thirdly, if necessary, with surgery; Sir William Osler, probably the greatest physician we have ever had in this country—all such men were very cautious about drugs, and drugs came largely second in their thoughts about what to do in treatment.

Let us also stop and ask how freely can the money flow in this deal from the drug industry to organized medicine?

Mr. Biemiller has already given the figures I was going to give you showing that the profit rates of the drug industry exceed those of all other manufacturing industries in the country.

I would only add that in 1958 the drug industry spent about $750 million for promotion and advertising, compared to a total of $200 million which was the total amount of money available to all the medical schools in this country for their educational program.

The reference for that statement is the AFL–CIO American Federationist for December 1961, page 2 of the reprint.

In this connection, a member of this committee asked Mr. Beesley, president of Eli Lilly & Co., what the relation was between his research and his advertising expense. Mr. Beesley did not know, but page 31 of Senate Report 448, 87th Congress, 1st sesssion, tells us that

for 22 leading drug manufacturers in 1958, research was 6.3 percent and selling expenses were 24.8 percent of the sales dollar. That is, they spent about four times as much on selling as on research.

Here is another full-page tranquilizer advertisement in the Maryland State Medical Journal for July 1962. It shows an alert doctor and two hands of a woman wringing a handkerchief. The caption is:

Safe, continous relief of anxiety and tension for 12 hours with just one capsule without causing autonomic side reactions and without impairing mental acuity, motor control, or normal behavior.

Presumably, any of these last bad things may happen with some other drug company's tranquilizer.

Here is another full-page, big-picture ad in the same journal—and let me say that from what I have seen this is the case in State medical journals all over the country, not just in Maryland—showing a woman selling hats to a customer, with this caption:

"How do you feel lately, Mrs. K?"

"Well, Doctor, some customers still 'get on my nerves' * * * but somehow this doesn't bother me as much * * *. I feel better now and people seem easier to get along with * * *."

And below this conversation—

This could be your "anxiety patient" on trepidone.

Incidentally, let me mention a practical little thing here of interest to anyone who may have a relative or someone on tranquilizers.

Here is a caution as to mixing alcohol, that is, drinking, with the tranquilizer meprobamate, a very common tranquilizer, which I find in the fine print of a big brochure, a big advertising spread, from Wyeth Pharmaceutical Co., which also reached me this week, I think on Monday.

Special care should be taken to warn patients taking meprobamate that their tolerance to alcohol may be lowered with resultant slowing of reaction time and impairment of judgment and coordination.

What I wonder is, if you are taking that stuff, what do you care about warnings? Anxiety is gone. You are tranquil. Let's face it and stop this mercenary deception; the fact is, you are doped.

Here is a full-page ad in Lippincott's Medical Science for August 10, 1962, again, a give-away magazine which is jammed with medical advertisements, showing a wistful, pretty girl with the caption:

If you don't ask her about premenstrual tension * * * she may never know the relief of Cyclex * * * helps you to return the patient to untroubled womanhood.

Cyclex contains several extra bonuses—a diuretic to increase the flow of urine, a special compound to dispel swelling, and meprobamate, the tranquilizer to "quell the psychic tension." This gem is made and advertised by Merck & Co. I forgot to quote what happens if you do not give her the drug: her premenstrual tension, which, let me say parenthetically, is a natural concomitant, to some degree, in every normal woman, this tension "can alter domestic and social behavior * * * complicate other illnesses * * * reduce work attendance and income," if you do not give this drug.

If I may offer a therapeutic opinion of my own, the first intelligent thought when anything goes wrong with the reproductive system

is the diet, just as it is in animals. The question always should be: What is that person eating? And top quality food cuts down and eliminates these troubles better than anything else there is.

But that is not the first thought of the drug advertiser, and, I am sorry to say, of the majority of doctors today.

It is probably not necessary to give more citations. I have 10 more which came out of the same journals, of just about the same caliber. Some of them tell how to take a synthetic male hormone type of thing, one of the exotic creations of synthetic chemistry, and use it for emotional and physical exhaustion, sort of a change from being tranquilized.

There are also special new drugs to shake up the metabolism in most complex manners so that a tennis elbow feels better.

All these medications usually constitute unscholarly meddling with delicate body mechanisms.

Here is the tennis elbow in a full-page advertisement.

Mr. Chairman, it seems to me that the kind of advertisements I have been reading are either exceedingly childish or degenerate, or both; and that a more strict control of drugs and their labeling in advertising is imperative.

H.R. 11581 is a step in the right direction. I think the efficacy phrases should be taken out, as Mr. Klump testified so eloquently, because, as has been pointed out by many witnesses, these phrases give great power to one man which even a group of men would not be wise enough to merit, so intricate is the human machinery.

There is never any question about our spectacular drugs. It is only those with more subtle action which work only under special circumstances and conditions, and we must we chary of setting a precedent of one man deciding and dictating that a drug is or is not efficacious in the complicated human animal.

On the other hand, we can achieve very much the same ends by a much better method.

For example, the bill would be greatly strengthened if an amendment were added stipulating that patients must give their written consent before being experimented on with a new drug not approved by the FDA.

The public will then know what is going on, just as they know more or less what to expect when they sign the standard hospital operation permission form. Both parties will stop and think a moment, which is just as it should be.

Of course, such written permission to receive a specific drug will act as a check on the testing of new drugs, and the pharmaceutical companies will not like that, but that is just what the public needs now, and I venture to say, will always need, in order to hold down the thoughtless promotion of drugs.

There will be no appreciable increase of paperwork, if the patient signs his name to show that he has been informed that such and such new drug will be given to him, because the doctor already has a sheaf of forms to fill out and sign himself for each patient to whom he gives a drug under test.

If a patient is not told that an experimental drug is being used on him, that patient is in the dark.

When the labeling which accompanies a drug, including its advertisement, misleads the doctor, that doctor is in the dark.

The American way is not to dictate any more than can be avoided what a man must do, but, rather, to turn on the light so that he can see what he is doing.

Mr. Chairman, I have a brief remark to make at the end of my prepared testimony in which I would like to respond to a point which you have made with clear emphasis on two occasions that I know of, Monday and today, to the effect that no testimony has been given here that H.R. 11581 would prevent the thalidomide type of accident.

I would like to answer your remark on that by saying that I believe this new bill would greatly reduce the risk of such an accident for the following reasons:

First, it lengthens the time over which the Food and Drug Administration can consider a new drug; and the deluge of drugs which descends upon the FDA, which even Dr. Klumpp referred to in his testimony as a terrible deluge of drugs, that would be reduced.

Much time is required to test a drug. It is amazing how long one should study these things and how many animals should be used; by slowing up the process the FDA can do a better job.

Secondly, as I understand it, the new bill puts a burden of proof upon the drug manufacturer to demonstrate that his new drug is safe.

It would not receive approval by default. As things stand now, unless the FDA comes up with adverse evidence within 60 days, the drug is automatically accepted.

That, again, will slow up things and give time for good work to be done by the FDA.

Thirdly, the amendment which I have mentioned above requiring revelation to the patient that he is participating in an experiment on a new drug will also slow up the deluge, and give time for a more scholarly decision.

If people know that they are taking an experimental drug, any abnormality which the patient experiences will cause him to report it, perhaps months ahead. He can be an intelligent guinea pig, if you will, and not an absolutely helpless, victimized person who has been given this drug as in the thalidomide case by some obstretician who never told the patient what she was getting.

So the warning would go out far quicker to cut off the supply to other patients of a dangerous drug.

For those three reasons, and by enforcing labeling, which is perhaps not so much a part of this bill, I do believe, Mr. Chairman, that the chance of a thalidomide type of accident would be greatly reduced.

We cannot entirely eliminate accidents in this field, any more than we can in air travel, but we can do much better than we have been doing.

Thank you, Mr. Chairman, for the privilege of giving you my testimony.

The CHAIRMAN. Doctor, the question I raised a couple of times was, in no way, questioning the fact that Dr. Kelsey had done a magnificient job, as has been so well and appropriately recognized.

The point that I have raised is that under present law, any such type of drugs could be denied clearance by the Food and Drug Ad-

ministration within the time to act upon it, and then the matter goes to a hearing.

That was the point that I have tried to make.

I have not at any time indicated that the provisions of this bill would not give more time for consideration. It may be that 180 days would be more sufficient time to make such a determination than 60 days, but under this provision precisely the same thing is involved, except, instead of having 60 days, you have 180 days.

You have got to make a decision and then go to hearing, if necessary.

Are you an M.D.?

Dr. ROBINSON. Yes, sir, I am.

The CHAIRMAN. In private practice?

Dr. ROBINSON. Yes.

The CHAIRMAN. You have given the committee an interesting discourse here which certainly is a wide variation from anything we have had.

Obviously, it is a thought that should be kept in mind.

There may be something to what you say.

I think probably it might be a good idea to have the drug people comment on this. I imagine they would probably welcome that opportunity, even though I am not suggesting that these hearings should go on and on.

But there is one thing in your statement that, to me, is a rather serious accusation, and even if the trend of thought of the American people, as you have described here, is questionable in the minds of other people, it is a very serious thing when you say that "There is collusion between organized medicine and the drug industry."

If that be true, I think that some serious consideration should be given to it. I simply cannot believe it myself. You are a doctor, and I assume you belong to the American Medical Association, do you not?

Dr. ROBINSON. I belonged for many years.

The CHAIRMAN. I assume you belong to your local medical society?

Dr. ROBINSON. Oh, yes, I belong to my local, county, and State medical associations. Aside from any other reasons, without these memberships I could not practice in hospitals, obtain standard malpractice insurance, or participate in Blue Cross or Blue Shield. But I disagree so much with what the A.M.A. does that by choice I have not belonged to the A.M.A. in recent years. I am not alone in that respect, for as the Montgomery County Medical Society Bulletin points out in its issue of August 1962, p. 239, "* * * a good many doctors do not belong to or believe in their own organization" (the A.M.A.).

The CHAIRMAN. The doctor is so important to the life of the individual and the family. I suppose the doctor probably is more intimate with family life than perhaps anyone else. And if the medical profession is putting itself in the position of being in collusion with the drug industry to commercialize on the lives of the American people, that is a pretty serious charge.

Dr. ROBINSON. Yes, sir.

May I say that some things acquire respectability through age alone, and for really many years the drug industry has contributed large sums, one-half the income of the AMA comes from the drug companies—you can find it in the AMA financial statement—and, as was

said earlier here today by, I think Dr. Miller of the U.S.P., up until 1955 the AMA made some effort to control the quality of drug advertisements in its journals.

But in about 1955 the AMA more or less threw in the sponge. It was just too much for them.

So far as the AMA being influenced by drug interests, it is like the old story from the South that if you will tell me where a man gets his corn pone, I will tell you what his politics are.

I think that does apply to the AMA. It cannot help but be strongly influenced by the pharmaceutical industry.

The CHAIRMAN. Doctor, I have never come to the belief that the intricate lives of the American people mean so little to physicians that, when you get down to it, the relationship is more basically commercial than it is to do something for humanity.

Any further questions?

Mr. ROBERTS. Doctor, one thing I would like to ask.

How easy is it to get some of the commonly known tranquilizers—take Equanil, Miltown—once a prescription has been given?

I mean are most of these refillable without another prescription?

Dr. ROBINSON. I have prescribed a tranquilizer only once, about 8 years ago so I am not sure how careful doctors and druggists are about this nowadays. The chances are that they are not refillable without the doctor's permission. But he may phone the druggist, or write on his prescription blank, "Do not refill at all," "Refill once," "Refill three times," or "Refill as needed," so there is plenty of leeway here.

Mr. ROBERTS. That is all.

Mr. MOSS. Mr. Chairman.

I want to take the opportunity to compliment you, doctor. It is to me a very refreshing thing to have an individual come here and from a background of professional knowledge undertake to share with the members of this committee his convictions gained from experience, and who, I might add, is sufficiently worldly to recognize that the appearance of a doctor here under these circumstances takes a small measure of courage, at least. I think, for your interest, demonstrated by your appearance, that you are certainly deserving of a degree of congratulation, and I certainly extend it to you.

Dr. ROBINSON. Thank you, sir.

Mr. Chairman, may I say that I agree with you absolutely that there is not an overwhelming commercial flavor to the practice of medicine.

There is not.

All that I was pointing out is that there is an undue influence from the pharmaceutical industry which has taken us away from our highest principles of Hippocrates, Sir William Osler, and Oliver Wendell Holmes, and we have gone too far in this business of drugs, well shown by the advertisements which I have read. Our predicament is tied up with the financial connection between the AMA and the drug industry.

I should add that those things develop so gradually that one drifts into it.

We have now generations of doctors who have been indoctrinated too much in the way of drug therapy, and that sort of thing progressively permeates and colors the situation imperceptibly without any

criminal intentions on the part of anyone. I was speaking out against that trend.

The CHAIRMAN. Doctor, I agree with Mr. Moss. It takes a lot of courage to do what you have done today, and if these things are true, as I have already said, it is a very serious situation indeed. I notice that you have been teaching at Vanderbilt Medical School in Nashville, the University of Pennsylvania Medical School, and if what you have just said is true, I think it is certainly a reflection on our medical institutions in not training our doctors in the proper concept. If we ever get to the point in this country where we cannot depend on the doctor to protect the lives of the people, then I think you are going to find some real revolution taking place in the practice of medicine, if the people come to that realization.

Mr. FRIEDEL. Mr. Chairman?

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. May I ask one question?

Doctor, have you ever made a written or verbal protest to the AMA?

Dr. ROBINSON. Yes, indeed, I have.

Mr. FRIEDEL. Once, twice, many times? When was the last time?

Dr. ROBINSON. Well, sir, it is a long story, but I had a major battle with the AMA, lawsuit and all the rest, at the time when I was out in Washington State and the AMA and its local societies were monopolizing medical practice through so-called medical bureaus.

The AMA and its State societies were arranging for the local doctors actually to own and operate these bureaus which were, in fact, simple commercial insurance companies, a very radical development that took place in a State, Washington State, which at that time was quite radical in its welfare programs.

The State nearly went bankrupt in giveaways in medical care.

So I had quite a battle with them out there because I observed that the system of doctors employing themselves in medical insurance companies was leading to decay in the profession. And so I have been very much in opposition to the AMA beginning about 10 years ago.

Mr. FRIEDEL. That is all.

The CHAIRMAN. Doctor, thank you very much for your presentation.

Dr. ROBINSON. Thank you, sir.

(The supplemental statement of Dr. Miles H. Robinson follows:)

SUPPLEMENTAL STATEMENT OF MILES H. ROBINSON, M.D., IN SUPPORT OF H.R. 11581, AUGUST 28, 1962

Mr. Chairman and members of the committee, a few days after I had the privilege of appearing before you on August 22, the Saturday Review of Literature, issue of September 1, 1962, was published. It contains a remarkable article by the science editor with many new facts bearing on the drug situation which I believe the committee would find useful to have at hand as it weighs the provisions of H.R. 11581.

For example, the article cites from the files of our Food and Drug Administration cases of concealment for as long as 5 years by drug companies of deaths caused by various new drugs (p. 40). It reveals the FDA figure of 19,822 Americans who took the tranquilizer, thalidamide (p. 38). It describes how U.S. Food and Drug Commissioner Larrick waited for 6 months and a public uproar before sending out his agents to round up what remained of Merrell's experimental pills in physicians' offices throughout the country. Germany had taken

thalidamide off the market 6 months before Mr. Larrick acted, as soon as that country confirmed the drug's complicity in birth of malformed babies.

The thalidamide story which has appeared in the press in necessarily scattered form as the details developed, is chronologically and adequately summarized in the Saturday Review article.

The whole picture of drug experimentation and promotion is brought into sharp focus, and further supports the testimony which I gave to the committee. For these reasons, I earnestly hope that you will include this article, in full, as part of my supplemental statement. If this cannot be done, I hope that the excerpts which I have marked can be included.

Enclosed is a copy of the magazine in question.[1]

The CHAIRMAN. Mr. Clinton R. Miller, who will be the final witness. Mr. Miller, you may proceed.

STATEMENT OF CLINTON R. MILLER, ASSISTANT TO THE PRESIDENT OF THE NATIONAL HEALTH FEDERATION; ACCOMPANIED BY CHARLES ORLANDO PRATT, ATTORNEY

Mr. MILLER. Thank you, Mr. Chairman.

I am accompanied today by the legal counsel of the National Health Federation, Mr. Charles Orlando Pratt.

Mr. Chairman, for the record, I am Clinton R. Miller, assistant to the president of the National Health Federation. Our main office is 709 Mission Street, San Francisco, Calif. Our Washington office is at 1012 14th Street NW., Washington, D.C.

The National Health Federation is a rapidly growing national organization, composed of thousands of members who believe in freedom of choice in matters of health where the exercise of that freedom does not endanger the health or safety of another, and thereby deny him an equal freedom.

In matters of health, the professional and commercial interests involved have been well organized for many years. The Pharmaceutical Manufacturers Association and the American Medical Association have represented their members' commercial interests extremely well, as evidenced by the profits of the former, and the top professional income position of the latter. Where this position has been gained within the framework of freedom and fair competition, we applaud and support their success. To the extent, however, that it has been gained as a monopoly, by suppressing freedom of choice, information, and competition, we condemn and oppose them.

In the present bill we find ourselves in both roles. We support their reasonable requests for certain language changes in the bill which would prevent giving unlimited, arbitrary powers to Government. One Dr. Henry Welch is too many.

We, on the other hand, point out that the AMA has been found guilty in the past of a criminal conspiracy to monopolize the healing arts. If the drug industry is guilty today of monopoly control, then they should be prosecuted under the laws that forbid trusts. The laws presently on the books are adequate for that.

In matters concerning their health, the average American has not been so well organized and represented as the commercial interests. Consequently, he has had very little protection from certain monopolistic forces in the field of health which have run rampant in America

[1] The material submitted by Dr. Robinson may be found in the files of the committee.

for many years. The National Health Federation was formed to fill this need. While no two people in America have identical beliefs in respect to the best approach to health, they all have one belief in common, and this is that every person should have the right of freedom of choice in what is done to his body. We weigh all proposed legislation on this scale, and believe that freedom of choice for the well-informed individual is the safest, fairest, and wisest position that a lawmaker can take.

MEDICAL EXPERIMENTATION WITH DRUGS WITHOUT PATIENT'S KNOWLEDGE OR CONSENT

We wish to focus the committee's attention on what we feel is the most glaring loophole in our present law: the absolute lack of any effective control of investigational drug experimentation on involuntary human guinea pigs. The fact is dawning on Americans that they have been, and are being, subjected to extremely hazardous and dangerous medical experiments on their bodies without their knowledge or consent. This is increasing on a vast scale, unprecedented in history.

Furthermore, there is nothing in the instant bill, H.R. 11581, to recognize, prevent, or correct this specific situation. No person should be denied the right to know that he is participating as a human guinea pig in a medical experiment, and that he is taking an experimental drug with unknown side effects.

THE PROPOSED NATIONAL HEALTH FEDERATION AMENDMENT

We respectfully urge that a new section be added under title I, part A. We suggest that it contain the following:

NOTIFICATION OF EXPERIMENTAL DRUG USE

The following statement must be signed by a doctor's patient, or the patient's legal guardian, before he may be given a new, experimental drug:

I have been advised that _____, an experimental new drug, as yet unapproved by the Food and Drug Administration, is to be administered to me for the purposes of testing its usefulness, safety, and/or possible harmful side effects. Signed by the patient or the patient's legal guardian.

The Washington Post of Sunday, August 19, 1962, carried the following information:

The FDA surveyed the investigational use of thalidomide in the United States, finding that, as of August 6, 3,372 women of childbearing age were known to have received the drug.

This points out the unlimited right to experiment on humans without their knowledge or consent.

Here are some hard-to-believe facts:

1. Americans will soon know that under the present and proposed law, there is no limit as to how long one can investigate with a new drug.

2. Under the present and proposed law, there is no requirement that the doctor even tell a patient that he is being used as an involuntary human guinea pig.

3. Under the present and proposed new law, there are no Federal requirements—and I will repeat this—there are no Federal re-

quirements that a doctor keep a record of any patient who receives an experimental drug.

4. Under the present and proposed law, there is nothing that prevents a doctor from charging a patient for a new, experimental drug.

5. Under the present and proposed law, there is nothing to prevent the drug company from charging the doctor for the experimental drug.

6. Under the present law, there is nothing to prohibit a drug company from changing to some degree the formula of thalidomide, and starting all over again as an experimental drug under a new name. Indeed, there is evidence that this is happening today.

7. Finally, where a drug company and a doctor may both charge for an experimental drug given to an involuntary human guinea pig, where they do not have to notify any governmental agency of their intent to start testing, or of the failure of any such tests, and where there is no limit to the number or length or extent of such tests, we have a loophole in which these commercial interests can operate business as usual without the knowledge, control, or consent of either a patient or his government.

The great uneasiness in America today is because at the same time that we are giving medals to FDA officials for keeping an untested drug off the market, the hard and stubborn fact remains that for all practical purposes the drug was on the market in this country, and was given to thousands and thousands of unsuspecting Americans without their knowledge or consent.

The National Health Federation amendment would at least require that this testing be done with the knowledge and consent of the individuals being used in the experiment. This is the very minimum that Americans can expect.

The Nuremberg war trials did not challenge the matter of testing with human guinea pigs. It did emphasize and establish that voluntary consent is the first prerequisite for human experimentation.

When convicts or political prisoners are used in America for human experimentation, it is done with their consent, and they may withdraw from the experiment at any time they choose. This same right should be afforded the rest of America.

To preserve the time of this committee, the balance of the National Health Federation testimony will be submitted in our written statement.

Thank you.

The CHAIRMAN. Very well.

You may submit the additional information for the record.

(The statement referred to is as follows:)

WRITTEN STATEMENT OF CLINTON R. MILLER, ASSISTANT TO THE PRESIDENT OF THE NATIONAL HEALTH FEDERATION

In my statement before the committee, I mentioned the Nuremberg war trials, and the rules that were set down as a result of these trials, concerning human

medical experimentations. The Tribunal's judgment, rendered August 19, 1947, of the Nuremberg medical trial gave the following judgment on:

PERMISSIBLE MEDICAL EXPERIMENTS ON HUMANS

"The greatest weight of evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical, and legal concepts:

"Nuremberg rule No. 1. *The voluntary consent of the human subject is absolutely essential.* [Emphasis ours.] This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. The latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

"Nuremberg rule No. 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

"Nuremberg rule No. 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated result will justify the performance of the experiment.

"Nuremberg rule No. 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

"Nuremberg rule No. 5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

"Nuremberg rule No. 6. The degree of risk to be taken should never exceed that determined by the human importance of the problem to be solved by the experiment.

"Nuremberg rule No. 7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

"Nuremberg rule No. 8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

"Nuremberg rule No. 9. During the course of the experiment the human subject should be at liberty to bring the experient to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

"Nuremberg rule No. 10. During the course of the experiment the scientists in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of good faith, superior skill, and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject."

A valuable reference book on the instant subject is, "Experimentation in Man," by Henry K. Beecher, M.D. It is published by Charles C. Thomas, 301–327 East, Springfield, Ill. The Library of Congress Catalog Card No. is 58–14065. The National Medical Library call No. is, W.50 B414e, 1954.

The National Health Federation amendment has only included part of the Nuremberg Rule No. 1. "The voluntary consent of the human subject is absolutely essential." There were 23 defendants in the Nuremberg Medical War Trials. Fifteen were found guilty. Seven were hanged. Four of the seven were physicians. It was freely admitted that in America there were human medical experiments similar to those of the accused war criminals but they were all performed with the consent of the human guinea pig. It was the failure to get voluntary consent that made the act of human medical experimentation criminal. The National Health Federation would like to see the 10 Nuremberg rules established as the standard to govern all human experimentation.

EXPERIMENTATION WITH HUMANS—AMERICAN STYLE

In a press release for Thursday, August 23, 1962, the Food and Drug Administration disclosed some shocking aspects of the present uncontrolled status of experimental drugs in America. The following quotes are from this press release by FDA officers Janssen and Brooks:

"Thalidomide was never approved for sale in this country, but under the law the manufacturer could distribute thalidomide tablets to doctors for clinical investigation. On this basis, the FDA survey shows more than 2,500,000 tablets were distributed to 1,267 doctors."

CLINICAL INVESTIGATION WITHOUT RECORDS

Lest any Congressman assume that the fancy words, "clinical investigation" imply a tight, safe, scientific, well-controlled and documented use of potential deforming or lethal drugs, consider the following from the same press release:

"FDA disclosed that 410 out of 1,168 doctors interviewed by its inspectors had at that time made no effort to contact patients to whom they had given the drug. Many of the 410 felt it was not necessary because of the time lapse, or they had no records to indicate which of their patients had received the drug.

For emphasis, we shall repeat that last statement—"or they had no records to indicate which of their patients had received the drug." Is this the picture that was painted by witnesses for the Pharmaceutical Manufacturers Association to members of this committee? Indeed not. Consider that over one-third of these "clinical investigators" either had no records, or had made no effort to contact patients. Would it be an improper function of Government to ask that the list of these 410 doctors be made public to protect their unsuspecting patients?

SO THIS "CLINICAL INVESTIGATION"?

Further incredible disclosure of the method of "clinical investigation" is in the following paragraphs from the same press release:

"A doctor in Kansas City, Mo., gave 50 tablets to a male patient who passed some of them on to his married daughter. She took the drug during the early stages of pregnancy and is due to deliver by October 1962. The case is being followed up."

FEATHERS IN A HURRICANE

For tightness of scientific control, this disclosure is hard to beat (also from the same press release):

"Six doctors donated supplies of thalidomide to religious groups for charitable distribution overseas and are unable to trace the present location of these drugs."

The FDA press release continues:

"Records furnished by the firms show that 2,528,412 thalidomide tablets were distributed to doctors for investigational use. They varied in strength (quantity of the active ingredient) from 12½ to 200 milligrams. Lesser quantities of liquids and powders containing the drug were also distributed.

"More than 50 percent of the doctors interviewed had no record of the quantities returned or destroyed pursuant to the manufacturer's instructions. *There is no way of knowing the amounts actually returned or destroyed*, FDA said. [Emphasis ours.]

"Most of the doctor-investigators said that they had received the manufacturer's advice in March 1962 to stop using the drug, but 85 said they were not warned of adverse reactions and 42 said they did not get any message from the manufacturer. The notice to discontinue was given by letters, with followup

phone calls and visits by detail men beginning in March and continuing through July 1962.

"Doctors interviewed reported that 19,822 patients had received thalidomide. Of these, 3,760 were women of childbearing age, of whom 624 were reported as pregnant. *According to the doctors* [emphasis ours], most of the pregnant patients got the drug in the last trimester of pregnancy or just prior to delivery. There are reports of 21 women who have not delivered. Three of these are reported to have received the drug in early pregnancy.

"Three cases of abnormalities have been reported in offspring patients who took thalidomide distributed in the United States, FDA said. * * *

"When asked if they had signed a statement on their qualifications, required by FDA regulations to be obtained by the manufacturer, 640 doctors stated they had signed such statements but 247 said they had not. Others said they could not remember or did not answer the question."

The release closes by updating figures in the August 7, 1962, progress report on FDA's survey of the investigational use of thalidomide in the United States.

	Aug. 7	Aug. 21
Number of pregnant women reported to have received the drug	207	624
Number of doctors reported as investigators or users of thalidomide	1,248	1,267

There is no explanation offered as to why an increase of 1½ in doctors reporting should increase by 300 percent the number of pregnant women reported to have received the drug.

One has the uncomfortable feeling in reading these reports that someone is trying to keep a lid on something.

In summary, no person should be denied the right to know that he is participating as a human guinea pig in a medical experiment, and that he is taking an experimental drug with unknown side effects. We respectfully urge this committee to amend H.R. 11581 to include this safeguard.

The CHAIRMAN. Any questions, Mr. Friedel?

Mr. FRIEDEL. At the proper time I probably will propose an amendment to the committee.

Mr. MILLER. Thank you very much.

The CHAIRMAN. Mr. Moss?

Mr. Moss. I have no questions, Mr. Chairman.

I might state that, in general, I agree with the proposal that there should be some agreement on the part of a patient before they are subjected to some of these very radical new compounds.

Mr. MILLER. Thank you, Mr. Moss.

The CHAIRMAN. Thank you, Mr. Miller.

This will conclude the hearings for today.

The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 4:50 p.m., the hearing was adjourned, to reconvene at 10 a.m., Thursday, August 23, 1962.)

DRUG INDUSTRY ACT OF 1962

THURSDAY, AUGUST 23, 1962

HOUSE OF REPRESENTATIVES,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The committee met, pursuant to recess, at 10:15 a.m., in room 1334, New House Office Building, Hon. Oren Harris (chairman of the committee) presiding.

The CHAIRMAN. The committee will come to order.

Yesterday Mr. Benjamin G. Habberton testified, and, in response to a question, he discussed the extent of the interest of the dairy industry and its products in the factory inspection provision of this bill.

This morning I have a letter from Mr. Habberton which he feels would be further responsive to the question raised at that time.

Therefore, the letter will be included in the record at the appropriate place.

(The letter referred to was inserted following the testimony of Mr. B. G. Habberton on p. 456.)

The CHAIRMAN. For the record, Mr. R. E. Horsey, of Givaudan Delawanna, 321 West 44th Street, New York, may include a statement at this point.

(The statement referred to is as follows:)

STATEMENT OF ROBERT E. HORSEY OF GIVAUDAN-DELAWANNA, INC., ON H.R. 11581

I am Robert E. Horsey, vice president of Givaudan-Delawanna, Inc., whose executive offices are located in New York City. I have been employed by this company for the past 20 years. This company is a wholly owned subsidiary of the Givaudan Corp. These companies are incorporated in the State of New Jersey. Our plant is located in Clifton, N.J., and in our New York City location we maintain our perfume laboratories.

My presence here is to voice our opposition to only the strengthening of factory inspection authority provision (section 201) of this bill.

We object to this increased inspection authority because, if enacted, it would jeopardize the very foundation of our business, namely the trade secrets which include our valuable formulas for perfume bases and unique processes for manufacturing perfume materials.

To understand why these trade secrets are such a valuable asset, it is necessary to explain our company's activity and its role within the fragrance industry and its relationship to the cosmetic industry.

Our companies are engaged in the manufacture and sale of perfume materials and compositions made from perfume materials which, for the purpose of this statement, we shall call perfume bases. These perfume materials and bases are sold to manufacturers of perfumes, colognes, cosmetics, soaps, and many other consumer products. Our companies were established in the United States in 1924. Prior to this time Givaudan products were imported into the United States and, therefore, have been supplied for these uses since the early 1900's.

During the past 38 years the scope of our operation has grown from a modest 80 to 500 employees and the plant value increased by twentyfold. We manufacture approximately 500 different perfume raw materials, and currently supply

several thousand different perfume bases to the cosmetic and other consumer products manufacturers.

At the outset, I would like to emphasize that we sell only to manufacturers, and our problems are not the same as those of the cosmetic industry. Therefore, we do not believe we should be subjected to the same regulation.

Givaudan initially entered the perfume industry by pioneering in preparing synthetically some of the constituents found in the odorous oils of plants and flowers. This came about from research into the constituents of natural products, synthesizing them in the laboratory, and finally developing processes which could produce, economically, commercial quantities.

It was quite a logical step to try to use these synthetically prepared materials to duplicate the elusive fragrance of the natural flower oils. Through the imaginative, creative, and artistic ability of our perfumers, we were successful in combining synthetic and natural substances into redolent creations. Many other original creations are produced each year.

The sale of these perfume bases constitutes a large part of our sales volume. An appreciable number of them have been sold continuously since the earliest days of our business. In spite of all the modern scientific tools, they have defied duplication by others. Obviously, access to formulations would make the task of duplication a simple one and, for this reason, we have, within our company, an elaborate security system whereby only a few responsible individuals have knowledge of the complete composition.

Equally important and valuable are the many unique processes developed to make perfume raw materials. The chemistry involved is fairly well known, but to produce, synthetically, perfume materials which have fine odor quality is not so simple. The fine quality and uniformity of the ones we produce are dependent on the processing skills and processes we have developed over the years.

In relation to the cosmetic and other consumer product manufacturers, I am sure you can appreciate that the public acceptance of their products is greatly influenced by the fragrance. The fragrance in many cases is as valuable as their trademarked brand names. For this reason, manufacturers are also anxious to preserve the secrecy of the fragrance for they have many dollars invested in these valuable franchises. Consequently, there is a great confidential business relationship between the fragrance supplier and customer.

The factory inspection (sec. 201 of H.R. 11581) has been proposed to better protect the public health. We, too, have a keen interest in protecting the public health, but we know of no evidence which indicates that perfume raw materials or perfume bases are endangering it. Neither can we understand how the public health could be better protected by broadening the factory inspection.

No arguments have been presented by the administrative agency proving that the present legal procedures for compelling disclosure of information in relation to a violation are inadequate.

We cannot see how the unlimited examination of our processes and formulas can better protect the public health, but we can foresee the potential damage to our business when any inspector would have the right during any inspection, routine or otherwise, to copy and take with him any or all our trade secrets, including formulas, processes, and confidential business relationships.

We have had to deal with the security problem of our formulas and processes since the inception of our company. For this reason we cannot treat lightly or rule out the possible inadvertent disclosure or deliberate misuse of confidential information by FDA inspectors. This is not an accusation of the FDA personnel, but over a period of years we could be subjected to a significant number of inspectors who may or may not remain in the employment of the agency. We do know that the danger of leakage of confidential matters is in direct proportion to the number of individuals possessing such knowledge.

If the administrative agency deems it necessary to strengthen the factory inspection authority for the control of safe drugs, we cannot agree this is a reason for extending it to other industries. We do not know the problems of the drug industry, but we are certain greater inspection of our establishment is not necessary. In fact, to the best of our knowledge, no need has been shown for increased inspection privileges or that the present inspection authority is inadequate in preventing the misbranding and adulteration of cosmetics.

In behalf of our company and others in the fragrance industry, we urge the committee to give careful consideration to our unusual dependence on protecting

our trade secrets and the irreparable harm we would suffer through their loss. We strongly recommend that section 201 in H.R. 11581 be limited to drugs, since that is the main scope of the bill. If, for some reason not obvious to us, this is not feasible, then we recommend a revision of section 201 be made which would exempt perfumes and fragrances from this broad factory inspection authority.

The CHAIRMAN. It is expected that the hearings on this proposed bill will conclude perhaps today, if not tomorrow. We have a number of witnesses yet to be heard, and we will undertake to get to them during the day.

If the witnesses and the members of the committee will keep this in mind, I think it can be concluded today.

At the conclusion of these witnesses the record will be kept open for a period of 5 days, and under the usual procedure the committee will receive any additional statements that anyone might desire to file. All statements pertinent to this proposed legislation will be received during that period.

The first witness this morning will be Mr. Philip F. Jehle, Washington representative and associate general counsel of the National Association of Retail Druggists.

Mr. Jehle?

STATEMENT OF PHILIP JEHLE, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL OF THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; ACCOMPANIED BY JOSEPH COHEN, ASSOCIATE WASHINGTON REPRESENTATIVE

Mr. JEHLE. I am Philip Jehle, the Washington representative and associate general counsel of the National Association of Retail Druggists. As you know, the NARD is a small business organization having a nationwide membership of more than 36,000 community drugstore owners. It is both an honor and a duty for the NARD to speak for these family pharmacists on all Federal legislative matters affecting their professional and competitive interests. Accompanying me this morning is Joseph Cohen, associate Washington representative of the NARD.

I deeply appreciate your kindness in granting this opportunity to offer the views of the NARD on H.R. 11581, the bill amending the Food, Drug, and Cosmetic Act. I do understand the many practical problems involved in arranging to hear the numerous witnesses desiring to testify on the proposed legislation. Accordingly, I shall try my best to keep my presentation this morning brief and to the point.

At the outset, Mr. Chairman, I would like to emphasize that the provisions of H.R. 11581 are directed mainly at the pharmaceutical manufacturers; that is, toward those engaged in the research, development, and production of prescription medications. Only in a few instances do the provisions of the measure have a direct application to those engaged in the retail distribution of prescription drugs. This being the case, our comments on the proposed legislation will be limited to those provisions which would have a significant impact upon retail pharmacy. Not having any drug manufacturers as members, the NARD does not presume to speak for them on legislative matters or

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otherwise. We speak only for our 36,000 independent retail pharmacist members.

As briefly as possible, our comments on H.R. 11581 are as follows:

(A) AMPHETAMINE AND BARBITURATE CONTROLS

In general terms, these provisions of the bill are intended to facilitate efforts of the Federal Food and Drug Administration to check illegal trafficking in amphetamines and barbiturates. With this praiseworthy objective, all concur including the NARD. Yet, such a goal, however commendable it may be in itself, should not be used to justify a move by Government officials to obtain more enforcement authority than is actually needed and which may be abused as a result. Specifically, I am referring to that provision which would enable FDA agents to inspect, among other business and professional records, the pharmacist's prescription files. For years, FDA officials have been trying in one way or another to get authority to search the prescription files of the retail pharmacist. Until now, Congress has consistently withheld such authority on grounds that a case for granting it has never been made. This fact, however, has had but little influence upon those intent upon assuming new and broader powers for themselves.

In the view of the NARD, prescription file inspection authority as it is being sought in H.R. 11581 should be denied the Federal Food and Drug Administration for the following reasons:

(1) It is unnecessary: For many years, the inspection of prescription files, including those relating to amphetamines and barbiturates, has been performed competently and diligently by appropriate State authorities. This is true in every State of the Union. It would be both unwise as well as frightfully expensive for the Federal Government to duplicate the fine enforcement work of State authorities. This committee should certainly find out from the appropriate State officials whether they are doing an effective job of inspecting pharmacists' prescription files.

(2) Unaccountably, the prescription file inspection authority being sought in the proposed legislation would cover all pharmacies while, at the same time, expressly exempting all medical practitioners, many of whom do a rather large business in the dispensing of prescription medications. Frankly, the NARD and its members are unable to understand why such unjust discrimination against the profession of pharmacy should exist in this bill. No satisfactory explanation has ever been offered.

(3) FDA agents already have sufficient legal authority to investigate all records including prescription files of any person who may be illegally handling or disposing of amphetamines and barbiturates. Where a search warrant for such investigation becomes necessary, it may be easily obtained by FDA agents. Once probable cause has been shown, the warrant may be issued and the search may begin. Every competent, experienced law enforcement officer would tell you that he has no trouble getting a search warrant when he needs it. I am also confident he would let you know that he is satisfied with existing procedures for obtaining it and has no need of legislative

shortcuts. He is happy to perform his job according to the Constitution.

For this committee to make it abundantly clear that H.R. 11581 does not authorize carte blanche prescription file inspection authority for amphetamine and barbiturate irregularities, a simple amendment may be made. Change line 6 of page 27 of H.R. 11581 to read as follows: "in subsection (b) (3) and (4)" et cetera.

The addition there is (3). That will make it clear that the exemption applies to the profession of pharmacy as well as to the profession of medicine.

(B) PRESCRIPTION DRUG ADVERTISING

Simply stated, these provisions of H.R. 11581 would require all prescription drug advertising, regardless of type of publication or other medium involved, to set forth clearly and fully such "basic information" as the medication's (*a*) quantitative analysis and generic name; (*b*) contraindications, and (*c*) side effects. The apparent purpose of such "affirmative disclosure" is to assure physicians of receiving all relevant information concerning the safety and efficacy of advertised prescription drugs.

In judging the merits of these provisions, our main concern has been the impact they would have upon the advertising of prescription drugs to the Nation's retail pharmacists. For, whether intentional or not, the informational requirements would apply to prescription drug advertising in our NARD journal and to the numerous State and local pharmaceutical association publications. By no means should it be thought that the scope of the challenged provisions would be limited to medical journal advertising.

Of course, the NARD understands and is sympathetic to H.R. 11581's avowed purpose of making certain physicians are fully informed concerning the unfavorable as well as the favorable aspects of all prescription medications. In fact, we are sure this is a universally supported objective. At the same time, however, we do not believe H.R. 11581 is an appropriate means of accomplishing such a laudable purpose. Among the major considerations militating against the proposed legislation in this regard are the following:

(1) It would be unnecessary: Physicians obtain information about the therapeutic effects of prescription drugs from recognized professional authorities, such as the Drug Index and the Merck Manual. Pharmacists, too, have their professional sources for such information. They use such sources as the United States Pharmacopoeia, National Formulary, and the United States Dispensatory.

No reputable physician would ever prescribe a medication that he know about only through advertising seen in a professional journal. Nor would a responsible pharmacist base his knowledge of the purpose, safety, efficacy, and dosage forms of a prescription drug upon the manufacturer's advertising statements. To even suggest that physicians and pharmacists would so conduct themselves seems almost scandalous.

Also to be noted in this regard are the FDA administrative regulations which became effective in March of this year requiring drug manufacturers to attach to or enclose with their prescription medicines and devices brochures (package inserts) containing all necessary

information for the sale, effective use of such drugs and devices. Such brochures or package inserts are filed by pharmacists for use in advising physicians of the therapeutic properties and effects of prescription drugs and devices. Through such means, physicians have another ready, competent source of technical information and advice.

(2) It is impractical: In effect, these provisions would compel prescription drug advertisers to ground their advertising copy upon their new drug applications and supporting materials. Although such extensive technical data could probably be condensed somewhat and the salient points extracted for advertising use, the process would be complex and extremely time consuming. As a result, many drug manufacturers would find such advertising inadvisable. Many others would shy away from the formidable legal risks involved in passing upon "full disclosure" or the propriety of the relative emphasis given favorable and unfavorable therapeutic aspects of a particular drug.

Drug advertising in professional journals is primarily for "reminder" purposes. It is not intended to be educational, except in a very general way. Drug advertisers recognize the virtual impossibility of using an advertisement to explain in a responsible manner the therapeutic properties and effects of a highly complex prescription medication.

(3) It entails much added expense: Under the provisions of H.R. 11581, lawyers trained in pharmacy and expert in food and drug law, including pertinent sections of the FTC Act, would be needed in passing upon all prescription drug advertising. Similar qualifications would be needed in the case of the advertising copy writers. Such technical authorities would be used by both advertisers and the professional journals. After all, the journal editors and publishers would want to be sure improper drug advertising were never run in their publications. Easily imaginable are the vigorous arguments which would arise between advertisers and publication representatives over whether advertisements complied with the requirements of H.R. 11581.

(C) FACTORY INSPECTION

As drafted, these provisions of H.R. 11581 would empower FDA agents to conduct the broadest kind of search of all places in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, either before or after entry into interstate commerce. Practically speaking, one can hardly imagine Congress granting more unlimited inspection powers over food, drugs, devices, and cosmetics to any Government agency. Such sweeping language would apply to all food and drugstores and hundreds of thousands of other retail and wholesale distributors handling food, drugs, devices, and cosmetics in any form. Retail pharmacists, as an example, would be faced with an army of FDA agents swarming over their business and professional records, including prescription files. And to refuse an FDA agent an opportunity to inspect would be a crime.

The NARD is opposed to the coverage of retail pharmacists by the factory inspection provision of H. R. 11581 for the following reasons, among others:

(1) Already, all retail pharmacists are subject to inspection of their facilities and records by appropriate State authorities. Those inspections by competent and diligent investigators should not be duplicated

by Federal FDA agents. Duplication by State and Federal agents would also be extremely costly as well as quite burdensome to the affected small drug retailers.

(2) Vague, rambling fishing expeditions by FDA agents should be discouraged by Congress, not encouraged. Advise the FDA inspector to seek a search warrant if the party he wishes to inspect refuses permission for a search.

And I might add that there are very few such instances of a drug retailer refusing an FDA inspector an opportunity to make an inspection, but if the agent believes probable cause exists, he can go to court and a warrant will be issued promptly.

I might add that, even now, most retail pharmacists, virtually all, I might add, are happy to cooperate with FDA inspectors by letting them enter the premises for the desired inspection.

As reviewed by the NARD, the committee should give its earnest attention to an amendment adopted by the Senate Judiciary Committee to exclude retail pharmacies. The text of the applicable amendment is as follows:

(1) Pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs, or patients under the care of such practitioners in the course of their professional practice and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail.

In conclusion, I think it highly significant to point out that a very large majority of the numerous business organizations appearing during your committee's consideration of H.R. 11581 have agreed upon the desirability of strengthening existing Federal drug laws so as to better protect the public health. Almost all have subscribed to the proposed legislation in both principle and purpose, asking only that the bill be carefully studied and, where appropriate, revised to insure that its provisions not be broader than is necessary to bring about a system of better, safer prescription drugs for the American people. With these views, the NARD concurs. We do believe, of course, that H.R. 11581 should be revised to protect the pharmacists' prescription files from Federal inspection and thus bring the bill into conformity with its Senate counterpart.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Mr. Jehle, on page 3 of your statement you propose a change on line 6, page 27 of the bill. The bill now reads "in subsection (b) (4)," with respect to drugs and so forth, and you suggest that it read "in subsection (b) (3) and (4)"?

Mr. JEHLE. Yes, sir.

The CHAIRMAN. (b) (3), I assume, has to do with pharmacists?

Mr. JEHLE. Yes, sir.

It would refer back to page 23 of the bill, line 16, which reads as follows:

Pharmacies, hospitals, clinics, and public health agencies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine.

So the professional exemption, then, if this amendment were accepted, the professional exemption would extend to pharmacies, hospitals, clinics, and public health agencies, as well as to medical practitioners.

The CHAIRMAN. The question that I had in mind is that this change would affect only amphetamines and barbiturates?

Mr. JEHLE. That is correct, sir.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I was a little late, but I noticed one thing in Mr. Jehle's last statement which I was glad to hear because almost all other witnesses who have testified are opposed to everything.

You say that this should not be broader than is necessary to bring about a system for better and safer prescription drugs for the American people.

You state you know there is room for improvement, but not to go too far?

Mr. JEHLE. That is correct, Mr. Friedel.

Mr. FRIEDEL. I want to compliment you and also Dr. Cohen, your associate, who, I might mention, is from Baltimore.

I am very happy to see him here.

The CHAIRMAN. We are always glad to have anybody from Baltimore before this committee.

Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

In regard to the advertising, I am wondering if possibly something should be worked out somewhere such as the control on investment advertising where they put in an advertisement and then they say this is subject to a circular approved by the SEC.

There they have the circular with all the details, but the details are not in the advertisement.

Do you think that something might be worked out on a limitation of advertising in that manner?

Mr. JEHLE. Yes, Mr. Younger.

I think that some type of accommodation along that line might be worked out, but I think that it will take a great deal more time than the committee has now available to it to work out such a compromise.

We would have no objection to that type of compromise, I am sure of that.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. JEHLE. It is difficult enough, Mr. Younger, for a national organization that has a lawyer on the staff and competent, experienced people working on the journal, to comply with something like this.

I think it would probably be difficult even for us, but for the publications of some of the smaller State associations and the very small local associations, it would be a virtual impossibility.

They would never be able to pass upon the legality of advertising as required by this proposed legislation.

Mr. YOUNGER. Just one other question.

When Mr. Larrick was before the committee, he said all the States except one had adequate laws governing pharmacies. Do you know which State that is?

Mr. JEHLE. No, sir.

We were under the impression that they all had adequate inspection authority.

I would like to take this opportunity to say that the NARD has a fine record of cooperation with FDA officials.

We like them very much.

We just think that they are wrong in this particular instance.

Mr. Cohen, do you know that?

Mr. YOUNGER. My recollection may be wrong, but I thought that he mentioned that all the States except one—we were discussing at that time the question of intrastate, where they were asking permission to go in to investigate and control the sale of these pep pills that they sell to the truckdrivers, and that that trade was out of hand, and while it is intrastate, they want authority to go in.

I asked him specifically how many States did not have adequate inspection, and he said all except one.

I forgot to ask him which one.

Mr. ROBERTS. Is it California?

Mr. YOUNGER. No, sir.

California has one of the most far reaching and adequate inspection laws of any State.

Mr. COHEN. Mr. Chairman, with your permission, we have a list of all the States and how the laws are enforced and who supervises them.

We would be glad to furnish this information for the committee.

The CHAIRMAN. You may supply the information, and we will find out what single State does not have adequate laws.

Mr. COHEN. According to this information, they all have it, Mr. Younger.

Mr. YOUNGER. That is all.

(The information to be supplied is as follows:)

STATE STATUTES HAVING INSPECTION PROVISION FOR DRUGS

1. Alabama: Amphetamines, and/or Other Stimulating Drugs Law Act 189, 1961 Special Session Laws of Alabama. Section 6—Inspection Provision.

2. Alaska: Food, Drug, and Cosmetic Act, chapter 129, Laws of Alaska, 1949. Section 22—Inspections—Examinations.

3. Arizona: Pharmacy, Dangerous Drug & Poison Law, title 32, chapter 18, Arizona Revised Statutes, Annotated. Section 32–1904 (7)—Power and Duties of Board of Pharmacy—Inspection.

4. Arkansas: Food, Drug, and Cosmetic Act, title 82, chapter 11, Arkansas Statutes 1947, Annotated. Section 82–1120—Inspection of Establishments—Examination of Specimens.

5. California:

Pure Drugs Act, Division 21, chapter 2, Health and Safety Code, 1947, Deering's California Codes, Annotated:

Section 26294—Prevention of Free Access of Agent to Establishment Manufacturing, etc. or to Vehicle Transporting, Drugs Unlawful.

Section 26330—Inspection of Factories and Vehicles.

Pharmacy Law, Article 8—Dangerous Drugs:

Section 4231—Stocks To Be Open to Inspection.

Section 4232—Records To Be Open to Inspection.

6. Colorado:

Food and Drug Act, chapter 66, article 22, Colorado Revised Statutes, 1953. Section 66–22–20—Inspections.

Pharmacy and Poison Law, chapter 48, article 1, Colorado Revised Statutes, 1953. Section 48–1–2—Powers and Duties, (g) Inspection.

7. Connecticut: Food, Drug, and Cosmetic Act, title 19, chapter 342, General Statutes of Connecticut, 1958. Section 19–237—Establishing Inspection.

8. Delaware: Pharmacy Law, title 24, chapter 25, Delaware Code Annotated. Section 2562—Inspections.

9. Florida:

Food, Drug, and Cosmetic Act, chapter 500, Florida Statutes, 1959. Section 500.21—Inspection of Factories, Warehouses, etc., by Commissioner and Board.

Pharmacy Law, chapter 465, Florida Statutes, 1959. Section 465.131—Authority To Inspect.

10. Georgia: Drug and Cosmetic Act, chapter 42–15, Georgia Code Annotated. Section 42–1515—Access to Factories, etc. by State Board of Pharmacy; Inspections; Examinations of Samples.

11. Hawaii:

Food, Drug and Cosmetic Act, title 7, chapter 51, Revised Laws of Hawaii, 1955:

Section 51–24—Inspection powers of Commissioner.

Section 51–25—Furnishing of Samples to Commissioner Required.

Section 51–26—Commissioner's Right of Inspection and Seizure.

Sale of Poisons law, title 7, chapter 53, Revised Laws of Hawaii, 1955, Section 53–5—Record of Prescriptions. The books and prescriptions shall be subject at all times to the inspection of the department of health or its agent.

12. Idaho:

Food, Drug and Cosmetic Act, title 37, chapter 1, Idaho Code, 1949. Section 37–133—Inspection of Establishments, etc.

Drug, and Medical Supplies Law, title 37, chapter 22, Idaho Code, 1949. Section 37–2209—Inspection.

13. Illinois:

Drug, Device and Cosmetic Act, chapter 38, Illinois Revised Statutes 1959:

Section 186.31—Carriers and Persons Engaged in Holding or Receiving Drugs, etc., in Commerce—Access to Records by Division.

Section 186.32—Factory, etc., of Vehicle—Entry and Inspection—Power of Superintendent.

14. Indiana:

Food, Drug, and Cosmetic Act, title 35, chapter 31, Burns Indiana Statutes, Annotated:

Sec. 35–3111. Availability of State Records.

Sec. 35–3113. Establishment Inspection.

Dangerous Drug Act, chapter 45—Acts of Indiana, 1961. Section 5. Records—Maintenance of.

15. Iowa:

Drug and Cosmetic Act, chapter 203A, Code of Iowa, 1958. Section 203A.16—Authority of Board—Inspection.

Pharmacists and Wholesale Druggists, chapter 155, Code of Iowa, 1958. Section 155.24—Inspection.

16. Kansas:

Food, Drug and Cosmetic Act, chapter 65, article 6, 1959 Supplement to General Statutes of Kansas, 1949. Section 65–674—Free Access to Establishments and Vehicles for Inspections and Samples.

Pharmacy Law, chapter 65, article 16, 1959 Supplement to General Statutes of Kansas, 1949. Section 65–1629—Inspection of drugs by board.

17. Kentucky: Food, Drug and Cosmetic Act, title XVIII, chapter 217, Kentucky Revised Statutes, 1960. Section 217.155—Department's Rights of Inspection; Requirement That Drug Inspector Be a Pharmacist.

18. Louisiana:

Food, Drug and Cosmetic Act, title 40, chapter 4, part 1, Louisiana Revised Statutes 1950. Section 631—Factory Inspection.

Pharmacy Law, title 37, chapter 14, Louisiana Revised Statutes 1950. Section 1178—Powers and Duties of the Board—Inspection.

19. Maine: Pharmacy and Poison Law, chapter 68, Revised Statutes of Maine, 1954. Section 1—Commissioners of the Profession of Pharmacy: Powers—Inspection.

20. Maryland: Pharmacy Law, article 43, Annotated Code of Maryland, 1957. Section 255—Inspection of Medicines, Drugs, or Domestic Remedies.

21. Massachusetts:

Food, Drug, Cosmetic, and Device Law, chapter 94, Annotated Laws of Massachusetts. Section 189A—Proceedings When Food, Drugs, Cosmetics, or Devices Suspected of Being Adulterated or Misbranded.

Narcotic Drug Law, chapter 94, Annotated Laws of Massachusetts:

Section 199. Sales by Pharmacists Upon Written Prescription; Requirements as to Prescriptions.

Section 203. Prescriptions, Orders, and Records Open Only to Certain Persons; Knowledge Not To Be Divulged; Exception.

Pharmacy Law, chapter 112, Annotated Laws of Massachusetts. Section 36C—"Wholesale Druggists" etc., Use of Term Restricted; Inspections; Reports of Violations.

22. Michigan: Pharmacy Law, Act 151, Public Acts of Michigan, 1962:

Section 18. All Prescriptions shall be preserved for a period of 5 years, subject to inspection by the board or its agents.

Section 5. The board shall appoint, inspectors who shall be registered pharmacists and who shall act as agents of the board within the provisions of this act and such rules and regulations as the board shall promulgate. Inspectors shall be hired from the eligible civil service roster of qualified persons.

Section 6. The board shall (b) regulate, control, and inspect the sale, character and standard of drugs, devices, and new drugs compounded, possessed or dispensed in this State, etc.

23. Minnesota: Pharmacy and Poison Law, chapter 151, Minnesota Statutes, 1957. Section 151.06—Powers and Duties—Inspection.

24. Mississippi: Pharmacy Law, title 32, chapter 9, Mississippi Code 1942, Annotated. Section 8852—Power of Board of Pharmacy, (d) Inspection.

25. Missouri: Food, Drug, and Cosmetic Act, chapter 196, Missouri Revised Statutes, 1959:

Section 196.055—Access to Places in Which Food, Drugs, Devices, or Cosmetics Are Manufactured.

Section 196.060—Carriers in Interstate Commerce Shall Permit Access to Records of Shipments.

26. Montana:

Food and Drug Law, title 27, chapter 1, Revised Codes of Montana, 1947. Section 27–112—(2591) Duties and Powers of State Board of Health—Regulations. (1) The board shall make all necessary investigations and inspections in reference to all food and drugs, etc.

Pharmacy, Regulation of Sale of Drugs and Medicines, title 66, chapter 15, Revised Codes of Montana, 1947. Section 66–1504—(3174) Montana State Board of Pharmacy—Powers of Board. (5) To enter and inspect by its duly authorized representative at any reasonable times any and all places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured.

27. Nebraska: Poisons Law, chapter 71, article 25, Revised Statutes of Nebraska, 1943. Section 71–2503—Poisons; Sale; Duty of Vendor to Record in Poison Register (Register Open for Inspection by Proper Authorities).

28. Nevada: Food, Drug, and Cosmetic Act, title 51, chapter 585, Nevada Revised Statutes. Section 585.240—Inspection of Factories and Vehicles.

29. New Hampshire: Food, Drug, and Cosmetic Act, chapter 146, New Hampshire Revised Statutes, 1955. Section 146:11—Enforcement; Rules; Inspections.

30. New Jersey:

Food, Drug, and Cosmetic Law, title 24, subtitle 1, New Jersey Statutes, Annotated. Section 24:3–1—Right of Entry: Opening Packages; Inspection.

Drugs, Manufacturers and Wholesalers, title 24, subtitle 1, chapter 6B, New Jersey Statutes Annotated. Sec. 24:6B–9—Right To Examine and Copy Records Listing Ingredients Used in Manufacture of Such Drug—If Believed Adulterated or Misbranded.

31. New Mexico:

Drug and Cosmetic Act, chapter 54, article 6, New Mexico Statutes Annotated, 1953. Section 54–6–16—Power To Make Inspections and Secure Samples.

Drug Store—Wholesaler—Manufacturer Registration Law, chapter 67, article 9. New Mexico Statutes, Annotated 1953. Section 67–9–24—Board Authorized To Hire Inspector.

32. New York: Pharmacy, Drugs, Devises, and Cosmetic Law, article 137, Education Law, McKinney's Consolidated Laws of New York. Section 6819—Factory Inspection.

33. North Carolina: Food, Drug, and Cosmetic Act, chapter 106, article 12, General Statutes of North Carolina, 1943. Section 106-140—Further Powers of Commissioner—Inspection.

34. North Dakota: Poison Law, title 19, chapter 19-04, North Dakota Century Code. Section 19-0403—Record To Be Kept of Poisons Dispensed; Examination of Record.

35. Ohio: Food, Drug, and Cosmetic Law, title 37, chapter 3715, Ohio Revised Code. Section 3715.70—Powers of the Director or Board of Pharmacy—Inspection.

36. Oklahoma:

Drug, Device, and Cosmetic Act, title 63, Oklahoma Statutes 1961. Section 266.15—Right of Access and Entry.

Pharmacy and Poison Law, title 59, Oklahoma Statutes 1961. Section 353.7—Powers and Duties of Board—Inspection (d).

37. Oregon: Poison Law, title 36, chapter 453, Oregon Revised Statutes. Section 453.020—Manufacture and Sale of Drugs To Conform to Standards; Substitutions Prohibited; File of Prescriptions (5) Original Prescriptions Received and Filled—Filed in Manner as Will Readily Be Accessible for Inspection by the Board of Its Duly Authorized Agent.

38. Pennsylvania:

Drug, Device and Cosmetic Act, title 35, chapter 6, Purdon's Pennsylvania Statutes Annotated. Section 780.17—Inspections.

Pharmacy Act, title 63, chapter 9, Purdon's Pennsylvania Statutes, Annotated. Section 390-6—Board of Pharmacy (h)(6) Inspection.

39. Rhode Island: Food, Drugs and Cosmetics Act, title 21, chapter 31, General Laws of Rhode Island, 1956. Section 21-31-21—Inspection of Establishments.

40. South Carolina: Pharmacy and Poison Law, title 56, chapter 22, Code of Laws of South Carolina. Section 56-1311.1. Additional Regulatory Powers of the Board.—The Board shall also regulate the practice of pharmacy, the operation of drug stores and pharmacies * * * and, in so doing, shall make, publish, supervise * * * The inspection of weights and measures used in the prescription department of drug stores and pharmacies and the compounding, dispensing and sale of drugs, medicines, poisons and physicians' prescriptions * * *.

41. South Dakota:

1960 Supplement to South Dakota Code of 1939; Title 22—Foods, Drugs, Oils and Compounds. Part I—General Administrative Provisions. Chapter 22.01—Department of Agriculture. Section 22.104—Assistance of public officers may be required (1) the Secretary of Agriculture, his agents or assistants by written or oral notice may require any police officer to inspect any place or product subject to the supervision of such Secretary under the provisions of this title, to determine whether its provisions are being complied with and to report the result of such inspection in accordance with the rules and regulations of the Department of Agriculture.

Barbiturates: Handling, Sale and Distribution, chapter 22, 12 A, South Dakota Code of 1939 (1960 supplement). Section 22, 13A07—Records: Availability to State Board of Health.

42. Tennessee:

Food, Drug and Cosmetic Act, title 52, chapter 1, Tennessee Code Annotated. Section 52-122—Inspection of Establishments.

Pharmacy and Poison Law, title 63, chapter 10, Tennessee Code Annotated. Section 63-1007—Inspection powers.

43. Texas:

Food, Drug and Cosmetic Act, Senate Bill 43, 1961 Acts of Texas. Section 21—Inspection Powers.

Dangerous Drug Law, title 12, chapter 3, article 726d, Penal Code, Vernon's Texas Statutes, 1960 Supplement. Section 6—Files or Records; Inspection, Inventory of Drugs.

44. Utah: Food, Drug and Cosmetic Act, title 4, chapter 26, Utah Code Annotated, 1953. Section 4-26-21—Power of Board To Have Access to Buildings, Vehicles, and Places—Inspection.

45. Vermont:

Food, Drug, Cosmetic and Hazardous Substance Labeling Act, title 18, chapter 82, Vermont Statutes Annotated. Section 4070—Inspection.

Poisonous Drugs Law, title 18, chaper 81, Vermont Statutes Annotated. Section 4026—Sale of Drugs; Record.

46. Virginia: Pharmacists and Drugs, title 54, chapter 15, Code of Virginia, 1950. Section 54–417—Power of Inspection.

47. Washington: Food, Drug, and Cosmetic Act, title 69, chapter 69.04, Revised Code of Washington. Section 69.04.370—Right of Access for Inspection.

48. West Virginia: Food and Drug Law, chapter 16, article 7, West Virginia Code of 1955. Section 1371—(3) Inspection of Analysis of Food and Drugs.

49. Wisconsin:

Pharmacy, chapter 151, Wisconsin Statutes, 1959. Section 151.01—Board. (3) The board (pharmacy) shall have the right to employ inspectors, special investigators, chemists, agents and clerical help for the purpose of carrying on the work of the board * * *.

Dairy, Foods and Drugs, chapter 97, Wisconsin Statutes, 1959. Section 97.34—Access to Buildings; Samples; Holding Order.—(1) The department (agriculture) or any of its authorized agents * * * may enter any place or building in which there is reason to believe that any food, drink or drug is made, prepared, sold or offered for sale, and may open any package or receptacle of any kind containing, or which is supposed to contain, any article of food, drink or drugs, and examine or analyze the contents thereof.

50. Wyoming: Pharmacy Act, title 33, chapter 22, Wyoming Statutes, 1957. Section 33–307—Powers of Board Pharmacy (4) To Inspect, etc.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Mr. Chairman, I am glad to see my old friend, Mr. Jehle, before the committee.

He said a number of things with regard to Food and Drug. He said at one point that he did not think it would be appropriate for Food and Drug to conduct vague, rambling, fishing expeditions.

Do you have any indication or any evidence that would indicate to you or to this committee that Food and Drug has been engaged in that kind of practice over the years?

Mr. JEHLE. Mr. Dingell, I would say that, based upon information supplied us by certain of our members, that sometimes an inexperienced, less-qualified FDA inspector might be guilty of such an investigation.

But the point we are trying to make here, sir——

Mr. DINGELL. This is a very serious charge you make.

Mr. JEHLE. There is no charge being made here. I am saying that——

Mr. DINGELL. You are telling us this morning that less-qualified, inefficient, and inexperienced food and drug investigators have occasionally gone in and meddled in your plants and constituent members' affairs.

Now, is this true or false?

Mr. JEHLE. I would like to have the point made exceedingly clear that the provisions of the bill would give an FDA agent the right to make that type of inspection.

Mr. DINGELL. I am not belaboring that point.

Mr. JEHLE. That is the only point I wish to make, Mr. Dingell.

Mr. DINGELL. At this time I wish to know: Do you have any evidence that would indicate that the Food and Drug Administration has in the past engaged in any activity that would meet your description of vague, rambling, fishing expeditions?

Mr. JEHLE. The statement that I made was not that such investigations have been made as a matter of course or routinely, but potentially they may be made. It is possible under the language of the bill.

Mr. DINGELL. Would you tell the committee this morning whether the Food and Drug has in the past engaged in this kind of practice?

Mr. JEHLE. No, sir; because they do not——

Mr. DINGELL. I beg your pardon?

Mr. JEHLE. Let me make it quite clear that FDA agents at present do not have the right to make such inspections without the consent—without the permission of the retail pharmacies.

Mr. DINGELL. I see.

So have you any evidence of Food and Drug agents having engaged in, or any information that would lead you to think that Food and Drug agents have at any point engaged in, vague, rambling, fishing expeditions into the affairs of retail pharmacies?

Mr. JEHLE. I said earlier that we have received complaints from members that FDA agents, even where granted permission by retail pharmacies, have made this type of rambling, vague——

Mr. DINGELL. You have received this kind of information?

Mr. JEHLE. Oh, yes.

I say it is not common. It is not a routine practice.

Mr. DINGELL. You would not object to presenting evidence before this committee on these vague rambling expeditions by Food and Drug?

You would not have any objection to documenting that they have conducted themselves in this manner?

Mr. JEHLE. The complaints that have been received—is that the type of evidence that you would require, Mr. Dingell?

Mr. DINGELL. I would just like to see some evidence that Food and Drug has behaved in this manner.

You have made the statement now that they have done this in the past.

I would like to see it documented.

Mr. JEHLE. I thought I made quite clear, sir, that these instances were sporadic. They are not a matter of routine, a matter of course, at all.

Mr. DINGELL. As a matter of fact, they are very few and far between, are they not?

Mr. JEHLE. Yes.

Mr. DINGELL. Practically nonexistent and not well documented at all, is this not true?

Mr. JEHLE. If this bill should pass, we might have a great many more.

Mr. DINGELL. We are taking this step by step, and I hope you will cooperate with me because we do not have unlimited time.

Mr. JEHLE. Yes, sir.

Mr. DINGELL. As a matter of fact, these inferences that you suggest this morning are not well documented, and they are rather few and far between, are they not?

Mr. JEHLE. I will not say that they are well documented. I can present the evidence, if it should become necessary.

Mr. DINGELL. What I am saying is that your statement is based on hearsay.

Mr. JEHLE. No, sir; absolutely not.

Mr. DINGELL. And not on sound knowledge of FDA practice.

Mr. JEHLE. I wish, sir, that my statement would be considered in the context in which it appears.

The point made is that the language is extremely broad, and I think that under that type of language, vague, rambling, fishing expeditions could be conducted by the FDA inspectors.

Mr. DINGELL. Now, let us get right down to this business.

You say that they can go in right now and can get information where they need to have it for law enforcement purposes through the use of a search warrant?

Mr. JEHLE. Yes, sir.

Mr. DINGLE. Is that correct?

Mr. JEHLE. Oh, yes.

Mr. DINGELL. The use of a search warrant is permitted only in one instance, is that not so, under traditional Anglo-Saxon law, and that is that it can be had only where the court is satisfied that there is probable cause to believe there has been commission of a crime, and that the warrant is needed for the purposes of gathering evidence useful in the prosecution of that crime?

Is this not a fact?

Mr. JEHLE. Probable cause; yes, sir.

Mr. DINGELL. This is the only time, probable cause that a crime has been committed and that the evidence is on the premises?

Mr. JEHLE. And this is a criminal statute with which we are dealing.

Mr. DINGELL. In the case of the Food and Drug Administration in the protection of the American public, they are not going to always have evidence that a crime has been committed, but, rather, they are going to very frequently be looking to make a check to discern whether or not good manufacturing practices are being used, whether dangerous and harmful drugs like amphetamines and barbiturates are being released upon the market through sundry channels. Is this not a fact?

Mr. JEHLE. Not that retail pharmacists manufacture.

Mr. DINGELL. I am not engaging in any fencing match.

Mr. JEHLE. That is what you just said. You referred to the manufacturing processes of the retail pharmacist.

Mr. DINGELL. No; I said this: I said, is it not a fact that this situation will not apply in many instances where the Food and Drug is involved because Food and Drug's function is not basically the prosecution of crimes?

Mr. JEHLE. Yes, sir.

Mr. DINGELL. But it is to assure that commodities are manufactured in a wholesome and safe way; that they are not adulterated, filthy or dangerous, is this not a fact?

Mr. JEHLE. Yes.

Mr. DINGELL. And so also it is a fact that Food and Drug will very frequently in its operations not have evidence of crime, but will simply be seeking to determine whether or not manufacturing processes are sound, safe, sanitary, and whether or not commodities of various kinds are safe, unadulterated and are fit for public use and not dangerous.

Is this not a fact?

Mr. JEHLE. That is correct; yes.

Mr. DINGELL. So, very frequently, where they need to perform their basic function, they will not have an opportunity to satisfy the re-

quirements of the law with regard to search warrants, and, yet, they must have certain information to carry out their basic function.

Is this not also true?

In other words, they must have the opportunity to gather information which will enable them to discern whether or not these commodities which they have responsibility over are actually safe and fit for public use; is this not true?

Mr. JEHLE. At the manufacturing level, yes.

Mr. DINGELL. At the manufacturing level, and I assume that in the course of their check, they are going to have to discern whether or not these commodities are on the shelves and in the stores of the retail pharmacies.

Mr. JEHLE. Let me say right now, Mr. Dingell, that the relationship between the NARD members and the FDA have been very fine for many years.

I think, as I told you, almost all of our members will cooperate with the FDA agents.

Mr. DINGELL. As a matter of fact, it has been so good over the years that you really have no cause to be fearful of any provisions of this bill, on the basis of your past experience, because your membership has been able to have a fine and wholesome relation with Food and Drug?

Mr. JEHLE. Why do we not just leave it on a voluntary basis, then? Why turn it into a compulsory process?

Mr. DINGELL. You have no reason to fear, on the basis of your past experience.

Mr. JEHLE. We do not want the compulsion, sir. We think that the State authorities are doing an excellent job of inspecting our files, our business records, and we would like to keep it that way.

Mr. DINGELL. Let us talk about the amphetamines. It is a fact, is it not, that there are large quantities of amphetamines that are getting into the marketplace, that are having a very dangerous effect upon the populace? This is true, is it not?

Mr. JEHLE. I think so; yes, sir.

All the evidence would indicate that that is true, sir.

Mr. DINGELL. And the Food and Drug indicates to us that controls under existing laws are not sufficient to protect interstate commerce and the people of this country from the large flow of both barbiturates and amphetamines; is this not correct?

Mr. JEHLE. That is correct.

Mr. DINGELL. And they are, of course, expert in the enforcement of law, and they have a good understanding of basic needs with regard to amphetamines, which I think perhaps is superior to the knowledge of the National Association of Retail Druggists, do they not?

Mr. JEHLE. I am not going to debate that, sir.

Mr. DINGELL. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Jehle, did I understand you to say that there is a voluntary understanding and cooperation between the pharmacists of the country and the Food and Drug inspectors?

Mr. JEHLE. That is correct.

I would like to have Mr. Cohen elaborate somewhat upon that in view of his experience.

Mr. COHEN. Mr. Chairman, in almost every instance where an FDA inspector comes into a retail pharmacy and identifies himself properly, he is treated very courteously and given the opportunity to get the information that he seeks.

Also, on the State level the FDA has had excellent cooperation with the State enforcement agencies. Where they have not been able to go into some isolated drugstores, they work through the State agencies.

I know of no instance where an FDA agent has had any problem getting the information that he seeks.

The CHAIRMAN. I have had some reports in my own district where on at least two occasions inspectors have gone into a drugstore and obtained the cooperation of the druggist, and, during the course of their inspection they came across certain things out of which came some charges. In one instance this caused some very serious problems for the druggist.

Have you had any similar reports?

Mr. COHEN. Yes.

There have been some reports to that effect.

The CHAIRMAN. I suppose they are not widespread. In my district, which is a rather large district, with a good many communities, and a lot of drugstores, there have been very few such instances reported to me. I can think of only one in which they did give the druggist a great deal of trouble and caused him a lot of concern.

But your great worry or fear is that if the authority of the agency is expanded, there will be a great many more such instances?

Is that your fear?

Mr. COHEN. Yes, sir.

It is very possible that that could happen.

The CHAIRMAN. Or is your objection based on the confidentiality of information between the doctor, the druggist, and the patient?

Mr. COHEN. That is a very important point, sir, because there has always been the feeling that the pharmacist should not disclose any information about a prescription unless the physician desires it or orders it.

He is very careful, in fact, to disclose information to the patient when such information is sought.

He usually, and in almost every instance, will refer the inquiry back to the physician.

Mr. JEHLE. And we might point out, Mr. Chairman, that those professional considerations apparently have moved the Federal Food and Drug Administration to exempt licensed medical practitioners from the provisions of this bill. I am referring to the patient-physician relationship.

The CHAIRMAN. Thank you very much.

Mr. SCHENCK. Mr. Chairman, may I ask one question?

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Thank you.

It was suggested during the testimony of one of the witnesses that information on the prescription or a duplicate copy of the prescription could be given to the patient by the pharmacist in the event that the

patient felt he might need that information, at a time when he was away from his home community and his own physician.

Is that possible or is that unethical or is it illegal for a pharmacist to do that?

Mr. COHEN. Mr. Schenck, the Durham-Humphrey law is very explicit in what the pharmacist may do in filling, refilling, or giving information on a prescription. He is not allowed to give a prescription out for the purpose of having it filled in another pharmacy, whether it is in the same State or another State.

However, he has the professional authority to write across the face of the prescription "for information purposes only."

In other words, if the patient will take this prescription to another pharmacy and try to get it filled, the pharmacist will respect that legend written across the face of the prescription and will not fill it because it is what we refer to as a legend drug and nonrefillable.

Also, if another physician or the physician would like to see the prescription or he does not have record of the prescription and he asks the patient to bring it in, this is the proper way to furnish that information.

That is the only way the pharmacist writes a copy of a prescription that comes under the regulation of the Durham-Humphrey law.

Of course, all prescriptions are not necessarily nonrefillable.

There are some that may be refilled, but this applies entirely to those prescriptions that are not allowed to be refilled unless you get the authorization of the physician either orally or by written prescription to refill the prescription.

Mr. SCHENCK. Thank you very much.

Mr. YOUNGER. Mr. Chairman, I would like to correct the record because I find now that Mr. Larrick did furnish that information.

The one State was Florida.

The CHAIRMAN. Mr. Rogers, of Florida, may have permission to extend his remarks at this point.

Mr. Jehle, thank you very much.

Mr. JEHLE. Thank you, sir.

The CHAIRMAN. Mr. Fuller Holloway?

STATEMENT OF FULLER HOLLOWAY, GENERAL COUNSEL, TOILET GOODS ASSOCIATION; ACCOMPANIED BY DR. EMIL S. KLARMANN, VICE PRESIDENT AND MANAGER OF THE TECHNICAL SERVICES OF LEHN & FINK

Mr. HOLLOWAY. My name is Fuller Holloway. I am an attorney admitted to the bar of the State of North Carolina and the District of Columbia and a member of the firm of Hamel, Morgan, Park & Saunders, of Washington, D.C. I appear here today on behalf of the Toilet Goods Association, for which trade association I am general counsel. The members of the Toilet Goods Association manufacture in excess of 90 percent of all toilet preparations sold in America.

I have with me, Mr. Chairman, Dr. Klarmann, who is the vice president and manager of the technical services of Lehn & Fink.

He holds the degrees of chemical engineer and a doctor of science.

He has published many papers and is renowned in his field and is

very knowledgeable in the manufacturing phase of this business, as well.

Mr. Chairman, bearing in mind your admonition of the limitations of the time of this committee, and, with your permission, I will refrain from reading the 10 pages of my prepared statement, but, rather, summarize it in my own words.

I think it will take much less time.

The CHAIRMAN. Your statement will be included in the record.

(The complete prepared statement of Mr. Fuller Holloway is as follows:)

STATEMENT OF FULLER HOLLOWAY ON BEHALF OF THE TOILET GOODS ASSOCIATION

One may inquire why an association of cosmetic manufacturers is interested in the terms of H.R. 11581, which is directed primarily at the drug industry. The reason is very simple. The definition of drugs in the Food, Drug, and Cosmetic Act requires that many products of the cosmetic industry are classified as drugs. It may surprise some members of the committee to know that products which they have regarded as cosmetics are in fact drugs by this definition. Some examples may be helpful. They include antidandruff shampoos and hair dressings, certain toothpastes, antiperspirants, some sunburn preventatives, depilatories, and so forth.

H.R. 11581 makes no change in the definition of drugs in the basic Food, Drug, and Cosmetic Act. All the provisions of the bill, therefore, with the exception of a few that name specific classes of drugs (such as barbiturates and amphetamines) apply equally to antiperspirants and antihypertensives, to dandruff remedies and diabetes injectables. It is a far cry from a prescription drug taken internally to affect a major body process to a product used topically for a strictly local effect. We believe that H.R. 11581 was drafted with prescription drugs in mind and without due consideration of proprietary drugs.

I would like to take a few minutes of the committee's time to point out how the bill would affect some cosmetic drugs.

PROVISIONS RELATING TO EFFICACY OF DRUGS

Part A of H.R. 11581 includes provisions relating to efficacy of drugs. Dr. Theodore Klumpp, testifying in behalf of the Pharmaceutical Manufacturers Association on Monday, August 20, 1962, presented a comprehensive review of the problems related to proof of efficacy, as this pertains both to the definition of new drugs and to the new drug clearance procedures. As Dr. Klumpp emphasized, medical opinion is not always unanimous with respect to the therapeutic effectiveness of drugs in the treatment even of well-characterized disease entities. We submit that the division of opinion may become even more marked when the problem deals with a condition like dandruff, the level of sweating, or the control of body odor. The evidences of these natural body functions are largely subjective in nature, and the effectiveness of a given product may perhaps best be judged by the user himself. The well-trained investigator, experienced in the art of "armpit sniffing" or in the exact measurement of sweat production, can predict no more than a probable response of users of products of these kinds. The submission of "substantial evidence" of the effectiveness of products developed to combat the personal problems of dandruff, sweating, and body odor should certainly be adequate to support a new drug application for such products. Even assuming that a given product is not effective for a certain percentage of users, these individuals can have lost at the most the price of a single package of the product. (Obviously, these statements are based on the assumption that the product has been demonstrated to be entirely safe for the purpose, to the satisfaction of both the manufacturer and the Food and Drug Administration.) And if, indeed, the product does not offer, to a sufficient number of consumers, the benefits that are claimed, the greatest loser will be the manufacturer, for he depends on consumer acceptance to recover the costs of research and development, and to show a profit to his shareholders. Certainly, products of this kind must comply with the statutory requirements that prohibit false and misleading labeling, but it seems unrealistic to require more

than substantial evidence of effectiveness to permit marketing of such products, when the ultimate judgment of effectiveness is made by the consumer himself.

One provision of the bill, section 102(a), materially amends the definition of "new drug" to include drugs which are not generally recognized as efficacious. Dr. Klumpp in his testimony last Monday discussed the subject at considerable length. I want to conserve the committee's time and am mindful of the chairman's injunction to avoid duplicating testimony. Let me say, therefore, that the Toilet Goods Association supports the views expressed by Dr. Klumpp as they appear on pages 18 to 20 of his prepared statement. We urge strongly that the criterion of effectiveness not to be added to the definition of new drugs, since this provision could result in a requirement that many products that have been on the market for long periods, with an excellent record of safety and acceptability, would needlessly go through the new-drug procedures again.

STANDARDIZATION OF DRUG NAMES

Part B of the bill covers the standardization of drug names. Section 111(a) adds a new section (508) to the Food, Drug and Cosmetic Act, giving the Secretary of Health, Education, and Welfare authority to promulgate regulations establishing a single standard name for a drug.

Section 112(a) amends paragraph (e) of section 502 of the Food, Drug and Cosmetic Act by deleting the provision which requires a drug to bear the common or usual name of the active ingredients and substituting provisions which would require that it bear the established name and quantity of each active ingredient. It further provides that the established name, which is either the name selected by the Secretary as mentioned earlier, or the name in an official compendium or the common or usual name, appear on the label preceding the proprietary name in type at least as large and prominent as that used for such proprietary name.

What would this do to the manufacturer of an antiperspirant who markets his product, we'll say, in a 1- or 2-ounce container bearing a label about a square inch in size? I remind the committee that, by present definition, this product is a drug and bears the information presently required under the Food, Drug and Cosmetic Act, including the name or names of the active ingredients. In the first place, the manufacturer would have to scale down the size of his trademark, the name by which his unique product is identified in the drug, or department store, or the supermarket. The buyer of cosmetic-drugs usually relies on the trademark to identify the desired product. Any provision which interferes with this free choice seriously handicaps the manufacturer who has established a valuable property right in the trademark and does a disservice to the consumer who would have difficulty in identifying the product of her choice. Further, the manufacturer, after reducing the size of his trademark, would have to find room to list the active ingredients—and there may be several—preceding the trademark in type of equal size and prominence. This morning I examined several antiperspirants. The active ingredients of one product are listed as aluminum sulfate, sodium aluminum lactate, and water-soluble lanolin; of another as zirconyl chloride and aluminum hydroxychloride; and of a third as basic aluminum formate and aluminum chloride. The problem of presenting the names of these ingredients on a small label, in the size and prominence required by the bill, together with other required label information, is self-evident. The identity of the product itself could be lost in a profusion of words.

In addition to listing the active ingredients as I have described, the manufacturer would also have to list the quantity of each. It is not clear whether this is to be an absolute figure or is to be stated as a percentage. In either event he is forced to give away a valuable trade secret for no apparent reason. Furthermore, he may be forced into an ingredient race with his competitor using the same active ingredient on the theory that a product which contains 5 percent of ingredient X is five time as effective as one which contains only 1 percent, whereas in fact that conclusion may be totally incorrect.

I have dwelt on this subject at some length to illustrate some of the difficulties that would confront the members of the cosmetic industry in the labeling of some of their products if part B of the bill is applied across the board to all drugs—proprietary as well as prescription.

The Pharmaceutical Manufacturers Association has fully explained to the committee the consideration with regard to the standardization of drug names

and the labeling of prescription drugs. We of the Toilet Goods Association are addressing ourselves to a completely different area. Regardless of the decision of the committee as to prescription drugs, we respectfully submit that the provisions relating to standardization of drug names would serve no useful purpose with respect to proprietary cosmetic type drugs.

We suggest, therefore, that the committee keep in mind the broad sweep of the drug definition in the act and consider whether it need apply the same legislative standards to the whole spectrum of drugs covered by this definition.

FACTORY INSPECTION

Section 201 of H.R. 11581 (pp. 30–32 of the print) greatly expands the authority of the Food and Drug inspector into the areas of records, files, papers and, perhaps, secret formulas and processes.

Under section 301(f) and section 303 of the Federal Food, Drug and Cosmetic Act, the refusal to permit inspection of anything authorized by section 704 of the act, including whatever is authorized under the proposed amendment, subjects the person to fines and imprisonment. On pain of criminal prosecution one must make sure that all records, files, papers, processes, controls, and facilities bearing on violations or potential violations of the act are within the scope of the inspector's examination. The proposed amendment would also include consulting laboratories (but restricted to those performing services for a fee or other remuneration), apparently whether or not such consulting laboratory has connection with interstate commerce or the shipment of goods therein.

It is said that inspection of consulting laboratories as well as the manufacturers is necessary because the Food and Drug Administration must be assured of the accuracy of data furnished it from such laboratories.[1]

A statutory confirmation of authority to inspect the records of both the manufacturer applicant and consulting laboratory relating to a specific product to validate data furnished the Food and Drug Administration with respect to that product (and to ascertain that the terms of an approval or certificate is carried out), may be in order. This is a very considerably different authority from that proposed in the bill.

Constitutional questions with respect to the application of the proposed provisions in the case of an unincorporated personal business are presented both as to the fourth[2] and fifth[3] amendments (as well as the interstate commerce problem with regard to consulting laboratories). Certainly the proposed language is deficient in that certainty required in criminal statutes.

Research with respect to development of new products ought not be stifled for fear of premature disclosure of discoveries made. Secret formulas must be protected. Consider, for example, a cosmetic product such as a perfume.

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[1] The Assistant General Counsel for Food and Drugs, Department of Health, Education, and Welfare, reported on Aug. 8, 1962, before the American Bar Association, San Francisco, some administrative self-help as follows:

"The list of [inspection] refusals is indeed a long one. It covers all types of business. It covers all kinds of requested information. And it all arises from the uncertain situation that prevails under existing law.

"In addition to asking the Congress to reexamine and to legislate on this problem, we have taken what steps we could by administrative action to improve the situation.

"As the reports of refusal of inspection increased in numbers and in variety of questions involved, we centralized them to be sure exactly what was going on. We found that some firms with a fixed policy against inspection were applying for effective new drug applications, certification of antibiotics, insulin, and coal tar colors, exemptions from certification, food additive regulations, and hazardous substance labeling exemptions. They were presenting data to us to support these requests, asking us to rely on it, but at the same time denying our inspectors the right to inspect to determine the accuracy of the data. So long as the refusals of inspection continue, we will—wherever the refusals are germane to the exercise of our statutory responsibilities—use every administrative means to withhold the new-drug applications, the exemptions, the regulations, and the certificates."

[2] Amendment IV: "The right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

[3] Amendment V: "No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when it actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

Perfume formulas have been devised after years of research by expert perfume chemists and the expenditure of oftentimes very large sums of money. The formula is the most valuable asset of the perfume company. It is what distinguishes its product from all others and makes possible its sales. The secrecy of such formulas is essential to the company. The formula of a popular perfume would be an extremely valuable item for sale by anyone coming into its possession.

It would not be fair to the manufacturers, to the consulting laboratories, or in fact to the inspectors themselves, to require under pain of criminal prosecution that such confidential or secret data and formulas be placed in the hands of any food and drug inspector who may happen to be assigned to the geographic area.

It is respectfully submitted that inspection authority, if extended beyond present limits, ought to be clearly defined and restricted to the coverage of records to substantiate data on which rests the administrative recognition of the product as lawful for its intended use.

Mr. HOLLOWAY. Also, Mr. Chairman, bearing in mind your advice that this hearing is limited to H.R. 11581, I will speak only to that bill and not H.R. 11582.

It is certainly a far cry from the type of products that you have heard mostly about here; that is to say, drugs having the capacity to alter the life processes of the body.

I speak only to those products which are applied, for the most part, topically, to the body's surface, which we will have to call, I believe, a hyphenated name, cosmetic-drugs.

We are only here really—I will change that for fear of making a very bad pun—we have been dragged into this drug bill because of the very broad definition of "drugs." Not only are those things which have the effect upon the life processes, that is, drugs, but those things which can in any way alter or change the structure of the skin surface are classified as drugs, such as antiperspirants.

Now, an antiperspirant inhibits the flow of sweat. It is compounded to have the end result of making one more acceptable among his fellows and perhaps himself lessening assault on the olfactory nerves.

The Pharmaceutical Manufacturers Association and the Proprietary Association representatives have gone into considerable detail with respect to the provisions of this bill regarding efficacy.

Those cosmetic-drugs such as the antiperspirants and the suntan lotions, which may also be devised to prevent sunburning, or such things as shampoos that have a germicide in them, are drugs under the definition, and we believe that in terms of the proof of effectiveness the best judge of the efficacy of these products is the consumer, because such products have a bearing on how that particular person—how he or she looks or smells and that sort of thing.

If I may make a reference to the Senate bill, which, I understand, has now been reported out of committee, the efficacy provisions in that bill have been changed, or at least they vary from the bill, H.R. 11581, and I believe, has terms that are much more acceptable than are in H.R. 11581.

The one thing I would like to emphasize most strongly before this committee is the provisions relating to the standardization of drug names.

This, in the first place, is an economic concept. What its bearing on prescription drugs may be, I am not prepared to cover.

With respect to proprietary drugs particularly, and with respect to cosmetic-drugs, we believe that the provisions of H.R. 11581 would be disastrous.

Take, again, the example of the antiperspirant, which usually is in a little jar, perhaps, the top of which is about the size of a silver dollar.

The present law provides that the active ingredients in that preparation must be shown on the label.

Many other things must also be shown on the label: the name and address of the manufacturer, the quantity of the contents, directions for use, the percentage of alcohol, all on this very small label.

The customer coming in to get a toilet preparation 99 times out of 100 chooses that toilet preparation because of its trademark, because of a trusted name, because of past experience.

It is not intended to have anything other than cosmetic application to him or her.

The Senate bill, again, the provisions of the Senate bill, as I read them, would require that the active ingredients be placed, or continue the requirement that the active ingredients be placed on the label.

A statement of the quantity of the active ingredients need not be shown.

As I understand the bill, although it is a little ambiguous, from a hasty reading, that the proprietary name, or, rather, stating it the other way, the active ingredients must be half the size, the print must be half the size of the proprietary name.

This, we believe, is still very bad. While the brand name or the trademark name need not be submerged in the ingredients, the design of the package is such that a consumer going along a supermarket shelf still wants to take a look and find out the brand of product that she wants. The Senate provision requiring a size of type relationship in connection with proprietary drugs cannot create anything but confusion.

Going over to the matter of factory inspection in H.R. 11581, it seems to me that after taking a look at what the Food and Drug Administration has really said that they are concerned with, which is the fact that they sometimes are not getting accurate information when they have to put out a certification or they are requested to clear a new drug or things of that nature, and that they really ought to have the authority to investigate and validate the information that is given them before they, in effect, approve what has been done, in terms of that it seems to me that this is a legitimate request.

That in the event information is supplied by an applicant, that information may come even from a consulting laboratory not within the control of the applicant. Then, as a basis for approval of the request, I would think the Food and Drug Administration ought to be able to go back to get to the original records to support it.

That is to say, the chart which the fellow made when he weighed the rats or the guinea pigs, or what he did back there, so that they can be sure that the basis of the Food and Drug Administration's approval or denial is well founded and can be validated.

But when we go over to the language of the bill that is before us now, it seems to me that the bill is asking that the entire facility of the manufacturer is to be opened up for inspection, and this, to my knowledge, has not been shown to be necessary.

In the area of consulting laboratories, it would seem to me again that there are problems with respect to the commerce clause of the Constitution as to whether actually they should be able to go into these consulting laboratories at all.

On the other hand, if the consulting laboratories file some data with them, then that would be that which would let them there for inspection.

These are the things that bother us, Mr. Chairman, and I respectfully submit that the matter of the standardization of drug names, insofar as proprietary drugs are concerned, should be deleted from this bill, and the matter of the factory inspection ought to be confined to the extension to which I have addressed myself.

Mr. ROBERTS. Thank you very much, Mr. Holloway.

Any questions by the committee?

Thank you very much.

Our next witness will be Mr. F. F. Dittrich, president of the Essential Oil Association of the U.S.A., 2 Lexington Avenue, New York 10, N.Y.

STATEMENT OF FRANK F. DITTRICH, TREASURER OF THE UNGERER CO., AND PRESIDENT, THE ESSENTIAL OIL ASSOCIATION OF U.S.A.; ACCOMPANIED BY R. E. HORSEY, VICE PRESIDENT, GIVAUDAN-DELAWANNA, INC., AND CHAIRMAN OF THE LEGISLATIVE COMMITTEE OF THE ESSENTIAL OIL ASSOCIATION OF U.S.A.

Mr. DITTRICH. I am Frank F. Dittrich, treasurer of Ungerer Co. of New York City, and have been engaged in the essential oil industry for more than 20 years. I am appearing here today in my capacity as president of the Essential Oil Association of U.S.A., and speak in behalf of its members.

Accompanying me here today is Mr. Robert Horsey, chairman of our legislative committee.

We are opposed to section 201 of H.R. 11581, the factory inspection provision, which is the only provision in this bill that directly affects our industry.

The Essential Oil Association comprises 78 companies which manufacture, process, and supply no less than 90 percent of the fragrances used in all the cosmetics, beauty preparations, and related articles of toiletry purchased by the American public. Fragrances also constitute a vital ingredient in soaps and detergents, and in many other commonly used articles. Therefore, we urge you to consider that virtually the entire population—in fact, each one of us—each day, no matter how simple his mode of life may be, buys and uses articles containing these fragrances. Moreover, our choice and enjoyment of them, and even the wish to use such articles at all, whether deliberate or unconscious, is decisively influenced by the fragrance which the article may have.

Thus, while our particular industry may be a comparatively small one, its influence in everyday life is great, and it is important, not

to any special group or class of people, but to all of us in a very personal way.

Another intriguing feature of fragrances is the fact that while their effect on the popularity, desirability, and usability of consumer goods is a vital factor, the amount of perfume oils needed to accomplish this vital effect is indeed very small. This is one reason why, in addition to the many years, and in some cases, centuries of safe experience with these materials, no hazard of any consequence is involved in their use. Amazing as this may seem to the layman, a few examples are cited to illustrate:

A widely used cosmetic, such as a cold cream, contains on the average of one-half of 1 percent of perfume oils. One point of perfume oils is used to impart the pleasant fragrance to 200 pounds of the cream, or 800 four-ounce jars. In terms of consumer use, this would represent 32,000 to 40,000 individual applications.

The ever popular cologne used so widely today contains about 3 percent of perfume oils. One pound of perfume oils prepared 4 gallons of cologne—or 128 four-ounce bottles—a common size unit sold on the retail market. If used lavishly by our charming ladies, this would be sufficient for 8,000 applications.

Thus, the concentration of perfume ingredients in contact with the body under normal usage is very low; and among all the literally millions of occasions on which such contact is made daily, nothing in our many years of experience indicates any adverse effect on the public health. Thus, there is not now, nor has there ever been, a problem which, as far as the perfume and fragrance industry is concerned, calls for the inclusion of our industry in the factory inspection authority of this bill.

The problems of our industry are entirely different from those of the manufacturers of drugs. I should like this committee to know what our problems are, for they have a direct bearing on the provisions to which this statement is directed—those of the factory inspection provision of H.R. 11581 (sec. 201).

The heart of our industry, and our most valuable assets, are the innumerable secret formulas, each of which contains anywhere from 20 to more than 200 ingredients. These formulas are the sophisticated end products of centuries of development—perfume making being as old as civilization itself. The creation of perfume bases is not just a skill or a craft; it is truly an art. All of the magic of a beautiful fragrance springs from the imagination and creative artistry of those few rare individuals whom we call perfumers. Using the vast multitude of ingredients—many from all corners of the earth—and after months and often years of experimentation, they finally produce the formula for that beautiful new scent which may be a perfume or a cologne, or a part of a beauty preparation such as a cream or lotion.

We possess nothing in our business that is more valuable than these formulas. All of our artistry, know-how, and experience repose in them. We must go to great lengths to protect their secrecy, and the inevitable loss which would result from formula disclosure would be a tragic blow to the companies in our field. The patent laws by their very nature do not, as a practical matter afford effective protection for perfume formulas. The only means available to duplicate or suc-

cessfully imitate these exclusive fragrances is to have access to the formula. It cannot be accomplished by analytical means. It is also notoriously difficult to obtain effective redress from the courts in situations where our trade secrets have been appropriated and used by third parties. Indeed, our only security is to take the most elaborate internal precautions against disclosure of the formulas, including the limiting of access to them to the fewest possible people.

The factory inspection provision, section 201 of H.R. 11581, would be tantamount to disclosure of our secret formulas and processes. It is not wholly inconceivable, nor entirely without precedent, that FDA personnel may, at some future time, be employed by competitors. Yet, under this bill, our industry will be under criminal penalty to show these formulas to FDA employees. What problem of national health and safety requires this endangering of our entire industry? We know of none.

Among the very few cases cited by FDA representatives where injuries were caused by cosmetics, not even one incident was given where the products of our industry were blamed as the cause of the injury.

We feel that we must strongly protest these proposed new broad powers as an attempt to grant authority for unreasonable search and seizure. There are well-established legal procedures for acquiring information or evidence where violation of laws is suspected. On the other hand, enactment of the proposed revision would, as a practical matter, open the door to unlimited browsing, fishing, and harassment at will by any one or more officers, any number of times, and of undetermined duration each time, under the cloak of entirely discretionary police powers ostensibly granted to every wearer of an official badge—with or without probable cause or suspicion of violation, or reasonable grounds for same. While the oppressive nature of such procedure is certainly apparent, we believe that its constitutionality is in grave doubt, to say the least.

From all our past experience, and from a careful and considered projection of how these broad new powers of inspection sought to be conferred upon the Food and Drug Administration would operate, we do not see how the inspection of our processes and formulas would confer any additional safety or protection on the consumer; but it would impose oppressive, expensive, and damaging burdens on us. The Essential Oil Association of U.S.A. strongly recommends that this committee take into consideration our industry's unique dependence upon the inviolability of its trade secrets, as well as its unique record of product safety; and exempt perfumes and fragrances used in cosmetics from the factory inspection provision of H.R. 11581.

We, however, suggest that the efforts to obtain drug legislation at this session of Congress should not be impeded by controversy involving other industries, arising solely by reason of this general factory inspection provision in its present form. For the same reason that this committee decided to restrict its hearing to H.R. 11581, and not take up at this time the complexities involved in H.R. 11582, we recommend that the factory inspection provision be revised to conform with those already approved by the Senate Judiciary Committee, which omits reference to foods and cosmetics.

On behalf of the members of the Essential Oil Association of the U.S.A., I express our appreciation for this opportunity to state our views on this bill.

Mr. ROBERTS. Thank you, Mr. Dittrich.

Any questions, gentlemen of the committee?

Mr. YOUNGER. Just one.

I judge from your testimony that one of the things that your industry fears is that some good promoter like Billie Sol Estes might very well get some Government inspector to copy a formula and disclose it.

Is that your feeling?

Mr. DITTRICH. Our feeling is that a man that would look at our formulas, and, necessarily, it is not erased from his mind as far as the disclosure of the formula is concerned, and there are certain ingredients that are specialties of particular houses that would be invaluable information, for example, to my house, which we do not know about, which help us to make a better product to compete with our competitors.

Mr. YOUNGER. That is all, Mr. Chairman.

Mr. ROBERTS. Anything further, gentlemen?

Mr. Glenn?

Mr. GLENN. Mr. Dittrich, I am curious as to what kind of oil this is that you use as the basic ingredients in these preparations.

Is that a trade secret?

Mr. DITTRICH. No.

I would just say that we use essential oils and aromatic chemicals, and I would say that maybe there are 4,000 to 5,000 of them in common usage.

Mr. GLENN. Is it an olive oil, or what?

Mr. DITTRICH. Oils from plants and trees and from nature itself, most of the oils, citrus oils which come from the peel of the lemon, the orange and the lime. There are oils from wood.

Mr. GLENN. Do you use any petroleum products at all?

Mr. DITTRICH. Not to a great extent.

Mr. GLENN. That is all. Thank you.

(The following self-explanatory letter was subsequently received with accompanying pamphlet:)

THE ESSENTIAL OIL ASSOCIATION OF U.S.A.,
New York, N.Y., August 28, 1962.

Re statement of Mr. Frank F. Dittrich, president, Essential Oil Association of U.S.A.

Chairman OREN HARRIS,
House Committee on Interstate and Foreign Commerce,
New House Office Building, Washington, D.C.

DEAR SIR: During the questioning period following presentation of my statement last Thursday, Representative Glenn inquired as to what were essential oils.

The attached pamphlet published by the association might be helpful to your committee in understanding our members' products and activities. It also lists the member companies.

If possible, we would appreciate if this pamphlet could be made a part of our statement.

Very truly yours,

FRANK F. DITTRICH, *President.*

ESSENTIAL OIL ASSOCIATION OF U.S.A., NEW YORK, N.Y., REPRESENTING THE PRODUCERS AND DISTRIBUTORS OF ESSENTIAL OILS, OTHER NATURAL MATERIALS AND SYNTHETIC AROMATIC CHEMICALS—FOR THE FRAGRANCE AND FLAVOR INDUSTRIES

ENRICHING OUR LIVES

In the simple daily routine of our lives, flavors and fragrances play an important part, subtle, at times almost unnoticed, but always adding enjoyment. In a sense they act as catalysts, helping to sell the profusion of consumer goods produced in the United States and making these goods more pleasing to the user. The refreshing tang of a tasty carbonated beverage, the clean smell of a cake of soap—our lives are enriched many times each day by the pleasures of taste and smell.

THE INDUSTRY—ITS SIZE AND SCOPE

Recorded history does not reveal when essential oils were first sold commercially, although there is evidence of the use of fragrances that goes back to the days of the early Egyptian dynasties. The development of the industry, however, as we recognize it today started over 100 years ago, maturing in terms of technological advancement at the time of World War I. Today, as a result of research and modern production techniques, it serves manufacturers of numerous finished products—foods, beverages, pharmaceuticals, soaps, cosmetics, toiletries, and many others. To give these products either a flavor or a fragrance—the essential oil industry gathers ingredients from all over the world—peppermint from the United States, lemongrass from southern India, rosewood from the rain forests of Brazil, citronella from the island of Formosa, civet from Ethiopia. Importing, collecting, processing, distilling, refining, the esesntial oil industry prepares these raw materials for use by other industries, whose products are merchandised directly to the consumer.

But the processing of these natural substances is only part of the story. In the last 20 years, the industry has advanced considerably in chemical technology, with the result that manmade materials today account for a large proportion of total tonnage produced. The modern "essential oil" plant now utilizes chemical research and all the complex tools of modern chemistry, including new production techniques used throughout industry. This swing to synthesis has required a much higher capital investment in manufacturing buildings and equipment, but the rewards have been substantial in terms of new materials, lower costs, better quality, and almost unlimited supplies.

In 1957 it is estimated that the essential oil industry produced over $150 million worth of flavor and fragrance materials, with a healthy outlook of steady and substantial growth in the immediate years ahead.

DEFINING THE PRODUCTS

Aromatic and flavor materials range, in broad terms, from the synthetic chemical compound emerging from a modern research laboratory to the jasmine oil or lemon oil extracted from natural materials. There are several hundred natural materials that are processed into essential oils. They include flowers, grasses, spices, herbs, citrus products, fruits, leaves, roots, wood, gums, and animal products. The processing of these materials by various methods, including distillation, extraction with a volatile solvent, maceration, and enfleurage (cold fat absorption), is done much the same way that it has been for many years, except that processes and equipment have gone through many stages of improvement and advancement.

Research has shown that these natural oils contain a multitude of chemical compounds, such as alcohols, esters, aldehydes, ketones, phenols, lactones, terpenes, and sesquiterpenes. They are reasonably uniform in composition and identifiable by such physical characteristics as specific gravity, refractive index, optical rotation, solubility in alcohol and other solvents.

Identification of these constituents in essential oils has led to the synthesis of many of them by researchers trying to duplicate nature's chemistry. In addition, modern research has produced a number of new synthetic aromatic chemicals similar in structure and odor to the constituents of the natural oils, as well as some that have entirely new odor characteristics. In all, there are perhaps 3,000 or more synthetic materials which have become important ingredients in the development of finished perfume or flavor compounds. With some of these compounds containing as many as 200 ingredients, it can be readily seen that the

synthetic is playing a vital role, not only from the standpoint of cost and quality, but from the standpoint of providing the perfume and flavor creative chemist with the tools that are necessary to produce better products.

SERVICE TO INDUSTRY

It is the aim of each member of the Essential Oil Association (EOA) to serve industry with products of superior and consistent quality, purity, and esthetic value. To maintain such standards, companies have worked together with the EOA, providing the leadership necessary for a growing, changing industry. This organization now has close to 60 active members—companies engaged in the production or sale of essential oils, aromatic chemicals, perfume, or flavor compounds in the United States and its possessions. There are a dozen associate members—U.S. representatives of companies engaged in these activities in other countries.

What is today a vital organization, started as a forum of 30 processors, importers, and dealers. Called together by E. V. Kileen of George Leuders & Co., they met to discuss problems confronting the trade in 1927. The Essential Oil Dealers Association evolved from that meeting. By December 1931, the association adopted a new constitution and a new name, in keeping with the growing scope of the industry—the Essential Oil Association of U.S.A.

As set forth in the constitution, the object of the association is the cultivation of sound relationships among essential oil producers, dealers, and distributors, by providing a meeting ground for the discussion of trade problems which are common to all. Promoting harmony and understanding grows in significance each year because of the international character of the essential oil industry, which brings American goodwill and trade to many countries throughout the world.

Guiding the Essential Oil Association are its three officers—and five members of the executive committee, elected annually. The headquarters of the association, at 2 Lexington Avenue, New York City, are under the direction of the executive director, Ray C. Schlotterer, who, with his staff, administers and coordinates the various functions of the organization. Reflecting the broad range of the association's activities are the standing committees.

COMMITTEES

Scientific.—The work of the Scientific Section, organized in 1937, is aimed to keep pace with the accelerated progress of the essential oil and aromatic chemical manufacturing industry, in their rapid advances in flavor and perfume manufacturing techniques. One of its responsibilities is to accept quality standards and specifications so as to facilitate the buying and selling of various commercial grades of essential oils and aromatics.

As of October 1958, some 150 specifications have been established with 21 test methods to aid in their determination. These have all beeen incorporated in the internationally accepted booklet "E.O.A. Standards and Specifications." This work, first released in 1946, has received worldwide recognition and has enhanced not only the professional stature of the industry, but has upgraded the increasing number of new products introduced during the years in commerce. This service to large-scale users filled a need which has not been covered previously by the official monographs of the United States Pharmacopoeia (USP) and the National Formulary (NF).

The Instrumental Analysis Committee, a separate section of the Scientific group, evaluates new spectroscopic developments in the analytical techniques of perfume and flavor materials as an aid to research and quality control. The preparation of pure organic compounds, and studying their idiosyncrasies under spectra, has been of considerable service to all interested.

Import.—The Import Committee is primarily concerned with U.S. customs and tariff regulations, ocean freight rates, and marine and war risk insurance on imported shipments. It represents the association before Government groups, and expresses trade opinion before Federal agencies. It contacts freight rate conferences and informs the membership of its activities through periodic bulletins. The committee also advises regarding difficulties with shippers as to weights, quality, etc.

Export.—The complex problems of international trade are reviewed by the Export Committee which keeps the membership informed of regulations and restrictions abroad. The committee takes an active interest in proposed re-

ciprocal trade agreements, export statistics, and legislation affecting shipments of these materials out of the continental United States of America.

Credit.—Members' inquiries concerning credit problems and policies are handled by the Credit Committee. It receives credit information from individual members and reports matters of importance to the membership through a bulletin service.

Trade names.—This committee publishes the "Coined Names and Trademark Catalog," and establishes the rules and principles which guide members in the selection of names for new products. Its list includes those names that have already been registered, and those that are in the coined-name category.

Legislative.—Proposed legislation affecting the essential oil industry is studied by the Legislative Committee for recommendation to the membership. This committee is the official representative of the association at all deliberations in Washington.

Arbitration.—Conflicts of interest between members of the association are submitted to the Arbitration Committee for settlement or advice.

There are many other fields of action of the association, all pointed to the promoting of fraternal relationship and goodwill. The EOA truly provides a common meeting ground for the discussion of trade problems common to all in the essential and natural oils, isolates, and synthetic aromatic chemical industries.

MEMBERSHIP

The members affiliated are as follows:

American Aromatics, Inc., 24 East 21st Street, New York City.
Aromatic Products, Inc., 235 Fourth Avenue, New York City.
Belmay, Inc., 116 East 27th Street, New York City.
Bertrand Freres, Inc., 443 Fourth Avenue, New York City.
Centflor Mfg. Co., Inc., 500 West 52d Street, New York City.
Ph. Chaleyer, Inc., 160 East 56th Street, New York City.
Charabot & Co., Inc., 114 East 25th Street, New York City.
Antoine Chiris Co., 212 East 23d Street, New York City.
Citrus & Allied Essential Oils, Inc., 61–63 Sheffield Avenue, Brooklyn, N.Y.
Dodge & Olcott, Inc., 180 Varick Street, New York City.
P. R. Dreyer, Inc., 601 West 26th Street, New York City.
Felton Chemical Co., 599 Johnson Avenue, Brooklyn, N.Y.
Firmenich & Co., 250 West 18th Street, New York City.
Fleuroma, Inc., 38 West 21st Street, New York City.
Florasynth Laboratories, Inc., 900 Van Nest Avenue, New York City.
Fries Bros. Inc., Post Office Box 8, Carlstadt, N.J.
Fritzsche Bros. Inc., 76 Ninth Avenue, New York City.
General Aromatic Products, Inc., 8044 N. Lawndale Avenue, Skokie, Ill.
Givaudan-Delawanna, Inc., 321 West 44th Street, New York City.
The Glidden Co., 52 Vanderbilt Avenue, New York City.
Hercules Powder Co., 380 Madison Avenue, New York City.
Hoffman-LaRoche, Inc., Roche Park, Nutley, N.J.
D. W. Hutchinson & Co., 700 S. Columbus Avenue, Mt. Vernon, N.Y.
Lauitier Fils, Inc. 321 Fifth Avenue, New York City.
George Lueders & Co., 427–9 Washington Street, New York City.
Magnus, Mabee & Reynard, Inc., 16 Desbrosses Street, New York City.
Mane Fils, Inc., 9 East 19th Street, New York City.
J. Manheimer, 214 East 21st Street, New York City.
Maywood Chemical Works, 100 W. Hunter Avenue, Maywood, N.J.
Neumann, Buslee & Wolf, Inc., 5800 Northwest Highway, Chicago, Ill.
New York Aromatics Corp., Post Office Box 15, High Bridge, N.J.
Norda Essential Oil & Chemical Co., 601 West 26th Street, New York City.
Noville Essential Oil Co., Inc., 1312 Fifth Street, North Bergen, N.J.
Orbis Products Corp., 601 West 26th Street, New York City.
Compagnie Parento, Inc., Croton-on-the-Hudson, New York, N.Y.
S. B. Penick & Co., 50 Church Street, New York City.
Perry Bros., Inc., 61–12 32d Avenue, Woodside, L.I.
Polak & Schwarz, Inc., 667 Washington Street, New York City.
Polak's Frutal Works, Inc., 33 Sprague Avenue, Middletown, N.Y.
Polarome Manufacturing Co., Inc., 73 Sullivan Street, New York City.
Reynaud, Ltd., 335 West 52d Street, New York City.
Rhodia, Inc., 60 East 56th Street, New York City.

F. Ritter & Co., 4001 Goodwin Avenue, Los Angeles, Calif.
P. Robertet, Inc., 221 Fourth Avenue, New York City.
Roubechez, Inc., 8 East 12th Street, New York City.
Roure-DuPont, Inc., 366 Madison Avenue, New York City.
Ryland-Johnson Co., Inc., 174 Front Street, New York City.
Schimmel & Co., 601 West 26th Street, New York City.
Standard Aromatics, Inc., 88 University Place, New York City.
Synfleur Scientific Labs., Inc., 33 Oakley Avenue, Monticello, N.Y.
Syntomatic Corp., 114 East 32d Street, New York City.
A. M. Todd Co., 1717 Douglas Avenue, Kalamazoo, Mich.
Tombarel Products Corp., 725 Broadway, New York City.
Trubek Laboratories, State Highway 17, East Rutherford, N.J.
Ungerer & Company, Inc., 161 Avenue of the Americas, New York City.
Van Ameringen-Haebler, Inc., 521 West 57th Streeet, New York City.
Albert Verley, Inc., 1375 East Linden Avenue, Linden, N.J.
Verona Pharma Chemical Corp., 26 Verona Avenue, Newark, N.J.
R. D. Webb & Co., Inc., 137 Boston Post Road, Cos Cob, Conn.

EOA Associate Members

J. Berlage Co., Inc., 11 East 44th Street, New York City.
L. A. Champon & Co., 303 West 42nd Street, New York City.
Doran & Schmiedel, 306 Main Street, Fort Lee, N.J.
Julian W. Lyon, 7 Dey Street, New York City.
Walter F. Mahneke, 75 Maiden Lane, New York City.
Calvert Mills Co., 44 Whitehall Street, New York City.
Ludwig Mueller Co., Inc., 24 State Street, New York City.
A. K. Peters Co., 501 Fifth Avenue, New York City.
Schmitz-Schoenwa!dt-Turner Co., 20 Vesey Street, New York City.
Ufinindo International Corp., 82 Beaver Street, New York City.
George Uhe Co., Inc., 76 Ninth Avenue, New York City.
John D. Walsh Co., Inc., 32 Broadway, New York City.

Mr. ROBERTS. Anything further?

Mr. DINGELL. Mr. Chairman, I am rather caught by surprise.

I would like to have permission of the Chair briefly to explore this with the witness, if I may.

Have you ever had any bad experience with the Food and Drug in the course of their factory inspections so far?

Mr. DITTRICH. No, sir.

Mr. DINGELL. None.

They have engaged in some factory inspections of your membership; have they not?

Mr. DITTRICH. Yes, sir.

Mr. DINGELL. And have you had any bad results of their inspections insofar as divulging of trade secrets or engaging in any other practice that might have been harmful to your industry or to your representatives?

Mr. DITTRICH. I do not believe they have had access to our trade secrets up to this point.

Mr. DINGELL. I see.

Now, what language in the bill—and I assume you have studied it—in the factory inspection section specifically authorizes the Food and Drug Administration to go into trade secrets and to engage in practices harmful to your industry?

Mr. DITTRICH. I believe the bill states that processes and formulas will be available for inspection.

Mr. DINGELL. If we put into the bill strict language making it a Federal criminal offense to divulge trade secrets except in cases where it is necessary to effect a criminal prosecution or to effect same action

by Food and Drug necessary to protect the public health and welfare, would this meet your objections to the bill?

Mr. DITTRICH. No, sir.

Mr. DINGELL. It would not.

Why not?

Mr. DITTRICH. Because, as we pointed out in our statement, it is impossible to determine whether or not a formula has been copied or whether somebody has duplicated it. These perfumers that we have, if we want to get into the intricacies of our business, are able to duplicate to a degree.

In other words, if Z company makes a perfume or a perfume base, we might duplicate it to a degree by determining through smell—odor—by determining by odor what is in there.

Therefore, we would not know whether this was divulged or not.

Mr. DINGELL. As a matter of fact, it is in the bill, there is language now that says:

> The using by any person to his own advantage of revealing other than to the Secretary or officers or employees of the Department or to the courts when relevant in any judicial proceeding under this Act as authorized by law any information required under authority under sections 404, 409, 505, 506, 507, 706.

Mr. DITTRICH. I am aware this is in the bill, but I do not think this is sufficient protection for us.

Mr. DINGELL. I would like to meet your objections and still have factory inspection of your industry.

Mr. DITTRICH. You have factory inspection at this point.

Mr. DINGELL. But I mean inspection of your books and records, too, and here is the reason.

You use, I assume, or could use benzine derivatives, do you not?

Mr. HORSEY. I do not know what you mean by "derivatives" here.

Mr. DINGELL. Coal tar derivatives.

Mr. HORSEY. Compounds made from coal tar products?

Mr. DINGELL. Yes.

You do use these?

Mr. HORSEY. That is possible.

Mr. DINGELL. And there are instances where some of these from time to time are found to be harmful to human life. Is this not a fact?

Mr. HORSEY. We do not know of any cases of the materials we make.

Mr. DINGELL. Well, for example, coal tar colors have been found from time to time to be extremely harmful. Do you use any coal tar colors?

Mr. HORSEY. No.

We only use colors that are prescribed under the regulations of the Cosmetic Act.

Mr. DINGELL. Have you ever used coal tar colors?

Mr. HORSEY. Yes.

Mr. DINGELL. Did you ever use red 1 and 2; did you ever use butter yellow?

Mr. HORSEY. No.

Mr. DINGELL. You do use aromatic hydrocarbons, though, do you not?

Mr. HORSEY. Not to my knowledge.

Mr. DINGELL. Aromatic hydrocarbons are benzine derivatives. You know what I mean?

Mr. HORSEY. I know what you mean.

Mr. DINGELL. You use these?

Mr. HORSEY. No; we do not.

Mr. DINGELL. Do you mean to say that your industry has never used benzine of benzine derivatives?

You said you used benzine derivatives.

Mr. DITTRICH. Coal tar products, we said.

There might be a different definition, in our opinion.

Mr. DINGELL. Essentially it is the same thing.

Benzine and benzine derivatives are essentially coal tar products, are they not?

Mr. DITTRICH. Mr. Horsey's concern makes aromatic chemicals. My company does not.

Mr. DINGELL. But aromatic chemicals you have used, have you not?

Mr. HORSEY. I did not follow your question.

Mr. DINGELL. Your industry has used aromatic chemicals?

Mr. DITTRICH. We use aromatic chemicals.

Mr. HORSEY. This is not the strict chemistry definition. When we speak of aromatic chemicals, we speak of chemicals that have an odor, an aroma.

Mr. DINGELL. I do not mean that definition of "aromatic." I mean derivatives of benzine, of coal tar.

Mr. HORSEY. There are benzine-derivative chemicals made.

Mr. DINGELL. Which are not found, let us say, in nature, but which are generally produced from coal tar distillates?

Mr. HORSEY. They may not have been found in nature, but whether they are present in nature may not have been ascertained.

Mr. DINGELL. How is Food and Drug going to discern the full safety of the substances used by your industry if they do not have authorization to look at books and records?

Mr. DITTRICH. First of all, you were talking before about some of these things, and I believe you think we are talking about internal or ingestion.

Mr. DINGELL. You are using them on the skin?

Mr. DITTRICH. On the skin, and the percentage, as I pointed out here is a larger percentage than normal usage.

For example, the example I gave on cold cream—a half of 1 percent is much larger than the average usage. Only one-tenth of 1 percent is used in an aerosol shave. It is a minute and miniscule portion.

Mr. DINGELL. But it is found from time to time that in foods and in drugs parts on the order of parts per million are harmful, is this not a fact?

Mr. DITTRICH. That is true.

Mr. DINGELL. So 1 percent is on the order of several thousand or perhaps 10,000 times larger than the level that is sometimes found to be harmful, is this not a fact?

Mr. DITTRICH. That is a fact.

As far as our information is concerned from polling our members, though, we have had no complaints.

In other words, when our finished-goods manufacturers—in other words, the witness before represented our customers, so to speak—

when they get a complaint, we would hear about it, if it came from our product.

We have never, to any great degree, I know of none in my own company, and in checking the industry we have heard of very few complaints that came from the items that we manufacture, that we sell to, say, the toilet goods manufacturers.

Mr. DINGELL. Thank you very much, Mr. Chairman.

Thank you, Mr. Dittrich.

Mr. ROBERTS. Anything further, gentlemen?

Thank you very much, Mr. Dittrich.

Our next witness is Dr. J. A. McCallam, American Veterinary Medical Association, 1507 M Street NW., Washington, D.C.

STATEMENT OF J. A. McCALLAM, V.M.D., WASHINGTON REPRESENTATIVE, AMERICAN VETERINARY MEDICAL ASSOCIATION

Dr. MCCALLAM. I am J. A. McCallam, local representative. Unfortunately, due to a chain of circumstances, our witness is not present this morning to testify, Dr. Jones from Chicago, nor did the statement arrive in time.

I talked with him this morning on the telephone. It is on the way, and at this time I request permission that it be included in the record of the hearings.

Mr. ROBERTS. Permission granted.

Dr. MCCALLAM. Thank you.

(The statement referred to is as follows:)

AMERICAN VETERINARY MEDICAL ASSOCIATION,
Chicago, Ill., August 24, 1962.

Hon. OREN C. HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.

DEAR SIR: The following statement of the American Veterinary Medical Association regarding H.R. 11581, 87th Congress, 2d session, is submitted for the consideration of the Committee on Interstate and Foreign Commerce.

The attention of the American Veterinary Medical Association (AVMA) has been called to the statement of D. L. Bruner, executive secretary, Animal Health Institute, given to your committee on August 21, 1962, concerning H.R. 11581.

The AVMA is unalterably opposed to the writing of a separate statute, or category, in the food, drug, and cosmetic (FDC) legislation for animal drug and feed products. Historically, animal drugs and feed additives did not meet their present high standard until controls for these products were included with the present FDC regulations for drugs used on man. Prior to this time the animal health field was commonly an outlet for drugs that were outdated, impure, not entirely safe, and otherwise undesirable. Recent FDA activities, authorized by a single statute applying to both man and animals, have provided the animal health field with effective, safe drugs. The veterinary profession strongly supports this situation.

It is altogether logical that the FDA statute for regulation of human and animal products remain as one, because:

1. Most of the drugs employed in man are in use to a greater or lesser degree in animals. These drugs come off the same production lines and differ only in respect to packaging. Thus, the problems of production, inspection, distribution, and even use are similar, if not the same, in many instances.

2. Many new drugs are now available for injection into, spraying on, or feeding to animals producing food for man. Many of these drugs will leave, for varying lengths of time, tissue residues in animal foods eaten by man.

3. As an agency with consumer protection responsibilities, we are frankly fearful of a backsliding of control over the products going into the animal health field if separate statutes are introduced for human- and animal-line products.

The animal outlet constitutes a massive market for a needed and effective drug; and this need should neither be hindered by excessive regulation, nor so loosely controlled as to constitute a hazard to the livestock industry and the public.

We do sympathize, however, with the current problem of drug manufacturers in getting new drugs approved under the "triplicate" control arrangement existing in the FDA. The necessity for many new drugs having to be cleared by three different sections of FDA (veterinary medicine, antibiotics, and food additives) with three different sets of requirements is unrealistic. Previously, all animal products were cleared by the Division of Veterinary Medicine to the reasonable satisfaction of parties concerned.

When the food additives amendment was passed in 1958, the legalistic interpretations were allowed to prevail over the knowledge and judgment of scientists within the FDA—resulting in the current state of confusion and delay in making desirable products available for use in the animal health field. The AVMA believes that the difficulties responsible for the current problems of manufacturers of animal health products and feed additives—and attributed by them to faulty legislation—can be corrected by returning all responsibility over animal health products to the Division of Veterinary Medicine to operate under current regulations. In this section there are veterinary scientists with knowledge and judgment to advise the Commissioner of the Food and Drug Administration for concise, prompt decisions.

The AVMA opposes any proposals to decrease the supervisory power of the Food and Drug Administration over the manufacture and use of nonprescription drugs and food additives. In fact, we feel that FDA supervision should be greater over food additives and nonprescription drugs than over prescription drugs, because with the latter there are professional practitioners controlling the dispensing and use of prescription products. Although the FDA cannot be expected to duplicate the supervision of prescription drugs provided by the professional man, we believe that increased control of nonprescription drugs and food additives for man and animals is necessary in the interest of greater consumer protection.

The AVMA firmly supports the general goal of consumer protection espoused by H.R. 11581, specifically, the efforts to "assure the safety, efficacy, and reliability of drugs," and to "authorize standardization of drug names." With respect to other items mentioned in H.R. 11581, the AVMA is willing to accept judgment of the Department of Health, Education, and Welfare in requesting the authorities contained in the bill and to support the provisions of H.R. 11581 not discussed above.

The AVMA presumes that it is not the intent of H.R. 11581 in title II, section 704, to regulate and limit the professional freedom of the practitioner to serve his patient. However, the wording of the above section is such as to cause the AVMA to urge that the following paragraph be included in the revised bill. "The provisions of section 201 and 704 shall not apply to practitioners of any profession who are lawfully entitled under a State or territory law to either prescribe, compound, or dispense any food, drug, device or cosmetic for patients within such State or territory, nor shall anything in this Act be construed as enlarging, reducing, or otherwise altering professional rights and privileges conferred by a State or territory law."

The AVMA, in behalf of the members of the veterinary profession in the United States, respectfully requests the committee's consideration of the views expressed herein and would request that this statement be also made a part of the record of the hearings conducted on H.R. 11581.

Respectfully,

L. MEYER JONES, D.V.M., Ph. D.,
Director of Scientific Activities,
American Veterinary Medical Association.

Dr. MCCALLAM. I should also like to request, Mr. Roberts, that the statement presented to your subcommittee, I believe on August 7, be included as part of the record of this hearing, if appropriate.

Mr. ROBERTS. Without objection, it will be so ordered.

88589—62——36

(The statement referred to is as follows:)

STATEMENT OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION RE H.R. 12420, H.R. 12437 AND H.R. 12715

Mr. Chairman and members of the committee, the veterinary profession, as represented by the American Veterinary Medical Association (AVMA), has a keen interest in all proposed legislation involving the Food, Drug and Cosmetic Act. We are vitally interested in having a constant supply of safe, efficacious and reliable drugs for treating and preventing animal ailments. We are also concerned that the drugs used in food-producing animals not affect the animal product in any way deleterious to man.

Most of the drugs employed in man are in use to a greater or lesser degree in animals. Some of the drugs used in animal feeds for growth stimulatory purposes and for mass medication are the same drugs used in human medicine, veterinary medicine, and as feed additives. Therefore, the American Veterinary Medical Association feels it should comment on these matters, since they do concern the practice of veterinary medicine.

The AVMA strongly supports the activities of the Food and Drug Administration, Department of HEW, its supervision of consumer foods, drugs and devices for man and animals. In the past, the FDA has extended its jurisdiction for protecting consumer interests over both man and animals. The AVMA will object strongly to any thinking and any effort to dissociate the supervision of foods, drugs and devices for animals from that of man. Newer knowledge about drug residues harmful to man in tissues of food-producing animals makes entirely clear the necessity for consumer protection through FDA supervision of drug usage in animal medicine. In particular, the AVMA commends the Division of Veterinary Medicine within the Bureau of Medicine, FDA, for many improvements in the area of animal drugs and feed additives within recent years. Furthermore, the AVMA urges that the scientists within the Food and Drug Administration be given full opportunity to use their scientific knowledge and judgment in determining a Government decision on problems arising under the Food, Drug and Cosmetic Act. This position is consistent with the White House Report of May 14, 1960, prepared under the chairmanship of Dr. Kistiakowsky, which stated that the supervision of drugs and feed additives for man and animals would not be improved until the scientists in the Food and Drug Administration were given the opportunity of making the decisions on the basis of their scientific knowledge and judgment.

The provisions of H.R. 12420 and 12715, as we interpret the language, provides the Secretary of HEW with authority to restrict a product if there is "substantial doubt as to its safety." We believe this feature is important and should be incorporated into the legislation as approved by this committee.

All three bills (H.R. 12420, H.R. 12437 and H.R. 12715) approach the problem of "prior sanction" as it affects the animal feed industry from an economic standpoint. The AVMA supports early correction and redress of this unfair and discriminatory situation among manufacturers of animal feeds and feed additives. The AVMA prefers the features of H.R. 12420 (Nelsen bill) and H.R. 12715 (Dominick bill) because of the previously mentioned safety clause.

The AVMA opposes any proposals to decrease the supervisory power of the Food and Drug Administration over the manufacture and use of nonprescription drugs and food additives. In fact, the AVMA feels that FDA supervision should be greater over food additives and nonprescription drugs than over prescription drugs, because with the latter there are professional practitioners controlling the dispensing and use of prescription products. Although the FDA cannot be expected to duplicate the supervision of prescription drugs provided by the professional man, we believe that increased control of nonprescription drugs and food additives for man and animals is necessary in the interest of greater consumer protection.

We view the proposed legislation outlined in H.R. 12420 and H.R. 12715 as support for the Food and Drug Administration. We would be opposed to any efforts to decrease FDA supervisory powers over drugs administered to animals, or added to their feed. If any changes are made, these should consist in more careful and extensive scrutiny of the safety, efficacy and reliability of chemicals and drugs distributed by nonscientific, nonprofessional persons for administering or feeding to animals producing food for man. The possibility of tissue residues harmful to man in food products from animals receiving drugs or chemicals is

not to be ignored. The only way such a circumstance can be prevented is to provide the FDA with the authority needed to insure the consumer public and the livestock feeders that drugs for animals are safe, efficacious and reliable.

In behalf of the practitioners of veterinary medicine, we wish to thank the committee for its courtesy and time in hearing this testimony.

Mr. ROBERTS. Mr. Ernest Giddings, National Retired Teachers Association and American Association of Retired Persons, 1346 Connecticut Avenue, Washington, D.C.

STATEMENT OF ERNEST GIDDINGS, DIRECTOR OF LEGISLATION, NATIONAL RETIRED TEACHERS ASSOCIATION AND AMERICAN ASSOCIATION OF RETIRED PERSONS

Mr. GIDDINGS. Mr. Chairman and members of the committee, my name is Ernest Giddings. I am director of legislation for two nonprofit organizations of older persons, the National Retired Teachers Association and the American Association of Retired Persons. I am appearing today on behalf of the 500,000 members of our associations to urge an early favorable report by your committee on H.R. 11581 in order that the bill may be taken to the floor of the House of Representatives for debate and action during the next few weeks before adjournment.

The associations I represent were organized to help older persons help themselves and to encourage them to accept a major share of the responsibility for making their later years meaningful and independent. Membership in the National Retired Teachers Association is open to any retired teacher. Membership dues are $2 a year. Membership in the American Association of Retired Persons is open to any person 55 years of age or over upon payment of the annual membership fee which is also $2. Both organizations are nonprofit and nonpartisan. The combined membership of the two organizations is approximately 500,000.

NRTA and AARP are dedicated to the purpose of serving the needs of their elderly membership. When our campaign for insurance protection was initiated there was no hospitalization or medical program exclusively for retired persons, and most programs designed to serve employed men and women arbitrarily excluded them from participation in the plan the day they reached the age of 65, or the company advanced the premiums with lowered benefits. To break this age barrier the officers of the two organizations worked for 7 years before convincing an insurance company to be daring enough to pioneer with us. The success of this breakthrough is attested by the fact that today more than 350,000 retired men and women are covered by a hospitalization program which was denied them until a few years ago, on no more valid grounds than that of age.

During the years 1958 and 1959 our members by the thousands protested the cost of the drugs. As a final result we established and have conducted for several years a nonprofit drug service for our membership. The major function of our drug service is to fill prescriptions and provide the vitamins ordered by our members. Several registered pharmacists are employed as well as total facilities to meet the regular standards of safety and sanitation.

Early in our experience with a drug service we invited the Food and Drug Administration to inspect our drug facilities and services as well as our labeling procedures for drug containers. We requested their comments and suggestions and their recommendations were accepted and carried out. We are not in the drug service by choice, but because our members take the position that they have no other way of securing the medicine they need at a price they can afford to pay.

Some organizations resent our entry into the drug field. As associations, we pay the same cost of drugs as they do. We ask no favors or concessions. We pay more than the going wage to our pharmacists. We conduct an ethical pharmacy. We share our potential profits with our members to keep them self-supporting on a limited income. This sharing seems to be the point of contention of those who resent our operation in the drug field. Yet we stand shoulder to shoulder with our critics in the defense of high ethical standards, of the purity of the products and the unquestioned spirit of mission that the dispensing of drugs generates.

Our members are vitally concerned with the subject before your committee for many reasons:

(1) The incomes of our people who were retired from public and private retirement systems were fixed 5, 10, 15 or 20 years ago and cannot readily be adjusted upward as our economy grows and as prices rise.

(2) Their ability to purchase the needed drugs often makes the difference between sickness and health and sometimes between life and death.

(3) When physicians, as is the general practice in writing prescriptions, identify the drug by its trade name instead of by its official name, they leave our aged sick little or no opportunity for reducing costs. The patient must buy the prescribed brand and is left no opportunity of shopping around to buy at a price he can afford;

(4) Those who exist on a bare subsistence level must often sacrifice on food or some other necessity in order to afford the prescribed drug or else deny themselves or ask for charity.

(5) The opportunity to buy drugs they need at a cost they can afford, will keep them physically fit, able to work part or full time to supplement their retirement incomes, and thus continue to do their part in the productivity of the Nation, and at the same time maintain their self-respect.

(6) When elderly people living on a subsistence income can be saved on drug purchases as much as $100 to $300 in 1 year, this saving alone may preserve their sense of self-sufficiency, their feeling of dignity, and keep them from being placed on the relief rolls of their local communities or State.

MONOPOLY

It is certainly to be expected that the work of your committee will result in a bill requiring improvement in the quality of drugs, requiring that physicians be provided with more adequate and complete information about drugs, and restricting the use of advertising matter of the overstated and misleading kind.

However, the bill makes little or no attempt to deal with the factor chiefly responsible for the high drug costs. Most sales of drug prescriptions are of patented drugs. The drug patent, like patents for a door lock or firearm, run for 17 years. This means that the owner of a drug patent is protected for 17 years in his exclusive monopoly, regardless of the fact that this monopoly control may be the single factor which prevents thousands of our members and millions of others of all ages from use of the drug. Cost is an extremely effective deterrent from the benefit of needed drugs in the case of older people with limited incomes. Much as we believe in the principles of free enterprise and protection of the profit motive, it is our position that no person or corporation should be allowed to withhold from public use products which relieve pain and suffering and which may make the difference between life and death. Only two other nations, Belgium and Panama, grant so much protection as we do in the nature of product patent monopolies on drugs without limitations on the drug producer to protect the public welfare.

Drug costs are not fiction; they are very real. Some reasonable part of the high costs can be charged to research. On the other hand, all the evidence indicates that drug industry profits lead all the rest by a wide margin.

Profits after taxes were 19.7 percent of investment in the drug- and medicine-manufacturing industries in 1961, according to reports published by the First National City Bank. This rate is almost double that of all manufacturing which was shown to be 10.1 percent in that year.

Markup on many drugs is appalling. Prednisone widely used in relieving pain from arthritis, has until recently cost the patient about 28 cents a pill or close to $30 a month. Until recently, the pill cost the druggist 17 cents each. After some investigations into drug costs, McKesson & Robbins commenced manufacture of the prednisone pill and found its costs to be approximately 1 cent per pill.

Our evidence is that tetracycline, an antibiotic, costs about 2 cents a pill to produce; costs the druggist about 30 cents and costs the patient about 50 cents.

We believe the interests of the drug industry can be adequately served and that the welfare of the sick and ailing at any age can be better served if your committee will write legislation to restrict the existing 17-year exclusive patent legislation now protecting the drug manufacturer at the cost of the consumer. We urge your committee to give full consideration to the licensing procedure proposed in S. 1552 in its original form.

Such a provision would require that the owner of a drug patent after a 3-year exclusive monopoly, license for production of the drug any qualified drug manufacturer, that manufacturer being permitted to agree to pay the patent owner up to an 8-percent royalty on all sales for the 14-year period.

Under such a plan competition would to a limited extent replace monopoly and drug costs to the ill and suffering of all ages should gradually become adjusted downward by a competitive marketing of the drug.

REGULATION OF LICENSE AGREEMENTS

A second factor contributing heavily to high drug costs is a practice common in the drug industry which results in price fixing by agreement. Such agreements are frequently entered into during the course of Patent Office hearings between rival applicants for a patent. The contracts thus agreed upon in these proceedings determine who shall receive the patent, who shall be licensed to produce the drug, and the price, usually uniform and identical, which each producer will charge for the drug.

We urge your committee, as it writes up the bill, H.R. 11581, to include an amendment requiring that all patent interference settlements be filed with the Patent Office. Terms of the agreements would therefore be available to both the Department of Justice and the Federal Trade Commission for use of either in any investigations into possible violations of the Sherman Act. We believe such a requirement would be of immeasurable assistance to these agencies. Since the Pharmaceutical Manufacturers' Association has agreed to the desirability of such a provision, it is our hope that your committee will write this requirement into H.R. 11581 before reporting out the bill. We believe such a requirement would greatly assist in lowering the excessively high prices of many drugs.

PROOF OF EFFICACY

Present law requires only that the Food and Drug Administration be satisfied that a drug is safe before it may be manufactured and sold to the public. Present law does not provide the Food and Drug Administration authority to require proof that the drug is effective in treating the sickness for which it is sold. In fact, and in practice, therefore, a drug may be legally marketed which is safe under current requirements but which is ineffective when taken by the patient for a specific illness. Frequently, the patient may be given the safe drug when he should be given one both safe and effective and in such a case the drug is positively injurious and harmful to the health of the patient. Medicines are too expensive and good health is too precious to receive so little protection from either the drug industry or from our Federal Government. By Federal law we give better protection than this to the products we sell to treat plant or animal diseases. It is our plea, therefore, that your committee insist upon perfecting section 102 of H.R. 11581, not only to require proof with application for a patent that the new drug meet a rigid efficacy test, but also proof of efficacy of every claim made for the drug after the patent has been granted and the drug is on the market.

The drug budget of our members is so limited and the health of all citizens is too vital to themselves and the national welfare to permit any degree of deception, however slight, in advertising a drug for human consumption.

NEW DRUG APPLICATIONS

Our recent experience with the baby-deforming drug thalidomide is ample proof that our Food and Drug Administration needs more protection by Federal statute in its terribly important duty to refuse

any and every new drug application as long as there is a shadow of a doubt about its possible dangerous side effects. A public official with less dedication to his or her tremendous responsibility than Dr. Kelsey might well have yielded to one of the more than 40 contacts from the new-drug applicant, the Merrill Co. In such a case deformed children would have been born by the thousands in our country.

The major impact of the thalidomide catastrophe occurred after the bill was introduced on May 3 of this year. It is to be assumed that you will greatly improve section 104, which, as it stands today, simply extends by a short time the opportunity of the Food and Drug Administration to require proof of safety of the new drug. We believe, the present requirement of automatic approval, whether after 90 days following application or after any other specified number of days, places unnecessary and dangerous pressure on the Food and Drug Administration staff. Some better plan than the automatic approval procedure must be devised.

In this brief statement I have tried to emphasize to your committee the position of our membership that drug prices are excessive. The incomes of older people are static and therefore buying power diminishes with every increase in the cost of living. If drug prices are needlessly high, it is our position that the Congress has a responsibility to the national welfare to seek out and apply the proper remedy. When freight rates became discriminatory decades ago, the Congress provided a partial remedy in enacting the Interstate Commerce Act. When the combinations known as trusts needed regulation in the last century, the U.S. Congress passed the Sherman Antitrust Act.

It seems to us that the Congress has ample evidence of the genuine need for the passing of an effective drug bill before the present Congress adjourns.

Mr. Chairman, I requested the manager of our drug service, Mr. James Browning, to prepare three examples of the difference in costs to our members when their prescriptions call for the drug by its trade name instead of by its generic name.

His reply was as follows:

In our drug service at 1000 Vermont Avenue here in Washington we fill approximately 6,000 prescriptions weekly. If these could all be filled with generic drugs, rather than with the same drugs carrying trade names, the savings to our members would be tremendous. As an illustration, we have many members using a trademarked drug prescribed for heart conditions.

In a 4-month period we dispense some 335,000 tablets of this drug. Sold under the trade name, this would amount to $13,187. If they were dispensed under the generic name, they would cost only $7,662, or a savings of $5,525. I find this is 41 percent below the trade-name price.

To use another illustration: a popular prescription for high blood pressure sells in the amount of 190,000 tablets per month, for a total of $10,250. This generic could be purchased for $3,945, or a saving of $6,301. This is a saving of 61 percent below the trade-name price.

A well-known tranquilizer sells up to 120,000 per month, with a cash value of $6,840. Purchased under the generic name, they would cost $3,000, or a saving of $3,840, or a saving of 56 percent.

These three drugs alone would have saved our members a total of $15,666 if brought under their generic name.

I want to thank your committee for the opportunity of appearing here before you today.

Mr. ROBERTS. Thank you, Mr. Giddings.

The committee appreciates your appearance and appreciates your support of the bill.

I wonder, though, over on page 7, you talk about the regulation of license agreements.

I wondered if you could give us any examples where that is taking place. You talk about agreements that entered into that go to Patent Office hearings between rival applicants for a patent.

If you do not have any specifically in mind, you could supply some of those for the record.

Mr. GIDDINGS. I would be glad to do that.

(The information requested follows:)

SUPPLEMENTARY STATEMENT TO TESTIMONY PRESENTED AUGUST 23, 1962, BY ERNEST GIDDINGS, FOR THE NATIONAL RETIRED TEACHERS ASSOCIATION AND AMERICAN ASSOCIATION OF RETIRED PERSONS, REQUESTED BY REPRESENTATIVE ROBERTS

The three license agreements named below were submitted by the corporations concerned to the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, during the 2d session of the 86th Congress and printed in 1960, as a part of the hearings before that subcommittee. The specific volume is titled "Part 17: Administered Prices in the Drug Industry."

Example I

Agreement between Rhone-Poulenc and American Home Products Corp., January 1, 1957, relating to Sparine.

The complete text of the license agreement on Sparine between Rhone-Poulenc and American Home Products Corp., executed January 1, 1957, is printed on pages 10078 to 10089, inclusive, in part 17: Administered Prices in the Drug Industry.

Example II

Agreement between CIBA, Ltd., a Swiss corporation, and S. B. Penick & Co., a Delaware corporation, regarding the manufacture of Reserpine.

The license agreement between CIBA and S. B. Penick & Co., regarding the manufacture of Reserpine, was executed January 1, 1956. The text of the agreement is printed on pages 10145 to 10157, inclusive, in part 17 referred to above.

Example III

Agreement between Carter Products, Inc., a Maryland corporation, and American Cyanamid Co., a Maine corporation, regarding the manufacture of Meprobamate.

The agreement between the above-named corporations was entered into July 3, 1957. The text of the agreement appears on pages 9690 to 9701, inclusive, of part 17 mentioned above.

Mr. ROBERTS. Any questions, gentlemen?

Mr. SCHENCK. Mr. Chairman, I have no questions, but I want to commend Mr. Giddings and his association for their splendid statement.

Mr. GIDDINGS. Thank you.

Mr. SCHENCK. I can assure Mr. Giddings and his associates that the committee will give it every consideration.

Mr. ROBERTS. Anything further, gentlemen of the committee?

Mr. DINGELL. I would like to also commend the witness for a very fine statement this morning.

Thank you, sir.

Mr. GIDDINGS. Thank you.

Mr. ROBERTS. Thank you very much.

Our next witness is Mr. Eugene P. Grisanti, general attorney, International Flavors & Fragrances, Inc., 521 West 57th Street, New York.

STATEMENT OF EUGENE P. GRISANTI, GENERAL ATTORNEY AND ASSISTANT SECRETARY OF INTERNATIONAL FLAVORS & FRAGRANCES, INC.

Mr. GRISANTI. My name is Eugene P. Grisanti, and I am general attorney and assistant secretary of International Flavors & Fragrances, Inc. I am appearing today to state our company's opposition to the factory inspection provision, section 201, of H.R. 11581, the only provision of the bill which materially affects our company.

International Flavors & Fragrances, Inc., is a medium-sized American corporation with its principal offices in New York and with manufacturing facilities in New York, New Jersey, Texas, and Oregon. In addition, it has 15 foreign subsidiaries in various countries throughout the world.

In the United States, the major portion of our sales consists of perfume compounds and other fragrance products, all of which, for ease of reference, I shall call "fragrances." Some of these fragrances are sold to manufacturers of perfumes, toilet waters, and colognes. Other fragrances are sold to manufacturers for the purpose of imparting a fragrance to cosmetics, soaps, and detergents and other similar consumer products.

We also manufacture flavors which are used in prepared foods, beverages, baked goods, confections, and ice creams and other dairy products.

We are in agreement with the statement filed with this committee by Mr. McCormick in behalf of the Flavoring Extract Manufacturers' Association concerning the harm which section 201 will cause to the flavor industry. In the time allotted to me, therefore, I should like to address myself to the detrimental effect section 201 will have upon the fragrance business, in the knowledge that the same arguments apply, for the most part, with equal validity to the flavor business.

To begin with, why is our company and industry so particularly vulnerable to irreparable damage from the inspection procedures proposed?

The art of perfumery has for centuries depended upon the secrecy of formulas. Formulas for a single fragrance may contain as many as 200 or more separate ingredients. In some instances, a single formula may be worth many millions of dollars. There is no effective way of protecting these formulas under our present patent laws. As a result, each individual company must still rely on its own security precautions, closely guarding its formulas as the most valuable of its trade secrets. Its stock-in-trade, therefore, literally reposes in its formula files.

Of course, if there was an overriding public need which required the disclosure of these formulas to protect the public health, I am sure that our company, as well as others in our industry, would respond to

that need under proper protective procedures, whereby disclosure to the appropriate governmental authority could be made with a minimum of risk. We are firmly convinced, however, based upon our own experience in the fragrance field, that no such public need exists.

Since the inception of our company in 1909, not a single judgment has ever been entered against us for injury from a fragrance supplied by us, nor has any payment in settlement ever been required to be made by us. One of the reasons for this remarkable record of safety, apart from our own testing programs, is the long experience of safe use of many fragrance ingredients. In addition, it should be noted that our fragrance products always represent only a minor percentage of the finished product in which they are used. A perfume, which traditionally has the highest fragrance content, contains only about 25 percent of fragrance itself, while the cosmetic creams or powders, for example, contain amounts ranging from one-tenth of 1 percent to 1 percent of fragrance. The danger of injury from the individual fragrance ingredients is in such cases, as a practical matter, nonexistent.

To illustrate more graphically the safety of fragrances, the experience of one of the largest cosmetic companies in this country shows the remarkably low record of complaints of injury per million units of cosmetics sold. Even these complaints are often due to an unusual allergenicity or hypersensitivity of the individual involved, misuse of the product, or, in some cases, coincidental factors not related to the product at all.

In any event, these figures show the highest number of complaints was for cosmetic creams, and that, at the low level of 5.1 complaints per million units sold. The point I wish to make, however, is this. Cosmetic creams have one of the lowest fragrance contents of any cosmetic, about one-fourth of 1 percent of the finished cream. The same company's statistics show that their perfumes, which have the highest fragrance content of any of their products, I repeat, about 25 percent of the finished perfume, or about 100 times the fragrance content of the creams, had the lowest complaint record, only 0.78 complaints per million units sold.

Similar experience has been had by other cosmetic companies, clearly indicating that no significant safety problem has existed or exists today with respect to the fragrance in a perfume or a cosmetic.

Against this truly unique record of safety, let us contrast the sweeping inspection powers which are sought to be added to the already broad provisions of section 704(a) of the act. Any employees of the FDA can today, simply upon presenting "appropriate credentials and a written notice" inspect one's, and I quote—

> factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

Section 201(a), of H.R. 11581, would add to this the right to inspect, and again I quote—

> all things therein (including records, files, papers, processes, controls and facilities).

An honest analysis of the entire provision leads to the inescapable conclusion that no portion of any office or factory involved will be inviolate from examination by an inspector claiming that his search bears "on violations or potential violations of this act."

This provision, we believe to be unconstitutional. The courts have consistently refused to sanction unlimited access to a company's records and files by a governmental officer or agency. The courts have consistently required the party seeking to examine such files to specify the violation committed and the particular papers relevant to such violation. General browsing to determine whether a crime has been committed has never been countenanced.

There have been implications by proponents of this measure that only those companies which have something questionable to hide, will oppose the proposed factory inspection provision. Nothing could be further from the truth. Americans have always deeply resented the indiscriminate invasion of the privacy of their homes and businesses by officers who demand to search without warrant upon the showing of a badge. It was just this resentment that gave rise to the fourth amendment of our Bill of Rights. It is not un-American to challenge such an invasion. It is un-American not to challenge it.

There are few citizens who do not have a healthy respect for the Food and Drug Administration and the formidable task of protecting the public health which has been entrusted to it. For this very reason, particular vigilance must be exercised to prevent a legislative grant of unconstitutional powers; and it would be difficult to envisage a provision which does greater violence than does section 201 to the safeguards against unreasonable search and seizure, of the fourth amendment. Is it, for example, consistent with the fourth amendment, or for that matter, our traditional concepts of fair play, that a businessman must allow his formula and trade secrets to be examined by any FDA employee during a routine inspection, or be in violation of Federal criminal law, if he does not?

If a formula becomes relevant in an administrative or judicial proceeding under the act, there are existing means for compelling its disclosure, under proper safeguards, enforced and protected by courts of law. The Federal courts can act swiftly to order the production of such records if they are relevant to a suspected violation under the act. Has any sound reason been advanced showing the necessity for imposing upon entire industries such a blanket police power of inspection and surveillance, which bypasses all courts and administrative bodies?

To these urgent constitutional questions, however, must be added the particular plight of companies such as ours which are asked to lay bare the secret formulas and processes upon which their businesses depend, the development of which has cost millions of dollars, and the only protection for which is their own ability to prevent disclosure. This last safeguard is taken from them by the proposed factory inspection provision for the purpose of achieving a solution for a problem which, we believe, as far as the fragrance industry is concerned, to be nonexistent.

This committee has decided to limit the present hearings to H.R. 11581, the drug bill. Hearings on H.R. 11582, the cosmetic bill, have, for the moment, been delayed, for the desirable objective, I believe, of obtaining effective drug legislation during this session of Congress. Consistent with this reasoning, it is respectfully suggested that section 201, which affects the food and cosmetic industries, as well as our own, be modified to conform with the factory inspection

provision of S. 1552, recently approved by the Senate Judiciary Committee. H.R. 11581 would then truly be a drug bill, and extraneous issues involving other industries would not impede its orderly progress.

I am grateful to the members of this committee for giving me this opportunity to express, on behalf of International Flavors & Fragrances, Inc., why we feel that the proposed section 201 of H.R. 11581 should not be enacted.

Mr. ROBERTS. Thank you, Mr. Grisanti. We appreciate your appearance here.

Any questions?

Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. Grisanti, you have indicated you have never had trouble with the Food and Drug Association in the course of your association and in the course of your company's association with them through the years?

Mr. GRISANTI. I did not so indicate. As a matter of fact, we have not had any.

Mr. DINGELL. You say you have not had?

Mr. GRISANTI. Not to my knowledge.

Mr. DINGELL. I see.

They have had access to your plant through the years, have they not?

Mr. GRISANTI. They have, under the present provisions of the law.

Mr. DINGELL. The present provisions of the law, I am sure you are aware, in the words of the Assistant Secretary of Health, Education, and Welfare and a number of others who have commented on behalf of that Department, constitute authority for the Food and Drug Administration to have nothing more or less than a guided tour of plants subject to the control of the Food and Drug Administration.

This is the situation, then, which you and your company desire to have continued?

Mr. GRISANTI. I do not agree with that characterization at all.

I think that the present law is effective, and I think, if it were utilized, that there would be no need for any additional extension of power.

Mr. DINGELL. But you do have this difference of opinion with regard to the efficacy of the present law, is that correct?

Mr. GRISANTI. Difference of opinion with the Department of Health, Education, and Welfare?

Mr. DINGELL. That is right.

And your difference stems from fear that if this legislation goes through affecting your company, or including your company, that perhaps there will be loss of trade secrets and so forth, is that correct?

Mr. GRISANTI. That is our reason, plus the fact that we believe that this extension of power is quite clearly an example of an unconstitutional grant of power by the legislature.

Mr. DINGELL. Now, let us take, for example, in the case of health inspectors, they have full access, your State health inspectors have full access to your plants, do they not?

Mr. GRISANTI. They have access to the premises and to inspect the premises.

Mr. DINGELL. That is correct.

Mr. GRISANTI. I believe that their access is limited. If they wish to make an inspection, for instance, of our files, and did not specify what they wanted or how it was relevant to their search, we would not allow that inspection to proceed.

Mr. DINGELL. Food and Drug has access to check on narcotics and things of that sort, as does also the Alcohol Tax Unit of the Treasury, which has full access to books and records and so forth, do they not?

Mr. GRISANTI. If they are relevant to the issue, yes.

Mr. DINGELL. Alcohol Tax has full access to books and records, do they not?

Mr. GRISANTI. Relevant to their inquiry, yes.

Mr. DINGELL. Yes.

And this bill authorizes access for nothing more than what is relevant to the inquiry, does it not?

Mr. GRISANTI. No, I disagree there. I think that the difference lies in the broad language at the close of section 201(a), which states that they can investigate all records and papers and so forth, if they believe that they may bear upon violations or potential violations of the act.

Now, as a practical matter, we know that an inspector under this type of a provision would be able to come into a plant and state that he is investigating a potential violation of the act, and under this broad provision we would be very hard put to deny that he has the right to do so.

Mr. DINGELL. But you have no objection, then, on a constitutional basis to (b) upon violation of the act, is that right?

On a constitutional basis, you have no objection if it goes just as far as to the violation of the act?

Mr. GRISANTI. Mr. Dingell, I think that the act, as it now stands, gives the FDA full authority.

Mr. DINGELL. I recognize that, but that is not responsive to my question.

My question was, if we limit it just to violations of the act, then you would have no constitutional objection to the language of it, is that right?

Mr. GRISANTI. No.

I would have a constitutional objection to the language because the language, as it is written, does not make any qualification of the types of records or papers or controls which are relevant to the violation, and I think that if there were such a qualification and if there were some protection afforded by court review or even administrative review, there would be a better case for its constitutionality.

I think that an inspector who can just walk in without a warrant and want to look at all your files because he claims that there may be a violation of the act is taking constitutional rights away from the person he is investigating.

Mr. DINGELL. The bill here says "to inspect at reasonable times, within reasonable limits, and in a reasonable manner such factory, warehouse," and so forth and so on.

That is a very definite limitation upon the power that the inspector has, is that not right?

Mr. GRISTANTI. Of course, this is a question of legislative draftsmanship.

Mr. DINGELL. It is a very definite limitation and it is a very strong limitation.

Mr. GRISANTI. I do not know whether it is or not.

Mr. DINGELL. "Reasonable times," "reasonable manner," "within reasonable limits."

Mr. GRISANTI. I do not know whether you can draft a broad clause, as broad as this is, and simply by inserting the word "reasonable" take away from it all the vagueness in one stroke.

I do not think that that could be done.

Mr. DINGELL. Your basic objection, however, to this bill has to do with possible divulgence of trade secrets, is that not it?

Mr. GRISANTI. As far as our company is concerned, yes, sir.

Mr. DINGELL. For all intents and purposes, your constitutional argument really is thrown in as kind of a catchall to buttress your basic objection, is this not a fact?

Mr. GRISANTI. Well, if you consider a constitutional argument as a catchall, I suppose it is, but I consider it more than that.

Mr. DINGELL. We have gone into this from the standpoint of the fact that traditionally Food and Drug has had factory inspection authority. The Alcohol Tax Unit has had the authority to investigate books and records. The Internal Revenue has authority to investigate books and records. The State income tax, the State sales tax agencies have authority to have full access to books and records.

Mr. GRISANTI. I differ with you.

Mr. DINGELL. And you recognize these as being fully constitutional?

Mr. GRISANTI. I differ with you on that. I think in every case you will find that before they can do that, they have to go to court and get a proper warrant to do it, unless, of course, the party wishes to cooperate and give them such records.

Mr. DINGELL. Not in the State of Michigan, they do not. They just go in and they get access to books and records.

It is also true in the case of Alcohol Tax Unit. They just go in and they have access to books and records.

You know this of your own knowledge from years with the Alcohol Tax Unit.

Mr. GRISANTI. I do not think there is a right there, unless the books and records are relevant. I will say this, however:

I know of no State law, including Maryland, in the case of *Frank* v. *Maryland*, where the distinction is not made between books and records and inspecting the premises for general hygienic conditions.

I think that books and records and correspondence and confidential files have traditionally been classed under our legal system in a different category than a general health inspection, and where these have been involved, traditionally, there have been the safeguards of subpena and court warrant.

Mr. DINGELL. Now, let us talk a little bit about your objections.

The committee was told this morning that fragrances can substantially be duplicated.

Is that not true?

Mr. GRISANTI. Of course, I am not in the technical end of the business, but I have been told that a good perfumer can in some cases come close to duplicating a particular fragrance.

Mr. DINGELL. Come very close, and with modern methods, spectographic analysis, modern chemistry, and perfumers' knowledge, really, a perfumer's secret formula is not too safe, is this not a fact?

Mr. GRISANTI. No, that is not a fact.

Even the most modern methods, including gas chromatography, have not been able to analyze completely the ingredients in a perfume.

Mr. DINGELL. They have been able to come very close, though?

Mr. GRISANTI. Not close enough to duplicate.

Mr. DINGELL. But close enough to substantially duplicate?

Mr. GRISANTI. No, not close enough even to substantially duplicate. It requires a skilled perfumer who uses his nose.

Mr. DINGELL. Who uses his nose?

Mr. GRISANTI. To do it.

Mr. DINGELL. And supplemental information, using modern scientific results to duplicate?

Mr. GRISANTI. He may be able to.

Mr. DINGELL. Very close.

Thank you very much.

Mr. ROBERTS. Thank you, Mr. Grisanti.

Our next witness is Mr. P. T. Dalsimer, chairman of Lawyers Advisory Committee of the United States Trademark Association, 420 Lexington Avenue, New York City.

STATEMENT OF PHILIP T. DALSIMER, CHAIRMAN OF LAWYERS ADVISORY COMMITTEE OF UNITED STATES TRADEMARK ASSOCIATION

Mr. DALSIMER. Mr. Chairman, I believe I am the last witness.

Mr. ROBERTS. Yes, sir.

With all due respect to you, may I say we are glad to have you.

Mr. DALSIMER. On behalf of the United States Trademark Association, a statement has previously been filed through its president, Thacher Fisk, and I believe that statement, which is dated June 12, is already of record. I have submitted a brief supplemental statement and ask that it be included.

I just want to make a few brief comments.

The Trademark Association is a relatively old association. It has about 260 members, and among those members perhaps 30 are in the pharmaceutical business. But, essentially, the Trademark Association is not a pharmaceutical association.

I am appearing here to discuss trademarks in principle. I am not appearing here to discuss details of this drug legislation except insofar as they apply to the trademark aspects.

As chairman of the Lawyers Advisory Committee of the United States Trademark Association, I was instructed to do what I could to answer any questions which might be directed either to Mr. Fisk, as president, with reference to his previous statement, or any questions that might be raised by my remarks.

This past year I was chairman of the Federal Trademark Law Revision Committee 201, of the American Bar Association, and so I have had a long and continuing interest in the trademark field.

I am a member of a private law firm, Kane, Dalsimer & Kane, practicing in the field of patents, trademarks, and copyrights.

There are only two provisions of the present bill that we object to in principle.

The first is the one that has a requirement which ties the size and position of the established name directly to the trademark.

The second is the principle under which the Secretary is given permission to determine the established or standard name of a product without, in our opinion, any adequate judicial control.

And so I will direct my remarks only to those two provisions.

First, specifically to the bill, which requires giving the precedence in position to the established name and requiring it to be in type at least as large and prominent as that used for the proprietary name, the association's objection is on basic principle, and our objection applies equally whether the requirement is modified to making the size of the type half as large as the proprietary name, or in any other specified size which ties it directly into the proprietary name.

The association does not object to a requirement for the use of nomenclature which in proper generic terminology states what the product is.

The reference plane for the size of the generic name should, however, not be the trademark. The reference plane should be an independent requirement that the size of the generic name be adequate to accomplish the purpose of the information.

I make reference to the present requirement, which, as you well know, in the Food, Drug, and Cosmetic Act, section 502(c), is that it be—

placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

It appears to us that this provision of the statute is clear and proper and could well be applied in the present situation.

The association believes that Congress must aid in solving problems. However, if Congress needlessly legislates every detail of labeling, such as requiring the precise size and precise position of a generic word with reference to a trademark, Congress may not have solved problems, but may have created them.

All labels are not the same. Products vary greatly. Packaging is of many sizes, shapes, and types.

I would like to interpolate here by referring back to what Mr. Holloway had pointed out:

That, for example, in deodorant packages it would be quite difficult to talk in terms of the size of the type of the word "deodorant" or any other word that might be chosen as the generic name being as large as the name "Mum," for example.

Why subject hundreds of manufacturers and users to a rigid control in a society that believes in and has flourished with flexibility? Rigidity may not be necessary.

Why set up rigid, specific, tied-to-trademark-size, congressional standards, so rigid as to perhaps make them unworkable in operation?

Why not utilize the less rigid, more flexible provisions of the existing Food, Drug, and Cosmetic Act? To put it another way, we believe that a minor problem should not be answered with a drastic remedy that straitjackets and perhaps renders impotent long-estab-

lished trademark values. It is as though all are to be punished for the transgressions of a few.

I am aware of the fact that comment has been made today, while I was sitting here, about the need for a generic name in order to reduce drug prices.

Surely this bill, which applies to so many areas, so many products, should not use the destruction of trademark values, long-established, as the basis for indirectly trying to achieve what perhaps may be justified, I am not sure, but as one who has sought to protect trademarks over a period of many years, it seems to me ill befitting Congress to pass a law that would indirectly seek to lower drug prices by destroying trademark values.

The other basic objection which the association has is to the provision which permits the establishment of an established or standard name for a drug "whenever in the judgment of the Secretary such action is necessary or desirable," and permits this establishment to be, by the Secretary, without, as we see it, any further controls.

There appears to be no provision for preventing the Secretary from taking such action until a proper judicial action has been taken to protect the interest of the trademark owner.

As we read the provision, the Secretary could select as the standard name of the drug an existing trademark.

The association believes that decisions of this type should not rest solely in the judgment of the Secretary. Surely the association is not taking any position of worry over a given Secretary. Government employees do their best, but no person in an administrative tribunal or a Government agency can know all, and persons very closely connected with certain agencies sometimes get a set, warped perspective of value—not warped in the sense that it is totally detrimental, but that they become too close to their work.

And administrative tribunals that both make the decisions and then enforce them are in danger, sometimes, of losing perspective.

We think that proper safeguards should be written into the bill to provide for judicial decision.

The common expression is that "hard cases make bad law."

We urge merely that in this excitement of the moment Congress not enact bad legislation.

We trust that the two suggestions which we have made will be given the fullest consideration, and that their concepts will be embodied in amendments to the bill.

Mr. ROBERTS. Thank you very much.

Your statement is very clear. You take the viewpoint that in the case where the Secretary might select a trademark as the standard or established name, you could force competitors of that trademark to adopt the same name and thereby possibly destroy the competition?

Mr. DALSIMER. I would think that what would happen if the Secretary should choose a trademark as the generic name, that then no competitor could do anything but use that trademark, and, of course, you would have instantly destroyed the trademark for the owner.

This could occur before any further action could be taken, because there are no judicial safeguards in the provisions.

Mr. ROBERTS. And you believe, too, that the Congress, if it undertakes to prescribe size of type and other requirements under this bill,

it would destroy a great deal of the flexibility that you think the administrator should have in carrying out the provisions of basic law?

Mr. DALSIMER. I think it is important for the administrator to have the flexibility, and I believe it is important for the multitude of manufacturers with the multitude of products they sell to have some flexibility.

Mr. ROBERTS. Thank you very much.

Any questions, Mr. Dingell?

Mr. DINGELL. No questions, Mr. Chairman.

Mr. ROBERTS. This concludes the hearings on H.R. 11581. The record will remain open for 5 legislative days for statements to be filed.

Mr. DINGELL. Mr. Chairman, in order to make sure the record is complete, I would like to ask at this time that the record be kept open for a matter of 7 days, since probably the committee will not be able to meet on this matter before that time.

Mr. ROBERTS. Five legislative days.

Mr. DINGELL. In order to permit Food and Drug Administration to submit, and I would like to have the committee request that Food and Drug submit to this committee any additional statement which they feel would be necessary in view of the comments which have been made by industry witnesses today.

I think that there have been a number of points raised which require either clarification or comment by the Food and Drug Administration, and I hope that the Chair will request of the Food and Drug Administration such additional comment on this as they feel would be necessary or appropriate.

Mr. ROBERTS. The Chair will be glad to comply with the gentleman's request.

Mr. DINGELL. Thank you, Mr. Chairman.

(The additional comments from the Food and Drug Administration follow:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 30, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: In accordance with the desires of the Interstate and Foreign Commerce Committee, we are transmitting the Food and Drug Administration's comments on testimony that has been offered before the committee on H.R. 11581.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

FOOD AND DRUG ADMINISTRATION COMMENTS ON TESTIMONY, H.R. 11581

SECTION 101. REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

Everyone agrees that better quality controls based on good manufacturing practice should be required for drug manufacture. The primary dispute is whether these requirements should be established by regulation or left to litigation on a case-by-case basis.

Some of the industry witnesses who have appeared argued that these regulations not be a rule that must be complied with but rather that they simply be prima facie evidence in case of court contest. The net effect of this latter proposal would be to slow down Government action, forcing us to establish de novo

in each court action whether the individual operations conducted by a firm had or had not conformed to good manufacturing practice. The following example illustrates the dangerous weakness of that position.

In September 1961, we learned that a dicalcium phosphate product used by pregnant women and others was contaminated with diethylstilbestrol, a synthetic sex hormone. Some male patients taking the product were developing enlarged breasts. Some female patients who were using it had abnormal uterine bleeding. We required the manufacturer, Nysco Laboratories, Inc., Long Island City, New York, to recall outstanding shipments of the contaminated product. In April 1962, we learned that another drug, isonicotinic acid hydrazide, manufactured by the same firm, was contaminated with the same synthetic sex hormone. It was causing excessive breast development and other symptoms of precocious feminization of babies in a San Francisco hospital. This product was also recalled. Subsequent investigation of the firm revealed additional products (such as sodamint tablets and a nasal decongestant) contaminated with synthetic sex hormones. The firm was not cleaning out a mill used in the manufacture of tablets unless the color of the second batch differed from that of the first.

When we discovered the cause of the mixups we made an extensive check of the firm's line of products which were both prescription and nonprescription items. We found that a number of products had been contaminated with penicillin left over from earlier manufacturing operations and these were recalled. A number of other products had been contaminated with a poisonous insecticide after the firm had manufactured a stock of lindane tablets. These also were recalled. In each type of contamination both prescription and nonprescription drugs were involved. This manufacturer, although one of the largest private formula firms in the United States, did not follow good manufacturing practice and consequently jeopardized the health of people all over the country.

If the industry proposal prevails we could be forced to establish in court for each of over 1,000 drug manufacturers what constitutes good manufacturing practice. This would detract significantly from the consumer protection intended to be granted by the proposed amendment.

The proposed answer to this problem in H.R. 11581 is to authorize the Secretary to determine and promulgate standards for good manufacturing practice. Appropriate procedures for hearings and appeals would be provided.

We agree with the representative of the Pharmaceutical Manufacturers Association that the standards must not be extreme or so unrealistic or unreasonable that they can be met by no one. The hearing and court review provisions would offer adequate safeguards against our issuing improper standards.

The committee has heard objection also to giving the Government authority to consider whether the manufacturer has followed good manufacturing practice with respect to the qualifications of the personnel employed in manufacturing drugs. No one questions the desirability of determining the competence of a pharmacist before he may fill prescriptions. But it is even more important to have well qualified people manufacturing the drugs the pharmacist dispenses. Yet, under present law, the man who drops out of pharmacy school without completing the course or who fails his pharmacy board examination, and thus is barred from filling an individual prescription, may set up a drug manufacturing establishment and produce potent drugs to be dispensed by pharmacists all over the United States. Clearly, it is desirable and imperative for the Government to be able to look into the qualifications of the key employees in manufacturing plants.

SECTION 102. PREMARKETING SHOWING OF NEW DRUG EFFICACY

Most witnesses agreed that the promoters of new drugs should be required to prove them effective, as well as safe, before they are marketed. The major points in controversy here are over how much evidence is to be required to establish effectiveness and how the new requirements will apply to drugs already on the market.

The committee has heard testimony about the alleged difficulties of establishing whether a drug will or will not accomplish its intended purpose and about the authority that this proposal would vest in one man.

The difficulties have been magnified. Obviously it is necessary to make investigations to determine what a drug will do. The drug companies routinely assert through promotional material in labeling and by other means what they believe their products will accomplish. They do not hesitate to make claims. The only

question is whether they should justify these claims or show the facts upon which they are based.

We have evaluated the effects of drugs for years. Several witnesses have pointed out that we do consider the efficacy of a new drug whenever it is so toxic that we must weigh the disadvantages from its toxicity against its advantages. Additionally, present law requires us to pass on the effectiveness of all insulin-containing products and the five antibiotics and their derivatives which are subject to certification. This evaluation is a true examination of the therapeutic effect that the products will have, not just the "potency" as one witness indicated on August 21, 1962.

Secretary Ribicoff submitted for the record last June some examples of new drug applications that we have had to allow to become effective even though the labelings bore claims that, in our opinion, are not supported by valid evidence. Some of these drugs are offered for very serious conditions. For example, a conjugated estrogen substance is offered for control of various types of hemorrhage such as those associated with surgical procedures and gastrointestinal hemorrhage. Another preparation, edathamil disodium, is offered for removing calcium from pathological deposits such as calcified heart valves and calcified deposits in the kidney. Papain is offered for the treatment of injuries, infections, and inflammations.

These claims are based on something. If they are based on fact there is no reason why the manufacturer should fail to submit to the Government the facts that convince them that the drugs are useful. And if the facts do establish this, there is nothing in the proposed bill to prevent the claims from being made.

If a product is put on the market with claims that are false or misleading, the Government may proceed against the product by seizure action or against the responsible party through injunction or criminal prosecution. No one testified that it is impossible in bringing such actions to determine whether a drug is or is not effective. The only issue is whether the claims of effectiveness are going to be reviewed before a product is put on the market or sometime later when, if the claims are false, the public has wasted its money and has relied on an inadequate product for relief or cure.

The charge that this bill would give one man the authority to determine whether a drug may or may not be marketed is not true. In the case of every new drug that we have held up on safety questions, the manufacturer has a right to insist upon a filing of his application and to force us to a hearing as to the safety of the drug. If he is not then satisfied with the ruling, he can carry the case to the Federal courts. The same safeguards would be available in dealing with questions of efficacy under the proposed bill.

When there are difficult questions of medical fact to be resolved the Food and Drug Administration has routinely called upon the outstanding medical experts for advice and assistance. To mention only a few examples, we have within the past 2 years sought advice as to the labeling of antibiotics to be used for prophylaxis, the labeling of chloramphenicol, the safety of safrole in foods, the safety of quinine for certain uses in beverages, the safety of a vaginal device, the safety of the drug reticulose for sale without prescription, the toxicity of phenacetin, safety of certain iron preparations when sold without prescription, and the safety of an oral contraceptive pill. If this bill becomes law, we will continue to utilize the very finest scientific talent of the Nation in resolving troublesome questions.

The committee has heard it implied that if the efficacy provision were written into the law a drug might be ruled off the market unless it offered a 100-precent cure. This is not true. Where we have dealt with efficacy questions in the past in conection with new drug applications, we have not taken such a position. For example, we have allowed products on the market for the treatment of certain cancers. They may prolong a patient's life by suppressing temporarily the progress of the disease even though the drug will not cure cancer and will not be effective in all of the patients on whom it is used.

Further, the efficacy provision would not allow the Government to specify what drug a doctor shall use in his practice, as one witness suggested. It would merely require the full truth to be told about a drug's effectiveness. The doctor still would choose the particular drug, from the hundreds available, that he wished to use.

The testimony that the medical profession has made mistakes in judging the efficacy of new drugs or treatments has no bearing on this bill. If the medical

profession judges a drug to be effective and it is not, then we will make the same mistake because we must rely upon the profession. And we will make the mistake whether or not H.R. 11581 is enacted. If the medical profession believes that a new drug is ineffective, we will have to abide by that view. But if it is wrong the only thing the manufacturer needs to do is demonstrate effectiveness. And he has authority under the law to have experts conduct tests for this purpose. Certainly it would not be good public policy to allow drugs to be promoted for uses which, on the basis of sound experimental evidence, the profession itself judges to be false.

Much has been said about whether proof of efficacy should rest upon a preponderance of the evidence. In reaching a judgment our scientists would evaluate the total experimental data in an application and otherwise before us. They would evaluate the adequacy of each experiment, the test plan, the controls used, the confirmatory laboratory procedures, and other pertinent factors. If the total evidence showed that a drug would do what the manufacturer claimed for it, the claim would be allowed. Otherwise it would be denied. Of course, there would be occasions in which some tests appeared to discredit a drug but the total evidence clearly showed it to accomplish the benefits claimed. In such event the claim would be approved. There would be other cases where some preliminary testing appeared to support a claim but the total evidence clearly proved it wrong. In such event the claim would not be approved. This is exactly the process employed today in deciding whether a claim being made for a drug already on the market is true or false.

The committee heard much debate about whether the definition of the term "new drug" in the law should be amended to include efficacy. Those who oppose such amendment have ignored the key question. "Why should a product be permitted on the market with unproved claims just because it is recognized as safe?"

The answer is, of course, that it should not. But to leave efficacy out of the definition of "new drug" would permit new unproved claims to be made for safe drugs.

This brings us to the question of a grandfather clause. Some witnesses want a complete grandfather clause. This would mean that the thousands of products that have gone through the new drug safety clearance procedure could continue to be marketed with unproved claims for efficacy while the Government conducted tests or otherwise amassed data bearing on the truthfulness of the claims.

Why should a manufacturer be given a license to continue to promote a drug for conditions in which it has not been shown effective simply because he started doing so before a serious flaw in the act was corrected? On the other hand, we do not propose that these thousands of drugs be summarily taken off the drugstore shelves. We, of course, would suggest a reasonable transition provision.

SECTION 103. RECORDS AND REPORTS AS TO EXPERIENCE ON NEW DRUGS

There seems to be general agreement that drug manufacturers should promptly report to the Food and Drug Administration any clinical experience or other reports casting doubt upon the safety or effectiveness of new drugs or antibiotics (as provided in sec. 106 of the bill).

However, some witnesses would impose a requirement that such reports be made available only to medical officers of the Department. They suggest that medical ethics would demand this. That is not true.

There is no more reason to keep such reports from highly trained and skilled personnel of the Food and Drug Administration who are not M.D.'s than to keep the reports from nurses, pathologists, physical therapists, pharmacists, administrators, and others who properly have access to them in hospitals and clinics.

As the questioning on this point clearly revealed, an expert without an M.D. degree might be the very person best qualified to evaluate a particular report.

SECTION 104. PROCEDURAL CHANGES AS TO NEW DRUGS, AND ADDITIONAL GROUNDS FOR WITHDRAWAL OF SUSPENSION OF APPROVAL OF NEW DRUG APPLICATIONS

Most people recognize that the present time limits for handling new drug applications need improvement.

This brings us to the testimony about whether a new drug application should be "approved." No matter how you describe it, if the Government found that a new drug is safe and effective and allowed it to be marketed under the proposed claims, the drug would have Government approval. We do not understand the objection to saying so. One witness testified that with the concurrence of Secretary Ribicoff, Commissioner Larrick conceded that the law should not be changed to require affirmative approval. A review of the full testimony, to which he referred only in part, will show that the Commissioner made no such concession. We fully support affirmative approval.

H.R. 11581 would also establish additional grounds for withdrawal of approval of new drugs and thus significantly strengthen consumer protection.

Under present law a new drug application can be suspended only if we can prove that the applicant made false statements or if new tests show that the drug is unsafe (but while these tests are being run the product may remain on the market).

This situation leaves a serious gap in consumer protection.

H.R. 11581 would close this gap by authorizing the Secretary, when he finds that there is substantial doubt as to a new drug's effectiveness or safety, to give the applicant due notice and opportunity for a hearing on the question of withdrawing approval of the application by order. Further, if the Secretary finds that there is an imminent public health hazard, he may suspend the approval of a new drug application immediately upon notice pending the opportunity for a hearing.

Spokesmen for the PMA opposed giving FDA the power immediately to suspend an effective new drug application upon a finding that it poses an imminent hazard to health. They reason that we already have ample powers through publicity and by obtaining a temporary injunction to protect the public in such cases.

The point overlooked by these arguments is that our power to obtain an injunction would depend primarily on the suspension of the approved application. The courts are given jurisdiction to enjoin violations of the act—in this case the introduction into interstate commerce of a new drug for which there is no approved application. So suspension would be a necessary first step in invoking the injunction power of the district courts.

We could, of course, also seek an injunction by proving that the new drug was either misbranded or adulterated. But if we had an outstanding approval of the drug, both from the standpoint of safety and effectiveness, the courts would be reluctant to find that our approval was a mistaken one when we ourselves had not withdrawn it.

And a drug might pose an imminent hazard to the public health, before we were prepared to shoulder the burden of proving that it was adulterated or misbranded. Take a case like thalidomide—had it been approved, the very first notice to us that it was the probable cause of phocomelia would establish an imminent hazard to public health, calling for immediate withdrawal of the drug, even though all the facts had not yet developed to pin down the cause and effect.

An imminent hazard to the public health is one that allows no delay. It may arise from the certainty of injury to the public or from the grave consequences that would follow if the suspected dangers actually proved out to be attributable to the drug. In both situations, we think we should have the power immediately to suspend the new drug from the market while the hearing, on an expedited basis, was held to determine whether the suspension should be finalized.

SECTION 105. CERTIFICATION OF ALL ANTIBIOTICS

Batch-by-batch certification of all antibiotic drugs is needed primarily because antibiotics more than any other drugs are the first choice in treating life-threatening infectious conditions; use of a subpotent, ineffective or otherwise unfit antibiotic can deprive the victim of the narrow margin of time that means the difference between life and death.

Some industry representatives believe that the antibiotic manufacturers are now able to do an acceptable job without the added controls afforded by certification. This is not true for all manufacturers.

Within the past 3 years we have had to withhold for varying periods of time, certification services with respect to all certifiable antibiotics distributed by six firms until their operations were brought into compliance with the regulations which are designed to insure safety and efficacy of certified lots. The firms and dates of withholding are:

(1) Allied Bio Chemical Co., San Francisco, Calif.: Withheld in August 1959; resumed in March 1960. Withheld in September 1961, not yet resumed as of August 23, 1962.

(2) Philadelphia Laboratories, Philadelphia, Pa. Withheld in January 1961; resumed in February 1961. (Recently this firm, along with its president and vice president, was convicted of shipping illegal antibiotics. These included one lot of uncertified, subpotent bacitracin which was refused certification by FDA but which later turned up in New York City hospitals, and a batch of uncertified, low-potency penicillin tablets.)

(3) Success Chemical Co., Brooklyn, N.Y. Withheld in November 1961; resumed in March 1962.

(4) Difco Laboratories, Detroit, Mich. (manufacturer of certifiable antibiotic sensitivity disks). Withheld in April 1962; resumed as of June 1962.

(5) Bio Ramo Drug Co., Baltimore, Md. Withheld in May 1962; resumed as of June 1962.

(6) Jamieson and McKames Pharmaceuticals, St. Louis, Mo. Withheld June 1962; not yet resumed as of August 23, 1962.

In addition there have been a number of suspensions of certification for individual products of antibiotic firms because of unsatisfactory conditions with respect to their production.

Despite the manufacturers' check of each batch of antibiotics before submitting it for certification, in fiscal year 1961 samples from over 100 batches, and in fiscal year 1962 samples from over 120 batches of antibiotics offered for certification failed to meet the standards set forth in the regulations. We attach a listing of these rejections.

Several witnesses have testified to the great strides which have been made in manufacturing techniques relating to antibiotics. Penicillin has been discussed particularly and a statement was made that current techniques make it possible to produce penicillin which is "indefinitely stable."

In the past 19 months, there have been 83 recalls of drugs for human use. Sixteen of these recalls or almost 20 percent have involved penicillin-containing products and have been due to either a material variation from declared potency or because the penicillin was contaminated with excessive moisture (a condition that may speed up deterioration.) These products met the potency and moisture requirements of the regulations when manufactured; they were not "indefinitely stable."

It is not true as one witness suggested, that we want certification of all antibiotics for the additional fees which would be involved. The fees for the certification of antibiotics are paid into the Treasury and are subject to annual appropriation by the Congress.

In our opinion, certification of all antibiotic drugs would be in the public interest.

SECTION 106. RECORDS AND REPORTS AS TO EXPERIENCE ON ANTIBIOTICS

This was covered under section 103 above.

SECTION 107. BIOLOGICAL DRUGS

H.R. 11581 proposes to place biological drugs that are subject to licensing under the Public Health Service Act on the same footing as other drugs, that is, to require them to be proved efficiacious before marketing and to deem them adulterated or misbranded under the Food, Drug, and Cosmetic Act if they fail to meet licensing requirements. The Department believes the desirability of this improvement is self-evident.

SECTION 111. AUTHORITY TO STANDARDIZE NAMES

We believe there is general agreement regarding the need to standardize common names for drugs. The Secretary of Health, Education, and Welfare should have a standby authority to establish the official name for a drug if voluntary procedures are not effective in doing so.

It is not the intent of the bill, nor our intent, to make established names of trademarked names.

SECTION 112. NAME TO BE USED ON DRUG LABEL

One witness indicated that he believed the bill could be interpreted as requiring each of the ingredients of a proprietary drug to be listed ahead of the brand name of the proprietary. This is not what the bill says. Using the example the witness employed, the bill would not require any change in declaration of brand name or ingredients for Mentholatum.

PART C. SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

The primary objection raised in connection with this section of the bill was that it does not exempt retail druggists from the recordkeeping and inspection provisions relating to barbitruates and amphetamines, while exempting medical practitioners from these provisions. The witness expressed an inability "to understand why such unjust discrimination against the profession of pharmacy should exist in this bill."

The retail druggist has historically been the main source of illegal diversion of prescription drugs. From July 1, 1949, through April 1962, over 1,100 prosecution cases involving illegal sales of prescription drugs (a substantial portion of which were barbiturates or amphetamines) were treminated. Almost 1,900 defendants were convicted in these cases. In almost 88 percent of these cases, the defendants convicted were druggists or their employees. During the same period there have been only 17 cases against a total of 20 medical practitioners.

We do not believe there is a demonstrated need to require the same type of controls over the dispensing of barbiturates and amphetamines by physicians as are needed with respect to pharmacists.

PART D. AMENDMENTS AS TO ADVERTISING

The amendments relating to informative prescription drug advertisements are designed to require truthful statements in drug advertisements delivered to doctors and to require advertisements to give physicians information designed to enable them to do a better job of selecting drugs for use in their practice.

TITLE II. CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

The committee has heard testimony indicating that food and cosmetic factories, pharmacies, and consulting laboratories should be exempt from the complete inspection requirement and that proprietary drugs should be partially exempt.

In the case of proprietary drugs, such an exemption would create a situation in which we would be empowered to make a complete inspection of that part of a manufacturing operation that yielded prescription drugs but could be barred from inspection of essential data governing nonprescription items.

The representative who spoke for the Proprietary Association acknowledged the need for more complete inspection of proprietary drug manufacturers by recommending substitute language which specifies what records are subject to inspection. However, the suggested language is not satisfactory since it leaves gaps which would make it impossible to obtain the evidence needed to offer adequate consumer protection.

The following are examples of nonprescription drugs recalled from the market within the past 2 years because they were adulterated or misbranded:

C–F Solution, manufactured by Carbo-Fung Laboratories, Inc., Los Angeles, Calif., contained 4 percent phenol but the label of the product declared only 2 percent phenol.

Vi-Jon multiple vitamin tablets from the K. V. Pharmacal Co., St. Louis, Mo., were 50 percent deficient in vitamin B_1.

Elixir terpin hydrate and codeine was labeled by the Purepac Corp. of Elizabeth, N.J., as "paregoric."

Turpentine from Dunwody & Sons, Atlanta, Ga., was labeled as "castor oil."

"Elevens" vitamins and mineral capsules of the Fuller Pharmaceutical Co., Minneapolis, Minn., contained excessive folic acid.

In investigating such incidents the Government should be allowed to make a thorough inspection of all records pertaining to the adulteration or misbranding whether the drugs are intended for sale with or without a prescription.

Lax manufacturing procedures can have just as important a bearing on health with respect to nonprescription drugs as they can with respect to the prescription drugs.

During the Senate debate on S. 1552 on August 23, 1962, Senator Estes Kefauver said:

"Nonetheless, the factory inspection provision, in my opinion, should apply to proprietary drugs, but since whatever the reason, they did not have a hearing, I agreed to their exclusion from this bill, but I have filed a separate and companion bill applying the factory inspection provision to proprietary drugs. If they are included in the House bill, of course, that provision will go into conference." (Congressional Record, vol. 108, Thursday, Aug. 23, 1962, p. 16306.)

The potentiality for serious harm from food is significant and is increasing as food technology becomes more complex and more chemicals are used in food processing. We have just sent to the Department of Justice a case for legal action because of the shipment of a compound for bleaching peeled potatoes which had a deadly poison, a fluoride-containing compound, accidentally mixed into it. We were able to pinpoint the error by checking records in possession of

the manufacturer. Yet some witnesses do not want us to have authority to check records covering receipt for handling of raw materials in food plants.

The pesticide chemicals and food additives amendments allow poisons to be present in the food supply in small amounts that have been proved safe by adequate scientific procedures. This permits the public to receive the benefits of modern technology. But a necessary precaution is authority for the Government to make complete inspections in factories to determine that the poisonous materials are being added in safe amounts.

In past years we have had to take actions against food containing nonpermitted poisons. For example, a number of foods contained monochloracetic acid; oranges and frozen peaches contained thiourea. The first evidence that these poisons were being used came from factory inspection and then our chemists developed analytical procedures enabling us to detect the poisons without factory inspection evidence. But without the initial evidence we would not have known what chemicals to develop analytical methods for. Further the development of analytical method suitable for enforcement purposes may be a separate research jobs for each food in which the chemical is found. It is not possible to obtain adequate protection solely on the basis of the examination of interstate shipments.

The cosmetic industry is also reluctant to give us access to records needed to make complete inspections. It is the rule rather than the exception for cosmetic firms to refuse our inspectors access to complaint files. Yet frequently the first indication that a dangerous product is on the market comes through complaints from injured women to the cosmetic manufacturer.

When a dangerous prescription drug gets out on the market and we have to make a complete recall, even down to the ultimate consumer, it is imperative that our inspectors have the authority to inspect prescription files to determine what customers have received the product. In the case of thalidomide we have located a number of pharmacies that had stocks of the drug. Clearly, the Federal agent should be able to check prescription files to determine whether all stocks of this product have been removed from the home medicine cabinets.

Further, when we receive reports of serious abuses arising from the sale without prescription of potent drugs that should be restricted to sale on prescription, it is imperative that our inspectors have the authority to check on the prescription files in the suspect drugstore to determine whether the prescription drugs being received are in fact going out on bona fide prescriptions.

A consulting laboratory is merely an extension of a firm's own operations—an extension which does laboratory work which the firm itself either cannot or does not wish to do. It was said that a consulting laboratory might be criminally liable for guarding too zealously its clients' interests. If he refused to permit complete inspection as authorized by law, and this placed his clients' interests above the public interest, the bill would permit criminal action. It was intended to do so.

Some witnesses would have the committee believe that safety is seldom a factor in inspection actions being brought by Food and Drug Administration against food products. However, many of our more important food actions are because a food is a hazard to health; the value of the preventive enforcement that we are able to achieve through complete factory inspections is great.

The following examples show the need for complete inspection of food firms:

(1) During the spring and summer of 1958, independent investigations of vegetable farmers in the Walla Walla, Wash., area revealed that Birds-Eye Division of General Foods Corp. recommended pesticide uses to their contract spinach growers which were in excess of USDA recommendations. During inspections of the firm's plants in Walla Walla and Nampa (a distribution point), company officials refused to provide information about their spray program, coding system, production, and distribution. Refusals were received from the plant superintendent; local field department manager; manager of the quality control department of Birds-Eye Division, White Plains, N.Y.; local plant manager, and a

local fieldman. All of these supervisory personnel indicated that refusal to provide us with information in these categories was in accordance with company policy from the White Plains, N.Y., office. Company officials would not discuss the possibilities of excessive pesticide residues being in their finished frozen spinach products.

Field and factory samples collected by our inspectors showed many lots of frozen spinach to contain excessive amounts of DDT. Because the firm had refused to provide shipping information, extensive investigations were made at commercial shipping firms. Here it was found that many shipments were billed only as "frozen food," thus complicating the investigation. Finally, some interstate lots of spinach were located, sampled, and seized because of excessive DDT residues. As the number of seizure action increased, the firm's top management conferred with us and instituted a voluntary recall of the entire fall 1958 pack. All in all, over 700,000 pounds of frozen spinach were recalled and destroyed.

(2) Inspections of Tender-Rise Co. of America, Philadelphia, Pa., led us to believe the firm was using undeclared ingredients in some of its products. However, the firm's owners refused to allow inspection of formulas, shipping records, or pertinent information regarding raw materials.

During an inspection on September 25, 1961, the inspector observed the manufacturing of a meat-flavoring product, Adsflavor, which contained nicotinic acid, a food additive not permitted on meat. We attempted unsuccessfully to locate interstate shipments of the product. Within a week, use of Adsflavor by a Philadelphia meat market caused 6 persons to become ill because of the nicotinic acid. When inspected later, the firm said Adsflavor had been discontinued and all outstanding stocks recalled, but it again refused to permit examination of formulas and shipping information. The inspector suspected the firm was still manufacturing Adsflavor, and we did find a shipment of the adulterated product at a meat market in New Orleans in December 1961.

(3) In many other respects full inspection of food factories and pertinent records in them are essential to consumer protection. For example, within the past decade:

(*a*) Canned spray-dried egg yolk, which contained harmful bacteria, had to be recalled from the market when it caused salmonella poisoning in many babies.

(*b*) A canned spray-dried soya product used as a substitute for mother's milk had to be recalled when it made babies sick. It also contained harmful salmonella bacteria.

(*c*) Another canned product for infant feeding was recalled from the market when it produced convulsions in over 130 infants. In this case the manufacturer furnished complete information about manufacturing processes, formulas, and other pertinent data, and one of our scientists was able to pinpoint the difficulty. A change in the formula and processing operation gave a baby food too low in vitamin B_6. When this vitamin was added to the formula there was no more trouble.

(*d*) Inadequately processed canned mushrooms and canned goats milk have had to be taken off the market because of active spoilage. Our inspectors need to examine control records in canneries to determine whether the proper cooking temperature has been employed for the proper time to destroy all harmful bacteria.

(*e*) A child died and many other persons were made ill when they ate fish containing toxic amounts of preservative. The fishhouse—Universal Sea Food Co., Inc., Philadelphia, Pa.—denied ever having used the preservative, but we were able to prove through extensive investigation that it had added the chemical to a batch of fillets that was undergoing decomposition. The firm was prosecuted.

The need for clear authority to make complete inspections is growing because there is a trend among some of the regulated industries to discontinue the cooperation under which many firms have permitted complete inspections vol-

untarily. For example, after inspecting the Athens Canning Co., Athens, Tex., only July 6, 1962, our inspectors reported:

"Mr. Frank Dorsey, the president of the firm, was absent during the above discussions. After he returned, we discussed the FD–483—report of observations as provided for in section 704(b) of the act—and as has already been mentioned, and we then requested interstate shipments of this product. He stated, 'Is that a request?' We replied that if he put it that way, Yes, it was a request. He then stated that he would prefer not to give us such information. He stated that in the past he had been giving us that type of information and that he did not have anything to hide. However, he had just returned from a meeting of the National Canners Association and had been elected to the board of directors. At this meeting the National Canners Association decided not to give the Food and Drug Administration any information that was not required by law. He stated that this included such information as interstate shipments and formulas. He stated that since he was on the board of directors, he would have to go along with their decision not to give FDA this information. The National Canners Association is unfavorable of the bill now before Congress concerning FDA factory inspections.

"We asked Mr. Dorsey if this was going to be a policy of all members of the National Canners Association. He stated that all members would be requested to follow along with their suggestions; however, this is not binding on the individual canner.

"Mr. Dorsey showed us an information letter from the National Canners Association No. 1881 dated June 30, 1962. He referred us to an article on page 15 under the heading 'Statement of Policy on FDA Factory Inspection Bill.' He referred us to this article when he stated that he could not give us information concerning interstate shipments."

There is also need for authority to make complete inspections of cosmetic firms.

(1) FDA scientists believe that many if not most of the numerous injuries attributed to cosmetics each year may be caused by relatively few cosmetic ingredients. However, the facts needed to establish this, and to identify the offending chemicals have never been assembled in one place. The individual firm which knows the composition of its own products does not get the reports of injuries caused by competitive products and may not know the detailed composition of such products. FDA does not have either full reports of injuries or full information on ingredients used in cosmetics. Thus there is no way to determine whether it would be possible to eliminate hundreds or even thousands of injuries per year by the simple measure of ruling out of cosmetic formulations a few chemicals primarily responsible for the trouble. Complete factory inspection authority could well lead to the detection and elimination of primary offenders, and thus to a material gain in consumer protection.

(2) Early this year when we received a report that a shampoo manufactured by Andrew Jergens Co., Belleville, N.J., had caused a severe eye injury, we attempted to make an appropriate investigation at the factory. The firm refused to permit inspection. Seven weeks later, after the firm had been called to a hearing to show why it should not be prosecuted, the manufacturer furnished some of the information needed. It still declined to supply the quantitative formula for the product. However, the quantities of the ingredients in cosmetics frequently determine whether the products are safe. While our chemists do a marvelous job of determining what materials are present in cosmetics, analyses of these complex mixtures are time consuming and sometimes impossible to make completely without formula information.

(3) John H. Breck, Inc., Springfield, Mass., a manufacturer of shampoo and other hair preparations removes the labels from its raw materials and identifies the containers by code numbers. For the past 3 years the firm has refused to let our inspectors know what the raw materials are, thus nullifying any public protection which might be afforded by the examination of raw material labels.

We attach a list of refusals to permit inspection covering the period January 1 through June 15, 1962.

A number of witnesses have stated that any change in the factory inspection authority will make our inspections unconstitutional. On the other hand some of these same witnesses concede that complete inspections can be authorized for drug firms and can even be conducted in food plants by local health authorities. So it appears the problem of constitutionality clearly depends on the reasonableness of the inspection. And what is reasonable depends on the facts in each particular case. In our opinion the constitutional argument was met in 1953 by the extensive report of this committee.

Food and cosmetic firms argue for exemption from the inspection authority provided in the Senate bill on the ground that the same degree of inspection is not needed for food and cosmetic firms as for drug firms. Actually the scope of authorized inspection is limited to matters that bear upon actual or potential violations of the Act. Since the definitions of misbrandings and adulterations for foods and cosmetics differ materially from the definitions for drugs, the inspections also would differ in scope, and would be limited to matters reasonably related to compliance with the law. The Supreme Court noted this in another connection in the *Sullivan* case. But inspection powers at least as comprehensive as the substantive provisions of the law are needed for all articles subject to the act, whether food, drug, device, or cosmetic.

The concern over loss of trade secrets has been expressed by many, yet in almost every instance the witness has admitted that they have no knowledge of any trade secrets being divulged by our employees in the past. We are keenly aware of our responsibility to maintain trade secrets and the bill reemphasizes the penalties (provided in the general criminal code) for the unauthorized disclosure of any information obtained during a factory inspection.

The bill proposes to tighten the confidentiality requirement by forbidding disclosure not only of trade secrets but also of any other information except where disclosure is authorized by law. The PMA recommends that this be further restricted so as to permit disclosure only when required by law. We would feel constrained to object to this as too restrictive but would not object to changing that quoted phrase to read "required in the administration or enforcement of this Act."

Antibiotic rejections, fiscal years 1961 and 1962

Date	Product	Company	Batch size	Violation
July 8, 1960	Potassium Penicillin-G tablets	Success Chemical Co	98,400 tablets	Moisture.
July 13, 1960	Penicillin-dihydrostreptomycin-neomycin ointment	Strong Cobb Arner, Inc	7,142 (24-cubic-centimeter) syringes	Penicillin and dihydrostreptomycin potencies.
July 19, 1960	Tetracycline-novobiocin capsules	The Upjohn Co	136,500 capsules	Moisture.
July 26, 1960	Procaine penicillin-dihydrostreptomycin-neomycin ointment with sulfas (veterinary).	G. C. Hanford Manufacturing Co	28,298 (24-cubic-centimeter) syringes	Nonhomogeneous, potency.
Aug. 2, 1960	Bacitracin bulk	S. B. Penick & Co	29,837 grams	Moisture.
Aug. 11, 1960	Streptomycin sulfate bulk	E. R. Squibb & Sons	149,020 grams	Do.
Aug. 18, 1960	Chloramphenicol for aqueous injection	Parke, Davis & Co	33,537 (1-gram vials	Potency. Material thickens after standing 1 hour and all material cannot be withdrawn. That withdrawn is low in potency.
Do	do	do	33,958 (1-gram) vials	
Do	do	do	34,170 (1-gram) vials	
Aug. 24, 1960	Dihydrostreptomycin-streptomycin sulfate bulk	Chas. Pfizer & Co., Inc	100,000 grams	Potency. High streptomycin content.
Aug. 26, 1960	Penicillin-streptomycin ointment	Jensen-Salsbery Laboratories, Inc	48,400 tubes	Penicillin potency.
Aug. 30, 1960	Penicillin-polymyxin-neomycin ointment with hydrocortisone and chlorobutanol.	Vet Products Corp	3,804 (10-cubic-centimeter) tubes	Neomycin potency.
Do	Demethylchlortetracycline bulk	Lederle Laboratories	341,600 grams	Moisture.
Aug. 31, 1960	Streptomycin sulfate bulk	Chas. Pfizer & Co., Inc	230,000 grams	Sterility.
Sept. 1, 1960	Sterile bacitracin	Philadelphia Laboratories, Inc	2,700 vials (50,000 units each)	Potency.
Do	Nystatin bulk (to be used in manufacture of certifiable product).	E. R. Squibb & Sons	63.5 kilograms	pH (check test).
Sept. 9, 1960	Streptomycin sulfate	Bio Ramo Drug Co., Inc	130,000 vials (1-gram)	Potency and pyrogens.
Sept. 15, 1960	Buffered penicillin powder	Success Chemical Co., Inc	3,000 bottles (35 grams each)	Potency.
Do	Buffered Penicillin-G with sulfas	do	1,950 bottles (25 grams each)	Do.
Sept. 16, 1960	Chloramphenico pamitate	Parke, Davis & Co	380.80 kilograms	Melting point.
Do	do	do	387.05 kilograms	Do.
Sept. 19, 1960	Bacitracin-polymyxin ointment with proteolytic enzymes.	Armour Pharmaceutical Co	16,340 tubes (½-ounce)	Bacitracin potency.
			1,712 tubes (2-ounce)	Do.
Oct. 6, 1960	Buffered potossium penicillin tablets	Chas. Pfizer & Co., Inc	1,140,000 tablets (200,000-unit tablet).	Moisture.
Do	do	do	1,227,000 tablets (200,000-unit tablet).	Do.
Oct. 7, 1960	Buffered potassium penicillin powder	Success Chemical Co., Inc	3,337 (5-cubic-centimeter) bottles (1,200,000-unit bottle).	Potency.
Oct. 18, 1960	Procaine Penicillin G aqueous suspension	Chas. Pfizer & Co., Inc	50,000 vials (10-dose)	Sterility.
Oct. 25, 1960	Potassium Penicillin-G tablets (post seizure sample)	Morse Laboratories, Inc	556 bottles (100 tablets each; 200,000 units).	Moisture.
Oct. 24, 1960	Bacitracin-polymyxin B ointment with proteolytic enzymes.	Armour Pharmaceutical Co	1,014 tubes (2-ounce tubes)	Bacitracin potency.
			7,300 tubes (½-ounce tubes)	Do.
Oct. 26, 1960	Dihydrostreptomycin tablets with carob flour and vitamin A.	Vet Products Corp	31,500 tablets	Potency.
Nov. 3, 1960	Buffered Penicillin potassium, 152 tablets	E. R. Squibb & Sons	1,137,500 tablets	Moisture.
Nov. 4, 1960	Crystalline potassium Penicillin-G with probenecid	Merck Sharpe & Dohme	76,200 tablets (100,000-unit tablets)	Do.

Nov. 16, 1960	Procaine Penicillin-G for aqueous injection	Premo Pharmaceutical Laboratories	25,000 vials (1 cubic centimeter, 300,000 units).	Potency (poor draining).
Nov. 22, 1960	Procaine G-dihydrostreptomycin ointment with sulfas (veterinary).	Delta Laboratories	18,636 syringes (28 cubic centimeters).	Potency (air bubbles).
Nov. 23, 1960	Bacitracin nonsterile bulk	Chas. Pfizer & Co., Inc	14,700 grams	Potency (submitted for check test. Pfizer results OK).
Nov. 17, 1960	Amphotericin B bulk	E. R. Squibb & Sons, Inc	71.5 kilograms	Potency (check test).
Jan. 9, 1961	Penicillin-dihydrostreptomycin ointment (veterinary).	Delta Laboratories	9,720 syringes (6 cubic centimeters).	Moisture.
Jan. 5, 1961	Buffered potassium Penicillin-G tablets	Key Corp	1,000,000 tablets	Do.
Jan. 12, 1961	Potassium Penicillin-G ophthalmic ointment	Pharmich Laboratories	1,872 tubes (⅛ ounce)	Potency (extension of expiration date).
Jan. 16, 1961	Potassium Penicillin ointment	The Upjohn Co	5,441 tubes (1 ounce)	Potency.
Do	Dihydrostreptomycin-streptomycin sulfate solution (veterinary).	Philadelphia Laboratories, Inc	1,200 bottles (200 cubic centimeters); 685 bottles (500 cubic centimeters).	Do.
Jan. 5, 1961	Bacitracin ointment with enzyme	Armour Pharmaceutical Co		Potency (check test).
Jan. 27, 1961	Bacitracin topical powder	Chas. Pfizer & Co., Inc	24,000 vials (50,000 units each)	pH.
Jan. 23, 1961	Amphotericin B bulk	E. R. Squibb & Sons	90.0 kilograms	pH (check test).
Do	Penicillin-dihydrostreptomycin-bacitracin ointment with sulfas (veterinary).	Beebe Laboratories, Inc	19,562 tubes (10 grams)	Bacitracin potency (extension of expiration date).
Feb. 2, 1961	Chlortetracycline hydrochloride seed (veterinary)	Hartz Mountain Products Co	26,400 bottles (6.25 ounces each)	Potency.
Feb. 8, 1961	Dihydrostreptomycin sulfate bulk	E. R. Squibb & Sons	315,440 grams	Residual streptomycin.
Do	do	do	232,040 grams	Do.
Do	do	do	230,600 grams	Do.
Feb. 7, 1961	Bacitracin sensitivity disks (10 units)	National Bio Test, Inc	114 vials (100 each)	Potency.
Do	Tetracycline sensitivity disks (5 mcg.)	do	251 vials (100 each)	Do.
Do	Penicillin sensitivity disks (2 units each)	do	124 vials (100 each)	Do.
Do	Chlortetracycline sensitivity disks (30 mcg.)	do	244 vials (100 each)	Do.
Do	Chlortetracycline sensitivity disks (5 mcg.)	do	239 vials (100 each)	Do.
Do	Bacitracin sensitivity disks (2 units)	do	128 vials (100 each)	Uniformity.
Feb. 28, 1961	Chlortetracycline disks (5 mcg.)	Case Laboratories, Inc	55,800 disks	Do.
Do	Bacitracin disks (2 units)	do	30,240 disks	Potency and uniformity.
Do	Bacitracin disks (10 units)	do	31,320 disks	Do.
Do	Streptomycin disks (2 mcg.)	do	16,200 disks	Do.
Do	Tetracycline disks (5 mcg.)	do	19,800 disks	Do.
Do	Chloramphenicol disks (5 mcg.)	do	25,500 disks	Potency.
Do	Chloramphenicol disks (30 mcg.)	do	39,600 disks	Do.
Mar. 1, 1961	Chlortetracycline disks (5 mcg.)	Baltimore Biological Laboratories Inc	125,000 disks	Potency.
Do	Tetracycline disks (5 mcg.)	do	135,000 disks	Do.
Mar. 3, 1961	Buffered penicillin powder, 250,000 units per 5 cubic centimeters.	Bryant Pharmaceutical Corp	1,000 vials (60 cubic centimeters)	Do.
Mar. 6, 1961	Bacitracin-polymyxin-neomycin ointment	Kasco Laboratories, Inc	7,392 tubes (½ ounce)	Do.
Do	Bacitracin disks (2 units)	National Bio Test, Inc	11,400 disks	Do.
Do	Chlortetracycline disks (5 mcg.)	do	24,300 disks	Do.
Do	Tetracycline disks (5 mcg.)	do	25,500 disks	Do.
Do	Chlortetracycline disks (30 mcg.)	Baltimore Biological Laboratories	115,000 disks	Uniformity.
Do	Bacitracin disks (10 units)	do	100,000 disks	Potency.
Do	Bacitracin disks (2 units)	do	137,500 disks	Do.
Mar. 10, 1961	Chloramphenicol disks (5 mcg.)	do	140,000 disks	Uniformity.
Do	Tetracycline disks (5 mcg.)	Case Laboratories, Inc	23,100 disks	Potency.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Mar. 13, 1961	Chlortetracycline disks (30 mcg.)	Case Laboratories, Inc.	73,400 disks	Potency, uniformity.
Do.	Chlortetracycline disks (5 mcg.)	do.	23,100 disks	Potency.
Mar. 21, 1961	Procaine Penicillin-G in aqueous suspension (600,000 unit syringe).	The Upjohn Co.	13,585 syringes	Potency due to syringibility.
Mar. 22, 1961	Crystalline dinydrostreptomycin bulk	E. R. Squibb & Sons.	304,760 grams	Residual streptomycin.
Do.	do.	do.	307,240 grams	Do.
Mar. 21, 1961	Penicillin-dihydrostreptomycin-neomycin ointment	Vet Products Corp.	3,768 syringes (24 cubic centimeters each).	Dihydrostreptomycin potency.
Mar. 24, 1961	Tetracycline disks (5 mcg.)	Case Laboratories, Inc.	62,640 disks	Potency.
Mar. 29, 1961	Procaine and buffered penicillin-streptomycin sulfate bulk.	Chas. Pfizer & Co., Inc.	32,000 grams streptomycin; 51,000,000,000 units penicillin.	Moisture.
Apr. 3, 1961	Chlortetracycline disks (5 mcg.)	Case Laboratories, Inc.	54,000 disks	Potency.
Apr. 7, 1961	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories.	132,500 disks	Do.
Apr. 11, 1961	Dihydrostreptomycin sulfate bulk	E. R. Squibb & Sons.	257,300 grams	Do.
Apr. 26, 1961	Bacitracin-neomycin ointment with hydrocortisone	Walerk Laboratories, Inc.	12,650 tubes (⅛-ounce)	Bacitracin potency.
Apr. 17, 1961	Dihydrostreptomycin disks (2 mcg.)	Case Laboratories, Inc.	72,350 disks	Potency and uniformity.
May 3, 1961	Penicillin-bacitracin-streptomycin dental paste	Procosal Chemical Co., Inc.	Few hundred tubes	Request for extension of expiration date. Low bacitracin and streptomycin potency.
May 5, 1961	Procaine Penicillin-G-dihydrostreptomycin-neomycin ointment (veterinary).	United Co-operatives, Inc.	10,650 syringes (24 cubic centimeters each).	Neomycin potency.
May 16, 1961	Bacitracin bulk	Commercial Solvents Corp.	7,717 grams	Pyrogens.
May 11, 1961	Penicillin-dihydrostreptomycinsulfas uterine boluses (veterinary).	Stevenson-Turner & Boyce Guelph, Canada.	864 boluses	Import detention; not certified.
May 22, 1961	Bacitracin-neomycin ointment	Eli Lilly & Co.	14,288 tubes (½-ounce)	Bacitracin potency.
Do.	do.	do.	14,349 tubes (½-ounce)	Do.
May 23, 1961	Potassium Penicillin G tablets	Allied Biochemical Laboratories, Inc.	300,000 tablets (50,000 units)	Potency and moisture.
Do.	do.	do.	220,000 tablets (50,000 units each)	Do.
Do.	do.	do.	301,000 tablets (100,000 units each)	Moisture.
Do.	do.	do.	275,000 tables (200,000 units each)	Do.
Do.	do.	do.	do.	Do.
Do.	do.	do.	120,000 tablets (100,000 units each)	Do.
Do.	do.	do.	120,000 tables (200,000 units each)	Do.
Apr. 14, 1961	Tetracycline disks (30 mcg.)	Baltimore Biological Laboratories, Inc.	200,000 disks	Uniformity.
May 23, 1961	Bacitracin disks (2 units)	Case Laboratories, Inc.	75,600 disks	Do.
May 25, 1961	Potassium Penicillin-G tablets	Chas. Pfizer & Co., Inc.	1,220,000 tables (200,000 units each).	Moisture.
May 29, 1961	Streptomycin sulfate (1 gram)	Koninklijke Nederlandsche Gist-En Spiritusfabriek.	60,000 vials	Do.
Do.	do.	do.	64,500 vials	Do.
Do.	Soluble potassium penicillin tablets (200,000 units)	Pure Laboratories, Inc.	401,700 tablets	(1).
Do.	Soluble potassium penicillin tablets (100,000 units)	do.	221,500 tablets	(1).
Do.	Soluble potassium penicillin (250,000 units)	do.	320,300 tablets	(1).
Do.	Buffered potassium penicillin tablets (50,000 units)	do.	600,000 tablets	(1).

Do	do	do	553,785 tablets	(1).
Do	Buffered potassium penicillin tablets (200,000 units)	do	599,500 tablets	(1).
Do	Buffered potassium penicillin tablets (100,000 units)	do	480,000 tablets	(1).
Do	Buffered potassium penicillin tablets (200,000 units)	do	600,000 tablets	(1).
Do	do	do	do	(1).
Do	Buffered potassium penicillin tablets (250,000 units)	do	620,000 tablets	(1).
Do	Buffered potassium penicillin tablets (100,000 units)	do	600,000 tablets	(1).
Do	do	do	500,000 tablets	(1).
Do	Buffered potassium penicillin tablets (250,000 units)	do	733,200 tablets	(1).
Do	Buffered potassium penicillin tablets (400,000 units)	do	220,000 tablets	(1).
Do	Buffered potassium penicillin tablets (500,000 units)	do	100,000 tablets	(1).
June 6, 1961	Sodium Penicillin-G disks (10 units)	Baltimore Biological Laboratories	147,500 disks	Potency.
June 16, 1961	Chlortetracycline disks (5 mcg.)	do	142,500 disks	Do.
Do	Chlortetracycline disks (30 mcg.)	do	137,500 disks	Do.
Do	Tetracycline disks (30 mcg.)	do	145,000 disks	Do.
June 19, 1961	Penicillin disks (2 units)	National Bio Test, Inc	20,000 disks	Do.
Do	do	do	21,400 disks	Do.
Do	Chlortetracycline disks (5 mcl.)	do	23,100 disks	Do.
June 6, 1961	Procaine and buffered sodium penicillin for aqueous injection.	Bio Ramo Drug Co	30,000 vials (500,000 units per vial)	Do.
June 14, 1961	Crystalline didhydrostreptomycin bulk	E. R. Squibb & Sons	262,640 grams	Pyrogens.
June 22, 1961	Demethylchlortetracycline disks (30 mcg.)	Baltimore Biological Laboratories	132,500 disks	Potency.
June 27, 1961	Buffered potassium penicillin-G tablets (100,000 units)	Success Chemical Co., Inc	389,700 tablets	Moisture.
June 29, 1961	Demethylchlortetracycline disks (5 mcg.)	Baltimore Biological Laboratories	62,500 disks	Potency.
July 6, 1961	Zinc bacitracin bulk	Merck Sharp & Dohme	2.3 kilograms	Moisture (recertification).
July 7, 1961	Procain penicillin G in aqueous suspension	Chas. Pfizer & Co	13,000 vials (10 cubic centimeters each).	Potency (extension of expiration date).
July 12, 1961	Bacitracin bulk	do	147,000 grams	Heavy metals.
Do	Bacitracin vials	do	4,204 vials (50,000 units per vial).	Do.
Do	Penicillin disks (10 units)	Baltimore Biological Laboratories	142,500 disks	Potency.
July 13, 1961	Buffered penicillin powder with sulfas	Philadelphia Laboratories	2,942 bottles (60 cubic centimeters)	Do.
July 21, 1961	Penicillin-dihydrostreptomycin-neomycin ointment with sulfas and cobalt (veterinary).	United Co-operatives, Inc	30,266 syringes (6 cubic centimeters each).	Neomycin potency.
Do	Penicillin disks (2 units)	National Bio Test, Inc	20,800 disks	Potency.
July 25, 1961	Procaine penicillin-dihydro-streptomycin-polymyxin-neomycin in oil with sulfas and cobalt (veterinary).	Rhinecliff Laboratories	6,292 syringes (30 cubic centimeters each).	Neomycin potency.
Do	Tetracycline phosphate complex-amphotericin B capsules.	E. R. Squibb & Sons	1,444,000 capsules (250 mg-T, 50 mg.A).	Amphotericin potency.
July 28, 1961	Procaine penicillin and buffered sodium for aqueous injection.	Eli Lilly & Co	23,491 vilas (10 cubic centimeters each).	
Do	do	do	110,597 vilas (1 dose each)	Contaminated with Tylosin.
Do	do	do	8,095 vials (10-dose)	
Do	do	do	118,529 vials (1-dose)	
July 21, 1961	Bacitracin bulk	Chas. Pfizer & Co., Inc	94,000,000 units	Heavy metals.
July 31, 1961	Potassium Penicillin-G tablets buffered	Burroughs Bros	176,000 tablets (200,000 units each)	Moisture.
Do	Tetracycline-TAO capsules (167 mg.) (83 mg.)	Chas. Pfizer & Co., Inc	768 capsules	Do.
Aug. 1, 1961	Buffered potassium Penicillin-G tablets (200,000 units)	American Chemical & Drug Co	200,000 tablets	Do.
Do	Streptomycin sulfate bulk	Eli Lilly & Co	141.09 kilograms	Do.
Do	do	do	126,902 kilograms	Do.
Aug. 4, 1961	Dimethoxyphenyl penicillin disks (5 mcg.)	Baltimore Biological Laboratories	140,000 disks	Potency.
Do	do	do	62,500 disks	Do.

See footnotes at end of table, p. 588.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Aug. 18, 1961	Procaine penicillin (100,000 units) and dihydrostreptomycin (300 mg.) in oil with sulfas.	Bristol Laboratories	42,500 tubes (7.5 milliliters each)	Dihydrostreptomycin potency.
Aug. 16, 1961	Penicillin disks (2 units)	National Bio Test, Inc	22,100 disks	Potency.
Aug. 18, 1961	Bacitracin bulk	Commercial Solvents Corp	2,641 grams	Pyrogens.
Do	Buffered penicillin tablets	Merck Sharp & Dohme	600 packages (12 each)	Moisture.
Aug. 4, 1961	Penicillin disks (10 units)	Baltimore Biological Laboratories	137,500 disks	Potency (extension of expiration date).
Do	Penicillin disks (2 units)	do	140,000 disks	Do.
Sept. 8, 1961	Tetracycline hydrochloride capsules with TAO	Chas. Pfizer & Co., Inc	1,050,000 capsules	Moisture.
Sept. 7, 1961	Streptomycin disks (2 mcg.)	Difco Laboratories	167,000 disks	Potency.
Sept. 8, 1961	Dimethoxyphenyl penicillin disks (5 mcg.)	Baltimore Biological Laboratories	147,500 disks	Potency and uniformity.
Sept. 19, 1961	Procaine Penicillin-G ointment (veterinary)	G. C. Hanford Manufacturing Co	55,726 tubes (7.5 grams each)	Potency.
Do	Bacitracin bulk	Chas. Pfizer & Co., Inc	2,090,000,000 units	Heavy metals.
Oct. 5, 1961	Chloramphenicol for aqueous injection	Parke, Davis & Co	34,362 vials (1 gram each)	Potency.
Oct. 6, 1961	Nystatin bulk	E. R. Squibb & Sons	149.0 kilograms	pH (check test).
Oct. 18, 1961	Bacitracin-polymyxin-neomycin ointment	American Pharmaceutical Co	4,948 tubes (½ ounce)	Bacitracin and neomycin potency.
Do	Streptomycin sulfate solution	E. R. Squibb & Sons	124,378 vials (2.5 cubic centimeters each).	Pyrogens.
Oct. 27, 1961	Bacitracin bulk	Chas. Pfizer & Co., Inc	512,000,000 units	Heavy metals.
Do	do	do	1,000,000,000 units	Do.
Oct. 30, 1961	Potassium phenethicillin tablets foiled, 125 mg	Bristol Laboratories	50,000 tablets	Moisture.
Do	Benzathine Penicillin-G bulk	Chas. Pfizer & Co., Inc	201,000,000,000 units	Sterility.
Nov. 2, 1961	Buffered Penicillin tablets with sulfas (300,000 units penicillin, and 0.5 grams sulfas).	Nysco Laboratories, Inc	50,000 tablets	Moisture.
Oct. 31, 1961	Streptomycin disks (10 mcg.)	Baltimore Biological Laboratories	70,000 disks	Potency.
Nov. 2, 1962	Demethylchlortetracycline disks (30 mcg.)	Case Laboratories, Inc	74,500 disks	Do.
Nov. 1, 1961	Multiple antibiotic sensitivity disks	Difco Laboratories	53,600 rings	Tetracycline, streptomycin erythromycin potency.
Nov. 7, 1961	Streptomycin sulfate bulk	Chas. Pfizer & Co., Inc	65 kilograms	Sterility.
Nov. 13, 1961	Bacitracin bulk	S. B. Penick & Co	44,772 grams	Ash content (check test).
Nov. 17, 1961	Penicillin-dihydrostreptomycin-neomycin ointment with sulfas, cobalt, and chlorobutanol.	Masti-Kure Products Co	17,392 syringes (14 milliliters each).	Penicillin potency.
Do	Dimethoxyphenyl Penicillin disks (5 mcg.)	Difco Laboratories	72,500 disks	Uniformity.
Nov. 27, 1961	Penicillin disks (2 units)	National Bio Test, Inc	15,000 disks	Potency.
Do	Chloramphenicol for aqueous injection	Parke, Davis & Co	26,065 vials (1 gram each)	Do.
Nov. 30, 1961	Procaine Penicillin-G in dihydrostreptomycin solution (veterinary).	Chas Pfizer & Co., Inc	23,000 vials (10 cubic centimeters each).	Do.
Dec. 1, 1961	Neomycin bulk	do	57.72 B.U	Moisture.
Dec. 8, 1961	Dihydrostreptomycin-neomycin-polymyxin aerosol	Phillips Roxane, Inc	4,982 bottles	pH.
Dec. 12, 1961	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories	60,000 disks	Potency.
Jan. 3, 1962	Sensitivity testing device	Ankh Laboratories, Inc	3,036 packages	Erythromycin and penicillin potency, penicillin uniformity.
Do	Procaine G bulk	Chas. Pfizer & Co., Inc	1,140,000,000,000 units	Contaminated with Arquad.
Do	Buffered potassium Penicillin powder	Morse Laboratories, Inc	3,037 vials (60 cubic centimeters)	Potency, short volume.

Jan. 10, 1962	Dihydrostreptomycin disks (2 mcg.)	Difco Laboratories	87,500 disks	High potency.
Jan. 8, 1962	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories	70,000 disks	Low potency.
Jan. 24, 1962	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	354,160 grams	Pyrogens.
Do	do	do	349,380 grams	Do.
Do	do	do	343,120 grams	Do.
Do	do	do	309,960 grams	Do.
Do	do	do	314,060 grams	Do.
Do	do	do	318,460 grams	Do.
Do	do	do	106,600 grams	Do.
Do	do	do	322,440 grams	Do.
Feb. 6, 1962	Potassium penicillin-G with sulfas	do	500,000 tablets	Moisture.
Feb. 19, 1962	Procaine (300,000 units)-sodium (200,000 units) and streptomycin (0.5 gram) for aqueous injection.	Bio Ramo Drug Co	100,700 vials (1-dose)	Penicillin and streptomycin potencies.
Do	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	296,800 grams	Pyrogens.
Do	Chlortetracycline hydrochloride dressing	Surgical Projects, Division American Cyanamid Co.	4,260 dressings (8 by 12 inches)	Impregnation and potency.
Mar. 5, 1962	Procaine penicillin-G for aqueous suspension	Bio Ramo Drug Co., Inc	30,250 vials (1-dose)	Potency and syringeability.
Mar. 2, 1962	Bacitracin-neomycin topical ointment Bacitracin-neomycin ophthalmic ointment.	Pharmich Laboratories	1,454 ⅛-ounce tubes (300 ½-ounce tubes).	Extension of expiration date. Neomycin potency.
Do	Procaine penicillin-G in aqueous suspension	Chas. Pfizer & Co., Inc	273,000 vials (10 doses each)	Sterility.
Do	Nystatin bulk	E. R. Squibb & Sons	105.4 kilograms	pH (check test).
Mar. 15, 1962	Sodium methicillin vials	do	16,400 vials (1-gram)	Potency.
Mar. 19, 1962	Sodium penicillin-G bulk	Castillon, S.A	(?)	Heat stability.
Do	do	do	(?)	Do.
Do	do	do	(?)	Do.
Do	do	do	(?)	Do.
Mar. 14, 1962	Chlortetracycline disks (5 mcg.)	National Bio Test, Inc	23,100 disks	Potency.
Do	Penicillin disks (10 units)	do	30,100 disks	Do.
Do	Penicillin disks (2 units)	do	31,000 disks	Do.
Do	Chloramphenicol disks (5 mcg.)	do	23,000 disks	Do.
Do	do	do	22,900 disks	Do.
Mar. 20, 1962	Procaine Penicillin-G-dihydrostreptomycin-neomycin ointment with sulfas and cobalt.	G. C. Hanford Manufacturing Co	27,064 tubes (7.5 grams each)	Neomycin potency.
Do	Tetracycline-amphotericin sirup	E. R. Squibb & Sons	127,296 vials (5 cubic centimeters each).	Tetracycline potency (not uniform).
Mar. 26, 1962	Procaine penicillin-buffered sodium penicillin for aqueous injection.	Castillon, S.A	66,100 vials (1-dose)	Sterility.
Do	do	do	59,400 vials (1-dose)	Do.
Mar. 23, 1962	Multiple antibiotic sensitivity disks	Difco Laboratories	50,850 disks	Neomycin potency.
Apr. 16, 1962	Streptomycin sulfate solution	Pure Laboratories, Inc	16,000 vials (5-gram)	Potency.
Apr. 18, 1962	Procaine, potassium penicillin for aqueous injection (also streptomycin).	Chas. Pfizer & Co., Inc	76,000 vials (1-dose)	Do.
Apr. 24, 1962	Procaine Penicillin-G in dihydrostreptomycin solution (veterinary).	Philadelphia Laboratories	Approximately 4,000 vials (100 cubic centimeters each).	Contaminated with streptomycin.
Apr. 26, 1962	Tetracycline base bulk	Chas. Pfizer & Co., Inc	678,000 grams	Moisture.
May 3, 1962	Potassium Penicillin-V for oral solution	Abbott Laboratories	1,724 bottles (80 cubic centimeters each).	Potency.
Do	Tetracycline hydrochloride intramuscular	Chas. Pfizer & Co., Inc	90,000 vials (100 milligrams each)	Potency. Extension of expiration date.
Apr. 26, 1962	Oxacillin disks (1 mcg.)	Baltimore Biological Laboratories	139,650 disks	Uniformity.

See footnotes at end of table, p. 588.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Apr. 30, 1962	Penicillin sensitivity disks (2 units)	National Bio Test, Inc	213,000 disks	Potency.
Do	Penicillin sensitivity disks (10 units)	do	196,000 disks	Do.
Do	Penicillin sensitivity disks (2 units)	do	208,000 disks	Do.
Do	Penicillin sensitivity disks (10 units)	do	203,000 disks	Do.
Do	Bacitracin sensitivity disks (2 units)	do	209,000 disks	Do.
May 4, 1962	Procaine Penicillin-G and buffered sodium penicillin for aqueous injection.	Laboratorios Castillon, S.A	66,666 vials (1 dose)	pH.
Do	Bacitracin bulk	S. B. Penick & Co	[2]	Ash content.
May 22, 1962	Potassium Penicillin-G ophthalmic ointment	Morse Laboratories, Inc	7,447 tubes	20 times labeled potency.
Do	Tetracycline hydrochloride topical spray powder	Davis & Geck	1,300 grams (1,300 cans)	Potency.
May 24, 1962	Procaine Penicillin and buffered sodium penicillin for aqueous injection.	Laboratorios Atral	33,000 vials (500,000 units each)	Do.
Do	do	do	50,000 vials (500,000 units each)	Do.
May 9, 1963	Procaine penicillin and buffered sodium penicillin for aqueous injection.	Laboratorios Castillon, S.A	66,666 vials (1-dose)	pH.
June 1, 1962	Procaine Penicillin-G and buffered sodium penicillin for aqueous injection.	Laboratorios Atral, Lda	50,000 vials (1-dose)	Potency.
Do	do	do	do	Do.
June 4, 1962	Procaine Penicillin-G bulk	Wyeth Laboratories, Inc	112,940 grams	Sterility.
June 7, 1962	Procaine Penicillin-G-polymyxinneomycin ointment with hydrocortisone (veterinary).	Hamilton Pharmacal Co	4,271 syringes (10 cubic centimeters each).	Not homogeneous Potency (all above).
Do	Tetracycline sensitivity disks (5 mcg.)	National Bio Test, Inc	38,000 disks	Potency.
Do	Methicillin sensitivity disks (5 mcg.)	do	20,100 disks	Do.
June 11, 1962	Tetracycline syrup	E. R. Squibb & Sons	3,616 pint bottles	Do.
Do	Tetracyline phosphate complexnystatin capsules	do	624 bottles (100 each)	Potency. Extension of expiration date.
June 15, 1962	Buffered Penicillin-G tablets	Bryant Pharmaceutical Co	64,000 tablets (200,000 units each)	Potency.
June 20, 1962	Procaine Penicillin-G in aqueous suspension	H. E. Maurry Biological Co	1,528 syringes (300,000 units per cubic centimeter.)	Do.
June 26, 1962	Nystatin bulk	E. R. Squibb & Sons	161.7 kilograms.	pH (check test).
June 28, 1962	Tetracycline tablets	A. Wassermann, S.p.A	1,466 bottles (100 each.)	Moisture.

[1] All or portions of batches distributed before samples submitted for certification.
[2] Not given.

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 15, 1962

FOOD FIRMS

Firm name	Address	Date of refusal [1]
Refusal to permit inspection:		
Health Food Distributors, Inc	Detroit, Mich	[2]Apr. 3, 1962
Weiss Noodle Co	Cleveland, Ohio	[2]May 3, 1962
Refusal to divulge status or responsibility of individuals:		
Procter & Gamble Manufacturing Co	Dallas, Tex	May 1, 1962
Bowman Biscuit Co	Denver, Colo	Mar. 8, 1962
Continental Baking Co	Gary, Ind	Apr. 17, 1962
Health Food Distributors	Detroit, Mich	Feb. 19, 1962
San Joaquin Bakeries, Inc	Modesto, Calif	Mar. 2, 1962
Refusal to furnish qualitative or quantitative formulas:		
Hall-Omar Bakery	Somerville, Mass	May 11, 1962
Kraft Foods Division	Portland, Maine	Mar. 28, 1962
Hall Bakery Co	Buffalo, N.Y	May 17, 1962
Kraft Foods	Dunkirk, N.Y	Apr. 30, 1962
The Red Wing Co., Inc	Fredonia, N.Y	Mar. 29, 1962
J. W. Allen & Co	Chicago, Ill	Mar. 1, 1962
American Chicle Co	Rockford, Ill	Mar. 15, 1962
Chippers, Inc	Chicago, Ill	May 8, 1962
General Mills, Inc	West Chicago, Ill	Apr. 23, 1962
Home Juice Co	Melrose Park, Ill	Mar. 29, 1962
Henri's Food Products	Milwaukee, Wis	Mar. 5, 1962
Instant Whip	Chicago, Ill	Mar. 27, 1962
Lauritzen & Co., Inc	Norridge, Ill	Feb. 1, 1962
L. D. Schrieber & Co	Green Bay, Wis	Mar. 20, 1962
American Dairy Co	Evansville, Ind	Apr. 11, 1962
E. Berghansen Chemical Co	Cincinnati, Ohio	Mar. 22, 1962
Brand X Corp	do	Mar. 12, 1962
The Continental Baking Co	Indianapolis, Ind	Mar. 26, 1962
General Baking Co	Louisville, Ky	May 1, 1962
M & R Dietetic Labs, Inc	Columbus, Ohio	Mar. 16, 1962
The Pillsbury Co	New Albany, Ind	Apr. 3, 1962
Procter & Gamble, (Duncan Hines Division)	Cincinnati, Ohio	Apr. 24, 1962
Stokely-Van Camp, Inc	Indianapolis, Ind	Apr. 11, 1962
Strietmann Biscuit Co	Cincinnati, Ohio	Apr. 3, 1962
Adams Extract Co	Austin, Tex	Apr. 16, 1962
Best Foods, Inc	Dallas, Tex	Mar. 26, 1962
Harrell-Morris Candy Co	Clinton, Okla	May 7, 1962
Procter & Gamble Mfg. Co	Dallas, Tex	May 1, 1962
Stokely-Van Camp, Inc	do	Apr. 5, 1962
Superior Foods (Procter & Gamble)	do	May 11, 1962
Triple AAA Co	Oklahoma City, Okla	May 18, 1962
Bowman Biscuit Co	Denver, Colo	Mar. 8, 1962
National Biscuit Co	do	Mar. 22, 1962
Wolf Cereal Processing Co	Colorado Springs, Colo	Mar. 26, 1962
Campbell Soup Co	Napoleon, Ohio	Mar. 19, 1962
Continental Baking Co	Gary, Ind	Apr. 17, 1962
General Foods Corp	Battle Creek, Mich	Apr. 19, 1962
Hol'n One Donut Co	Flint, Mich	Mar. 5, 1962
Campbell Soup Co	Omaha, Nebr	Jan. 17, 1962
Continental Baking Co	Sioux City, Iowa	Apr. 25, 1962
Dr MacDonald's Vitamized Feed Co., Inc	Fort Dodge, Iowa	Apr. 19, 1962
Perk Foods Co	Kansas City, Kans	Mar. 26, 1962
Dip 'N Sip, Inc	Santa Monica, Calif	Apr. 23, 1962
Smithers Sons, Ltd	Los Angeles, Calif	Apr. 6, 1962
Union Sugar Co	Betteravia, Calif	Apr. 19, 1962
Emarald Food Inc	Emerald, Wis	Apr. 4, 1962
The Pillsbury Co	Grand Forks, N. Dak	Mar. 28, 1962
Sanna Dairies Inc	Menomonie, Wis	Apr. 4, 1962
A. W. Thompson Co. (Prairie Division)	Chien, Wis	Apr. 27, 1962
Goodhill Prepared Foods, Inc	Ponchatoula, La	Feb. 14, 1962
Wright Root Beer Co	New Orleans, La	Jan. 31, 1962
Hollywood Brands, Inc	Centralia, Ill	Apr. 20, 1962
Kitchen Craft Foods Corp	Brooklyn, N.Y	Apr. 2, 1962
Leeds Dixon Laboratories	South Hackensack, N.J	May 17, 1962
Penick & Ford Ltd., Inc	Pinckneyville, Ill	Apr. 9, 1962
B. M. Reeves Co., Inc	Brooklyn, N.Y	Feb. 1, 1962
Scheff Bros. Foods	South Hackensack, N.J	May 17, 1962
Germantown Manufacturing Co	Philadelphia, Pa	Mar. 22, 1962
Beatrice Foods Co	Kankakee, Ill	Mar. 28, 1962
Continental Baking Co	St. Louis, Mo	Jan. 12, 1962
Do	do	May 16, 1962
Hollywood Brands, Inc	Centralia, Ill	Apr. 20, 1962
Morris Elevator	Bushnell, Ill	Mar. 6, 1962
Rio Syrup Co	St. Louis, Mo	Apr. 26, 1962
Whistle & Vess Beverage Co	do	Apr. 24, 1962
Pillsbury Co	Reedley, Calif	Mar. 22, 1962

See footnotes at end of table, p. 592.

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 15, 1962—Continued

FOOD FIRMS

Firm name	Address	Date of refusal [1]
Refusal to furnish qualitative or quantitative formulas—Continued		
Planters Peanuts	San Francisco, Calif	May 17, 1962
Priscilla's Viennse Baking Co	do	Jan. 26, 1962
Riva Distributing Co	do	Mar. 15, 1962
The Borden Co	Albany, Oreg	Mar. 20, 1962
Tumarkin Bros	Boston, Mass	May 16, 1962
The Julep Co	Sycamore, Ill	Apr. 11, 1962
Great A. & P. Tea Co	Altoona, Pa	May 22, 1962
Fresno Milling Co	Fresno, Calif	May 24, 1962
Pure Foods, Inc	Chicago, Ill	May 16, 1962
Golden Crown Products, Inc	Los Angeles, Calif	Apr. 5, 1962
Magic Nut	do	Mar. 30, 1962
Refusal to disclose or permit observation of manufacturing procedures: American Dairy Co.	Evansville, Ind	Apr. 11, 1962
Refusal to permit review of control records:		
Douglas Packing Co., Inc	Nassawadox, Va	Mar. 27, 1962
Kraft Foods	Portland, Maine	Mar. 28, 1962
Hall Bakery	Buffalo, N.Y	May 17, 1962
Kraft Foods	Dunkirk, N.Y	Apr. 30, 1962
The Red Wing Co., Inc	Fredonia, N.Y	Mar. 29, 1962
American Dairy Co	Evansville, Ind	Apr. 11, 1962
Procter & Gamble (Duncan Hines division)	Cincinnati, Ohio	Apr. 24, 1962
Drenthe Creamery Co	Drenthe, Mich	May 2, 1962
Procter & Gamble Manufacturing Co	Dallas, Tex	May 1, 1962
Campbell Soup Co	Omaha, Nebr	Jan. 17, 1962
Sarna Dairies, Inc	Menomonie, Wis	Apr. 4, 1962
Leeds-Dixon Laboratories	South Hackensack, N.J	May 17, 1962
Scheff Bros. Foods	do	Do.
The Kellogg Co	Memphis, Tenn	Apr. 3, 1962
California Packing Corp	San Francisco, Calif	Apr. 19, 1962
Pillsbury Co	Reedley, Calif	Mar. 22, 1962
The Borden Co	Albany, Oreg	Mar. 20, 1962
Consumers Peanut Manufacturing Co	Billings, Mont	Mar. 26, 1962
Kraft Foods	Rome, N.Y	May 24, 1962
Refusal to permit review of complaint files:		
New England Tea Packing Co., Inc	Boston, Mass	Apr. 18, 1962
Hall Bakery	Buffalo, N.Y	May 17, 1962
Kraft Foods	Dunkirk, N.Y	Apr. 30, 1962
The Red Wing Co., Inc	Fredonia, N.Y	Mar. 29, 1962
Continental Baking Co	Indianapolis, Ind	Mar. 26, 1962
The Pillsbury Co	New Albany, Ind	Apr. 3, 1962
Procter & Gamble (Duncan Hines Division)	Cincinnati, Ohio	Apr. 24, 1962
Stokely-VanCamp, Inc	Indianapolis, Ind	Apr. 11, 1962
Bowman Biscuit Co	Denver, Colo	Mar. 8, 1962
Continental Baking Co	Gary, Ind	Apr. 17, 1962
Peterson Nut Co	Cleveland, Ohio	May 17, 1962
Modern Aids, Inc	New York, N.Y	Mar. 20, 1962
A. E. Staley Manufacturing Co	Decatur, Ill	Apr. 16, 1962
Planters Peanuts	San Francisco, Calif	Mar. 6, 1962
Refusal to permit taking of photographs:		
Continental Baking Co	Gary, Ind	Apr. 17, 1962
California Packing Co	Sacramento, Calif	Apr. 18, 1962
Refusal to permit review of shipping records:		
Bush Bros. & Co	Dandridge, Tenn	May 22, 1962
Hall Bakery	Buffalo, N.Y	May 17, 1962
J. W. Allen & Co	Chicago, Ill	Mar. 1, 1962
Glacier Groves, Inc	Cincinnati, Ohio	Jan. 30, 1962
Napoleon Creamery	Napoleon, Ind	Mar. 20, 1962
Ralston Purina Co	Louisville, Ky	Apr. 9, 1962
Midland Produce Co	Denver, Colo	Jan. 2, 1962
Continental Baking Co	Gary, Ind	Apr. 17, 1962
O-So-Good Food Products Co	Omaha, Nebr	Mar. 23, 1962
Smithers Sons, Ltd	Los Angeles, Calif	Apr. 6, 1962
The Pillsbury Co	Grand Forks, N. Dak	Mar. 28, 1962
Sanna Dairies, Inc	Menomonie, Wis	Apr. 4, 1962
Goodhill Prepared Foods, Inc	Ponchatoula, La	Feb. 14, 1962
Nutritional Foods, Inc	New Orleans, La	Mar. 16, 1962
Sea Coast Canning, Inc	Biloxi, Miss	Mar. 23, 1962
Balanced Foods, Inc	New York, N.Y	Apr. 5, 1962
Modern Aids, Inc	do	Mar. 20, 1962
Nutra Food, Inc	Valley Stream, N.Y	Mar. 30, 1962
Scheff Bros. Foods	South Hackensack, N.J	May 17, 1962
Germantown Manufacturing Co	Philadelphia, Pa	Mar. 22, 1962
Beatrice Foods Co	Kankakee, Ill	Mar. 28, 1962
Continental Baking Co	St. Louis, Mo	May 16, 1962
William Davies Co., Inc	Danville, Ill	Feb. 28, 1962
Planters Peanuts	San Francisco, Calif	Mar. 6, 1962
Barbey Packing Co	Astoria, Oreg	May 3, 1962
Consumers Peanut Manufacturing Co	Billings, Mont	Mar. 26, 1962

See footnotes at end of table, p. 592.

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 15, 1962—Continued

DRUG AND DEVICE FIRMS

Firm name	Address	Date of refusal [1]
Refusal to permit inspection: Central Surgical Supply Co.	Fitchburg, Mass.	[4]Apr. 24, 1962
Refusal to divulge status or responsibility of individuals:		
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Cyclo Manufacturing Co.	Denver, Colo.	Do.
Refusal to furnish qualitative or quantitative formulas:		
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	Do.
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Basic Formulas, Inc.	Salt Lake City, Utah	May 8, 1962
Halls Remedy Co.	do.	Apr. 16, 1962
Difco Laboratories.	Detroit, Mich.	Feb. 13, 1962
Frederick Laboratory.	Oregon, Ohio.	Apr. 30, 1962
North American Mogul Products.	Chagrin Falls, Ohio.	Apr. 10, 1962
Dorsey Laboratories.	Lincoln, Nebr.	May 15, 1962
Norden Laboratories, Inc.	do.	May 17, 1962
Vare Electronics.	Minneapolis, Minn.	Apr. 19, 1962
National Research Corp.	Lafayette, La.	Feb. 15, 1962
Lambert-Hudnut Manufacturing Laboratories, Inc.	St. Louis, Mo.	Apr. 11, 1962
Dr. J. H. McLean Medicine Co.	do.	Apr. 23, 1962
Mantho Kreoamo, Inc.	Clinton, Ill.	Mar. 20, 1962
Plough, Inc.	Memphis, Tenn.	Mar. 5, 1962
Schlicksup Drug Co., Inc.	Peoria, Ill.	May 3, 1962
Calodine Laboratories.	Oakland, Calif.	Apr. 26, 1962
Octogen Pharmacal Co.	Utica, N.Y.	May 23, 1962
Refusal to disclose or permit observation of manufacturing procedures:		
Chas. Pfizer & Co., Inc.	Groton, Conn.	Apr. 24–25, 1962.
Puritron Corp.	New Haven, Conn.	Mar. 29, 1962
Basic Formulas Inc	Salt Lake City, Utah	May 8, 1962
National Research Corp.	Lafayette, La.	Feb. 15, 1962
Refusal to permit review of control records:		
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Cyclo Manufacturing Co.	Denver, Colo.	May 2, 1962
Difco Laboratories.	Detroit, Mich.	Feb. 13, 1962
Parke Davis Co.	do.	Feb. 5, 1962
Dorsey Laboratories.	Lincoln, Neb.	May 15, 1962
Norden Laboratories, Inc.	do.	May 17, 1962
Schlicksup Drug Co.	Peoria, Ill.	Feb. 26, 1962
Caladine Laboratories.	Oakland, Calif.	Apr. 26, 1962
Refusal to permit review of complaint files:		
Chas. Pfizer & Co., Inc.	Groton, Conn.	Apr. 24–25, 1962
Puritron Corp.	New Haven, Conn.	Mar. 30, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Wm. S. Merrell Co.	Cincinnati, Ohio.	Jan. 17, 1962
Philips-Roxanne, Inc.	Columbus, Ohio.	Apr. 18, 1962
Pitman-Moore Co.	Indianapolis, Ind.	Mar. 21, 1962
Difco Laboratories.	Detroit, Mich.	Feb. 13, 1962
Norwich Pharmaceutical Co.	Norwich, N.Y.	Apr. 10, 1962
Irwin Neisler & Co.	Decatur, Ill.	Apr. 18, 1962
Caladine Laboratories.	Oakland, Calif.	Apr. 26, 1962
Jensen Salisbury Laboratories, Inc.	Kansas City, Mo.	May 11, 1962
Winthrop Laboratories.	Rensselaer, N.Y.	May 15, 1962
Refusal to permit review of shipping records:		
Dainty Maid, Inc.	Middlefield, Conn.	Mar. 20, 1962
Puritron Corp.	New Haven, Conn.	Mar. 30, 1962
Approved Pharmaceutical Corp.	Syracuse, N.Y.	Apr. 23, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Chattanooga Medicine Co.	Chattanooga, Tenn.	Mar. 15, 1962
Basic Formulas, Inc.	Salt Lake City, Utah.	May 8, 1962
Difco Laboratories.	Detroit, Mich.	Feb. 13, 1962
Coast Chemical Co.	Los Angeles, Calif.	Mar. 26, 1962
Walker Laboratories, Inc.	Mount Vernon, N.Y.	Mar. 14, 1962
Mantho Kreoamo, Inc.	Clinton, Ill.	Mar. 30, 1962
Caladine Laboratories.	Oakland, Calif.	Apr. 26, 1962
Bolton's Rexall Drugs.	Berkeley, Calif.	Mar. 14, 1962
Niagara of Fort Wayne.	Fort Wayne, Ind.	May 24, 1962
Winthrop Laboratories.	Rensselaer, N.Y.	May 15, 1962
Refusal to permit review of prescription files: Bolton's Rexall Drugs.	Berkeley, Calif.	Mar. 14, 1962

See footnotes at end of table, p. 592.

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 15, 1962—Continued

COSMETIC FIRMS

Firm name	Address	Date of refusal [1]
Refusal to permit inspection: Schratz Products, Inc.	Detroit, Mich	[3] Mar. 22, 1962
Refusal to furnish qualitative or quantitative formulas:		
John H. Breck, Inc	Springfield, Mass	Mar. 27, 1962
Chesebrough Pond's, Inc	Clinton, Conn	Apr. 10, 1962
Chesebrough Pond's, Inc., (Stamford Division)	Stamford, Conn	May 1, 1962
Clairol, Inc	do	Apr. 24, 1962
North American Dye Corp	Danbury, Conn	May 7, 1962
Franad, Inc	Chicago, Ill	Feb. 16, 1962
Colgate Palmolive Co	Clarksville, Ind	Nov. 29, 1962
Davis Young Soap Co	Dayton, Ohio	Feb. 20, 1962
Procter & Gamble	St. Bernard, Ohio	Jan. 15, 1962
United Western Laboratories, Inc	Denver, Colo	Apr. 23, 1962
Presto Products Co	Detroit, Mich	Apr. 9, 1962
Schratz Products, Inc	do	Apr. 27, 1962
Sanford Laboratories, Inc	Tuscaloosa, Ala	Mar. 16, 1962
Andrew Jergens Co	Belleville, N.J	Feb. 27, 1962
The Klutch Co	Elmira, N.Y	Apr. 17, 1962
Rosal Laboratories, Ltd	Philadelphia, Pa	Apr. 2, 1962
Golden Peacock, Inc	Paris, Tenn	Apr. 5, 1962
Gold Star Beauty Supply Co., Inc	Los Angeles, Calif	Apr. 30, 1962
J. H. Lewis, Inc	St. Paul, Minn	Apr. 17, 1962
Refusal to disclose or permit observation of manufacturing procedures:		
John H. Breck, Inc	Springfield, Mass	Mar. 27, 1962
Clairol, Inc	Stamford, Conn	Apr. 24, 1962
Refusal to permit review of control records:		
John H. Breck, Inc	Springfield, Mass	Mar. 27, 1962
Procter & Gamble	St. Bernard, Ohio	Mar. 15, 1962
Schratz Products, Inc	Detroit, Mich	Mar. 27, 1962
Rosal Laboratories, Ltd	Philadelphia, Pa	Apr. 2, 1962
Refusal to permit review of complaint files:		
John H. Breck, Inc	Springfield, Mass	Mar. 27, 1962
Chesebrough Ponds (Stamford Division)	Stamford, Conn	May 1, 1962
Clairol, Inc	do	Apr. 24, 1962
Procter & Gamble	Cincinnati, Ohio	Jan. 18, 1962
Refusal to permit taking of photographs: Clairol, Inc.	Stamford, Conn	Apr. 24, 1962
Refusal to permit review of shipping records:		
John H. Breck, Inc	Springfield, Mass	Mar. 27, 1962
Clairol, Inc	Stamford, Conn	Apr. 24, 1962
H. R. Distributing & Advertising Co	Philadelphia, Pa	Apr. 19, 1962
Andrew Jergens Co	Belleville, N.J	Feb. 27, 1962

[1] NOTE.—Firms may be listed under more than one category if they refused more than one phase of inspection during a given inspection.
[2] When visited again on Apr. 24, 1962, the firm permitted inspection.
[3] After being cited for refusal to permit inspection, the firm agreed at an informal hearing on June 7, 1962, to permit inspection in the future.
[4] When visited again on Apr. 25, 1962, the firm permitted inspection.
[5] When visited again on Mar. 27, 1962, the firm permitted inspection.

Mr. ROBERTS. The committee has received a great deal of material on this legislation. We will try to place as much as possible in the record and keep the rest of the files for reference.

(The following material was received for the record:)

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION RE H.R. 11581 AND S. 1552, BY F. J. L. BLASINGAME, M.D.

I am Dr. F. J. L. Blasingame, executive vice president of the American Medical Association. I would like to submit for the record the association's comments on H.R. 11581 and S. 1552, proposing certain amendments to the Federal Food, Drug and Cosmetic Act. The American Medical Association, as the national association of physicians of the United States, has a serious and long-standing interest in drugs and legislation concerning them. These bills will, in our opinion, directly affect the practice of medicine and the public health and are therefore within the area of knowledge and professional competence of physicians and the AMA.

This committee is, of course, aware of the increased public attention now being focused on drugs, drug investigations, drug marketing and drug legislation. The

uneasiness of the public, the newspapers, and, to some extent, the Congress, is precipitated in large measure by the birth in other countries of infants afflicted with congenital malformations (phocomelia) attributed to the ingestion of the drug thalidomide by the child's mother during the first few weeks of pregnancy.

We as physicians, who have dedicated our lives to the preservation of life and to the relief of human suffering, are particularly concerned over the recent increase in other countries of the birth of deformed children afflicted with phocomelia. We deplore the human suffering and heartbreak attending the birth of a deformed child.

In our opinion, however, the fact that should be uppermost in the minds of this committee and the Congress is that the drug was not released for prescription use here due to presently existing laws. These laws, which were supported by the AMA when they were before the Congress, authorize FDA to withhold a drug from the market for safety reasons and are demonstrably adequate to prevent the marketing of "unsafe" drugs.

The thalidomide incident may have affected the legislative climate, but it has not in any way changed the merits of the legislation which you are now considering. As physicians, we are apprehensive that thalidomide might have a serious and irreparable legislative side effect—the adoption of well-intentioned but ill-advised legislation. What is done by this committee and the Congress within the understandable emotional framework of the thalidomide incident may have serious repercussions affecting permanently the timely supply of new drugs for the alleviation of human suffering and the cure of disease.

It is our understanding that it is the intent, in part, of H.R. 11581 and S. 1552 to modify the framework within which prescription drugs are developed, marketed and used. It is also our understanding that these bills are being proposed in an effort to protect the American public from unsafe and ineffective drugs.

We believe, however, that there are provisions in these proposals which would have serious undesirable effects on the practice of medicine, on science, and on the availability of safe, efficacious and lifesaving drugs.

A prescription drug is, by definition, "unsafe" in the sense that its use in human beings can and does involve hazards. It is the existence of these hazards inherent in the use of all prescription drugs that leads to the requirement that they never be used except under the supervision of a physician. Only the physician can add the "safety factor" through the knowledge at his command of all of the consequences which may follow the administration of a specific dosage of a specific drug to a specific patient. Thus, clinical trials and, indeed, all drug research, are not intended primarily to determine "safety" or the lack of it. They are intended to discover all of the effects which may result to patients to whom the drug is administered.

When the physician knows all of the effects which will follow from a specific drug prescription, he can use that drug with a high degree of "safety" and bring about a net improvement in the health of his patient. It should be noted that the emphasis is on "net improvement." The vast majority of prescription drugs cause multiple effects in the human body.

Thus, when the physician is aware of all of the consequences, he can prescribe a drug which will cause more desirable changes in his patient than undesirable ones, and thus effect an improvement in the patient's health.

It is the association's sincere belief that if the above facts are kept in mind during the committee's consideration of this legislation, then the provisions of the bills can be judged on their true merit.

The AMA is justly proud of its long history of support and sponsorship of legislation in food and drug matters. In addition to our legislative interest and activity, the AMA has, over the years, had a close and continuing relationship with the Food and Drug Administration on constructive matters in the public interest. A chronicle of our support of Federal food and drug laws and a brief history of the highlights of our cooperation with the Food and Drug Administration is attached to our statement as exhibit A.

With this record of AMA support and cooperation as background information, we would like to cite the aims we, as physicians, are desirous of achieving.

We want all physicians to be well-trained and fully informed on all aspects of the practice of medicine, including a high degree of competency in the selection and proper use of drugs.

We want a continuing and expanding flow of useful drug products placed at the disposal of physicians.

We would now like to comment specifically on those provisions of H.R. 11581 and S. 1552 which cause us the greatest concern as physicians:

Efficacy of drugs.—Section 102 of H.R. 11581 would amend subsections (b), (d), (e) and (i) of section 505, the new drug section, of the Federal Food, Drug and Cosmetic Act so as to authorize the Food and Drug Administration to determine, evaluate and pass on the efficacy of new drugs prior to marketing. Section 8(c) of S. 1552 would require "substantial evidence" of "effectiveness," allowing the Secretary to determine if it is "adequate." Both bills would also amend section 201(p) of the present act to introduce the concept of drug efficacy or effectiveness into the definition of a new drug. Among other things, the bills authorize the suspension of an effective new drug application when doubts arise on the part of the FDA as to the efficacy of a drug which previously has been approved.

These proposals would require that the FDA come to some conclusion regarding a drug's power to produce effects when administered to human beings, a basic problem in medicine, one which physicians have concerned themselves with for centuries and one which for centuries has defied legislative solution. The problem is this: How much and what kind of knowledge must we have regarding a drug's power to produce effects before it can be used with certainty? And how do we go about obtaining such knowledge?

Under ideal conditions, the profession would be aware of all of the effects produced by a drug before it was administered to the first patient. However, even when a drug has been used over an extended period of time, in hundreds of thousands of cases, the physician must remain alert to the possibility of effects which have never been experienced before. He knows that his knowledge of drug therapy is, and must remain, tentative. No group of men, inside or outside of Government, can change this situation.

Over the years, the profession, in cooperation with others involved in the development of new drugs, has worked diligently to increase our knowledge of the power of drugs and to assure that their use in the treatment of disease will be effective.

Today when a prescription drug is made available to physicians, we know what toxic effects the drug has been known to produce under specified conditions and in a specified number of instances. And we are alerted to watch for other toxic effects as our experience with the drug expands. The FDA does not say that such a drug, in the absolute sense, is "safe." It approves even highly toxic drugs for use by physicians, knowing that the physician can be informed regarding their known toxic properties and will consider such properties when prescribing the drugs. When a drug is approved for widespread use, all physicians become part of a continuing "watch" for other toxic effects.

However, drugs are prescribed and used in the treatment of patients, not to produce effects which we have called "toxic," but to cure or alleviate pain and illness, and it is the power to produce these desirable effects that is referred to by the term "efficacy." We point this out because there is an understandable, but nevertheless, extremely important misconception on the part of many of the term "efficacy" as this term is used in medicine. Physicians seek to treat effectively the medical problems of individual patients. A physician does not treat 10 cases of hypertension, he treats 10 individual patients, each of whom has a medical problem he has diagnosed as hypertension. This difference becomes especially important when he elects to use drug therapy in the treatment of these 10 individual patients. He may find that the same dosage of the same form of the same drug will be efficacious in each and all of his 10 patients. Or he may find that one or more of them need different dosages, or different forms of this same drug. He may, indeed, find that one, two, or three of them are allergic to the nonactive ingredients used in one brand of the drug and that a different brand, with other nonactive ingredients, is the efficacious answer. Thus, in one patient, a specific dosage of a specific drug might be said to be efficacious, while in another it would be described as totally ineffective.

The point we are making is this. A drug's efficacy varies from patient to patient, sometimes for known reasons such as allergy, and at other times for unknown reasons. Hence, any judgment concerning this factor can only be made by the individual physician who is using the drug to treat an individual patient. A physician can be told many things about a drug, including its chemistry, its mode of action and, to some extent, its toxic properties. But he must judge its efficacy. A drug which is, on the average, less efficacious than another, must still be available to every physician since it may be completely efficacious in treating the medical problems of one of his patients. We do not

practice medicine on the average—we seek to solve or alleviate the problems of each and every patient.

If this precise usage of the word "efficacy" is kept in mind, the consideration of legislation which would request that an administrative agency of Government determine the efficacy of drugs can proceed more fruitfully.

The proposed amendments would prevent some apparently ineffective drugs from reaching the market. They would also, however, tend to stifle the development and distribution of other drugs which are or might later be shown to be highly efficacious. They would deprive the physician of exercising his professional judgment in deciding which drug was most efficacious for his patient, in that they would deny the physician the availability of certain drugs he might wish to prescribe. Also, they would substitute the judgment of governmental officials for the time-proven system of the concensus of the medical profession as to the ultimate usefulness and efficaciousness of a particular drug. It is our considered opinion that these proposed amendments would not, in the final analysis, result in better medical care for the American people, the objective, we are sure, all are seeking.

We are also concerned that, by granting to a governmental agency the statutory authority to pass on the efficacy of a new drug, Congress will be enabling that agency, through administrative interpretation of the law, to decide the relative or comparative efficacy of a new drug in terms of drugs already on the market. We are apprehensive that the Food and Drug Administration would, under these amendments to the act, decide that it had the authority to refuse to allow a drug to be marketed merely because it was, in their opinion, not the most efficacious drug for the purpose intended or was not as efficacious as one might ideally wish.

Virtually all medical scientists agree that the attempted evaluation of the relative merits and uses of different drugs by governmental employees would not only be a most unfortunate undertaking, but an impossible one. Physicians in the Food and Drug Administration, like physicians everywhere, have their own personal opinions as to the relative merits of drugs. This is the nature of medicine and of the medical profession. What concerns us is that the particular views of the physicians in government might well be translated into a denial of the availability of a particular drug which they, in all good faith, do not believe to be as efficacious as a drug already on the market. Subsequent events could well prove them wrong. Medical history is replete with examples of medical "authorities" who were badly mistaken as to the ultimate usefulness of a drug.

We have closely studied the language of the numerous legislative proposals which would purport to grant to FDA the authority to evaluate efficacy, while denying to it the authority to make determinations as to relative efficacy. We cannot conclude that any of these proposals would suffice to guarantee that administrative determinations, under such a statute, would not be made comparing the relative efficacy of various drugs.

Thus, the American Medical Association opposes those sections of H.R. 11581 and S. 1552 which would grant to the Food and Drug Administration the authority to determine, evaluate and pass on a drug's efficacy and thereby determine beforehand that a drug should not be marketed on that basis.

Factory inspection.—On April 21, 1953, the association submitted to the committee a statement urging enactment of a bill which would have authorized inspection of factories without the necessity of first making a request. It was the belief of the association that the principle of the bill was a proper one and the measure should be adopted "provided the proper safeguards are included to protect the physician-pharmacist-patient relationship." It was also pointed out that the association believed that language should be included which would clearly indicate that the bill has no application to confidential business and professional records "which have no specific bearing on the enforcement of the Food, Drug and Cosmetic Act."

The association continues to maintain this policy, although we are of the opinion that the provisions of section 201 of H.R. 11581 appear to be unnecessarily broad for the purposes for which it is intended.

Section 4 of S. 1552 specifically excludes certain data from inspection and therefore would be more acceptable to the profession. However, the provisions of this bill relating to the qualification of personnel, while not intended to establish Federal standards for personnel, could easily be administered to that end. This, we believe, would not be in the public interest.

Both of the provisions would authorize inspection of consulting laboratories. H.R. 11581 leaves the definition to the discretion of the Secretary. S. 1552 defines the term very broadly. While the association is convinced that the provision is intended to apply only to commercial consulting laboratories, we would suggest that appropriate language be added to any such provision to specifically exclude physicians' offices, hospitals and medical schools from its application. Such an amendment would be in accord with other provisions of section 4 of S. 1552 which exempts physicians' records from inspection and would give recognition to the patient-physician relationship and State laws which give statutory protection to it.

Standardization of drug names.—Section 111 of H.R. 11581 would authorize the Secretary of HEW to establish a single standard name for a drug under certain conditions. Section 10 of S. 1552 would grant similar authority, but would also require the Secretary to review all the official compendia to determine the necessity or desirability of revising official names "in the interest of usefulness and simplicity." Before designating such a name, the Secretary would first have to seek a recommendation from the compilers of compendia.

We believe that the powers which would be granted to the Secretary of HEW by these provisions are unnecessary and would tend to interfere with present successful, voluntary efforts and would create and compound confusion in drug nomenclature. In order to clarify for the committee our reasons for believing legislation in this area to be unnecessary, we would like to describe for you how nonproprietary drug names are currently established under improved, voluntary procedures.

For many years the AMA has played a leading role in the adoption of a drug's nonproprietary (standard) name. This procedure is explained in some detail in exhibit B attached to this statement. We will not repeat the full explanation included in the exhibit, but for the benefit of the committee, we will summarize briefly the present procedure.

Simultaneously with the early development of a new drug, consideration of a nonproprietary name is begun. It is the policy of the AMA that the early adoption of a nonpriprietary name should be encouraged to facilitate understanding by all concerned of the properties and proper usage of the drug. It is also our policy that the nonproprietary or generic name should be as simple as possible and that chemically related drugs, used within a given therapeutic area, should preserve some relationship in their nonproprietary names.

In order to improve and streamline the naming process, the AMA and the U.S. Pharmacopoeia formulated last year a joint program for the adoption of nonproprietary names. The objectives of this program are to facilitate the selection of suitable nonproprietary names for drugs and to encourage the use of such names wherever indicated in labeling, in advertising, as titles in the official compendia, and in the scientific literature. The new program represents a dovetailing of the nomenclature interests of the AMA and the U.S. Pharmacopoeia. Briefly, it consists of the modification of the Nomenclature Committee of the Council on Drugs. The joint A.M.A.–U.S.P. Nomenclature Committee consists of two members appointed by the AMA and two members by the U.S.P., and is staffed by the AMA. It is the responsibility of the Committee, after working and negotiating with the pharmaceutical manufacturer, to designate the nonproprietary drug name which will then be adopted by both organizations. In the event that a decision cannot be reached between this joint committee and the manufacturer as to the nonproprietary name to be assigned, either the committee or the manufacturer may take the matter to a Nomenclature Review Board, appointed jointly by the AMA and U.S.P., which determines the merits of the controversy and makes the final decision as to the name.

In addition to facilitating the adoption of nonproprietary names, the new program results in a faster and much wider dissemination of the newly adopted nonproprietary names of drugs. As in the past, all interested cooperating agencies throughout the world are consulted for their comments.

The U.S.P. will adopt the name so selected as the U.S.P. title, when and if the drug concerned is admitted to the U.S.P. The U.S.P. also undertakes to publish lists of the names at frequent intervals. The Journal of the American Medical Association publishes monthly a list of the names so selected which are denominated United States Adopted Name (USAN). In addition, the AMA and the U.S.P. have organized a concerted campaign to acquaint the editors of all other medical and pharmaceutical journals of the availability of USAN

nonproprietary names for all drugs that are likely to be the subject of published articles.

The American Medical Association believes that this system of adopting nonproprietary or generic names for drugs has been reasonably effective in the past, and that the recent Joint Nomenclature Committee is making it even more effective and expeditious. Further, the close cooperation of the AMA and U.S.P. in this program is greatly increasing the use of such names and eliminating any confusion that may have existed.

In summary on this point, we believe that the problems which remain in the field of drug nomenclature can and should be solved by the profession itself. Physicians and others will adopt and use nonproprietary names for drugs only when they are convinced that the use of such names will facilitate and improve the practice of medicine. We believe that the programs we have described will be most convincing to them.

Special control for barbiturate and stimulant drugs.—We would like next to briefly comment on part C of H.R. 11581 which embodies special control for barbiturates, amphetamines, and any other drug which the Secretary of HEW finds to be habit forming because of its stimulant effect on the nervous system. These provisions would apply to barbiturates and habit-forming stimulant drugs whether or not they enter or are destined for interstate commerce. They have been the exclusive subject matter of four similar bills now pending before the Congress—H.R. 646, H.R. 3967, S. 1939, and S. 3673—but hearings have not been scheduled on any of these proposals.

We can appreciate the concern of the Congress and this committee over the social effects of barbiturates and amphetamines. The AMA joins the Food and Drug Administration in deploring illicit traffic and sales of such drugs.

However, H.R. 11581 is an omnibus bill dealing with the broad spectrum of all drugs. In our opinion, it would be a serious mistake to include in this bill legislation specifically regulating two classifications of drugs—barbiturates and amphetamines. The time allotted to hearings on this proposal does not permit the necessary legislative inquiry as to the necessity for further Federal legislation with respect to these drugs; nor does it provide sufficient time for an inquiry as to the appropriateness of the measures proposed. The Senate Judiciary Committee in its consideration of S. 1552 urged no action on this provision pending the outcome of further study by the Senate Labor and Public Welfare Committee.

We do not believe that the necessity for, or appropriateness of, additional Federal legislation has been adequately demonstrated at this time. Accordingly, we would urge the committee to defer action on this part of H.R. 11581 pending further study of this portion of the bill.

In this connection, the American Medical Association and its Council on Drugs stands ready to cooperate with the Congress and the appropriate department of the executive branch of Government in studying the medical and social problems inherent in the illicit and medically unsupervised use of these drugs and the appropriateness of additional Federal legislation.

Prescription drug advertising.—Section 131 of H.R. 11581 and section 11 of S. 1552 are concerned with the advertising of prescription drugs to physicians. Generally, an advertisement would be deemed to be misleading in a material respect if such advertisement fails to contain (A) a conspicuous, full and accurate statement of the efficacy of the drug, and (B) a conspicuous and truthful disclosure of (i) the quantitative formula of the drug with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contraindications of the drug.

Advertisements for prescription drugs are directed to physicians in order to keep the name of a given product before the medical profession. Most physicians accept such ads for what they are—reminder information, not educational material. The proposals contained in these bills are quite obviously based on the erroneous, mistaken assumption that the purpose of prescription drug advertising is educational.

In 1914, when the Federal Trade Commission Act was adopted, it contained the exception to the false advertising provisions of the act that "No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of each drug."

The reason for such an exception is obvious to us as physicians. Prescription drug advertising is directed to a sophisticated, trained, and knowledgeable audience of professional people who can evaluate such ads for what they are—advertisement. The Congress recognized this fact in 1914, and the reasoning behind this exception is even more valid in 1962. With the great advances in medical education and postgraduate education, coupled with improved media of communication, today's medical practitioner is much better informed regarding drugs and drug usages than he was in 1914.

In addition to his training and experience, the physician receives a constant stream of information about available drugs and their effects from the medical literature, from impartial reports by pharmacologist and the medical profession, from informal discussions with colleagues and from numerous reference works.

It is not only medically impossible to include in an advertisement for a prescription drug complete data relative to efficacy, contraindications, and side effects—it is also physically impossible. Any abbreviation of this information could be extremely unwise, as this could only encourage doctors to rely on drug advertisements as a source of complete information.

Thus, in our opinion, these proposals could very easily have the opposite effect from that intended by their proponents. If prescription drug advertising were required to contain the proposed statements as to efficacy, side effects, and contraindications, it could easily result in the mistaken assumption by many physicians that continual study of scientific and authoritative medical literature would be unnecessary.

The AMA, of course, believes that advertising should be truthful. We cannot, however, make the assumption that physicians receive their education on drugs and drug therapy from pharmaceutical advertisements. We make every effort in the scientific publications of the AMA to insure a high quality in the advertisements appearing in our publications. A copy of the principles which guide us in the acceptance of advertising for our journals is attached to this statement as exhibit C. We will not dwell on the details of these principles, but merely indicate that the application of such principles results, in our opinion, in high quality, truthful advertising without distorting the purpose of advertisements by attempting to include the education of our physician readership.

In conclusion, the American Medical Association has endeavored in this statement to comment on those provisions of H.R. 11581 and S. 1552 as passed by the Senate which are of greatest concern to the physicians of America.

We are confident that this committee is aware of the vital responsibility which it bears. Undoubtedly, the legislation recommended by this committee will have serious and far-reaching effects on drug research, the availability of new, life-saving drugs, the practice of medicine and the health of our people. If ever there was a time for serious, considered, dispassionate deliberation, it is now.

We sincerely hope that our comments and suggestions have indicated the concern of the Nation's physicians and will be of assistance to this committee in arriving at a judicious result.

EXHIBIT A

HIGHLIGHTS OF AMA LEADERSHIP AND COOPERATION WITH FEDERAL AGENCIES IN FOOD AND DRUG MATTERS

As early as 1891, the AMA went on record as supporting the first proposals for a Federal food and drug law. It was not until 1905, however, coincident with the establishment of our council on pharmacy and chemistry, later to become the council on drugs, that the association threw its full weight into the struggle for a Federal pure food and drug law. The statute was enacted in 1906 following intensive legislative efforts by the AMA. Through the years, the AMA has closely followed the implementation and effectiveness of the 1906 act. As early as 1911, the association urged Congress to amend the act so as to prevent false statements being made as to the results to be obtained from the use of medicinal agents.

In 1933, the AMA, realizing that the existing act had certain deficiencies, urged "the formulation and enactment of effective national food and drug legislation adequate for the protection of the people." Activities of the association were instrumental in the passage of the present Federal Food, Drug, and Cosmetic Act in 1938. In 1951, we supported the Durham-Humphrey amendment, which is the law controlling the dispensing of prescription drugs. In 1953, the AMA supported a bill, which was enacted as Public Law 217, 83d Congress, authorizing the Food and Drug Administration to inspect pharmaceu-

tical manufacturing establishments without first obtaining the permission of the proprietors. During the 86th Congress, the AMA was one of the chief sponsors and supporters of the Hazardous Substances Labeling Act, which was enacted as Public Law 86–613 and is now administered by the Food and Drug Administration.

AMA has supplemented our legislative activities with a close and continuing relationship with the Food and Drug Administration. Our council on drugs, over the years, has had a number of members from the FDA, and numerous other Government physicians and pharmacologists have served as consultants to the council in its drug evaluation program. Our department of investigation has enjoyed a longstanding close relationship with FDA in developing information on quackery and medicines and devices of questionable value.

On October 6–7, 1961, the AMA and the FDA jointly sponsored the first National Congress on Medical Quackery in Washington, D.C. This was the beginning of a concerted cooperative drive against those practioners of pseudomedicine who bilk the public of millions annually. In March of this year, a followup conference was sponsored by the American Medical Association in Chicago. Attending this meeting were key people from the FDA, and other Government agencies and private organizations.

Our committee on cosmetics and the former committee on toxicology have also worked closely with FDA over the years, most recently concerning the above-mentioned Hazardous Substances Labeling Act. The council on foods and nutrition is most active in exchanging information with FDA and in cooperating with it, the Federal Trade Commission, and the U.S. Post Office in sponsoring an aggressive program against food faddism and food and vitamin quackery.

In addition to these cooperative activities, the AMA frequently comments on proposed administrative regulations of the Food and Drug Administration and other governmental agencies. We are now preparing comments on the proposed regulations of FDA for special dietary foods, including vitamin supplements, and the recently proposed regulations pertaining to new drugs for investigational use.

EXHIBIT B

THE AMERICAN MEDICAL ASSOCIATION-UNITED STATES PHARMACOPOEIA COOPERATIVE PROGRAM FOR THE SELECTION OF NONPROPRIETARY NAMES FOR DRUGS

The objectives of this program are to facilitate the selection of a suitable nonproprietary name for each single entity drug and to encourage the use of such selected names wherever indicated in labeling, in advertising, as titles in the official compendia, and in the scientific literature.

A joint committee known as the AMA–U.S.P. Nomenclature Committee has been established to negotiate with the manufacturers. This committee consists of four members. Two members are nominated by the AMA subject to the approval of the U.S.P.; the other two members are nominated by the U.S.P. subject to the approval of the AMA.

The American Medical Association maintains for the committee and will expand, as necessary, its present staff and facilities for receiving proposals of nonproprietary names from all sources, processes these proposals and initiates and conducts such negotiations as expeditiously as may be appropriate to settle upon a tentative name for all new drug entities.

It is probable that in a given number of nonproprietary name negotiations the AMA–U.S.P. Nomenclature Committee and the manufacturer(s) may fail to reach an accord satisfactory to each. The AMA and U.S.P. have appointed a board known as the nomenclature review board to determine the merits of such cases and to make a final decision thereon. This board acts upon the request of either the committee or the manufacturer(s) involved.

The nomenclature review board consists of five individuals of judicial temperament and highly respected status in medicine and pharmacy; the AMA recommended to the U.S.P. several names of potential candidates from which list two members were selected by the U.S.P. to serve on the board. The terms of board members overlap to insure continuity. One member is to be added to the board, on an ad hoc basis but without vote, to represent the firm making the protest. If more than one firm is involved, an ad hoc member from each will be added. The board functions primarily through correspondence.

The decisions of this board, which are final for this stage of the negotiation, is reported to all interested parties.

Tentatively adopted (as a result of above action) noproprietary names are referred to the cooperating agencies (N.F., WHO, B.P. Commission, French Codex, Nordic Pharmacopoeia) for their consideration and comment, in accordance with past policy leading to the final adoption by the committee for national use in the United States. This name when adopted is referred to as USAN (U.S. Adopted Name).

Names adopted by this nomenclature committee are the designations used in the council on drugs (AMA) monographs on individual drugs and are the nonproprietary names used in the scientific journals of the AMA. The AMA promptly notifies the editors of medical journals and professors of pharmacology of all medical schools in the United States of the adopted name.

The U.S.P. (1) adopts the names so selected as the U.S.P. titles when and if the articles concerned are admitted to the U.S.P.; and (2) undertakes to publish lists of the names at frequent intervals through appropriate channels.

It should be made clear, of course, that adoption of publication of the name implies no endorsement whatever, by the committee, the AMA, or the U.S.P., of the merits of the articles to which the name apply.

Both the U.S.P. and the AMA make reasonable efforts to notify the industry and the professions of medicine and pharmacy that the committee is maintaining this invaluable service on the common names for drugs. The committee also undertakes to notify other national and international agencies of the names selected.

The U.S.P. has organized a concerted campaign to acquaint the editors of all medical and pharmaceutical journals of this service and the availability of nonproprietary names for all drugs that are likely to be the subject of published articles. Efforts are being made to encourage the Food and Drug Administration and the Federal Trade Commission to extend their respective areas of authority to the limit in seeing that the selected names, and only those, are used wherever nonproprietary names appear in drug labeling and advertising.

In the name of the committee, the AMA staff maintains all contacts in connection with the process of selection and negotiation as at present, including all participating in the World Health Organization program.

Principles Governing Advertising in the AMA Scientific Publications

The American Medical Association seeks to promote the science and art of medicine and the betterment of public health. In serving these aims, the AMA communicates regularly with the members of the medical profession, with professional persons in allied fields, and with the public. A substantial part of this communication is carried on through the regular production and distribution of several publications.

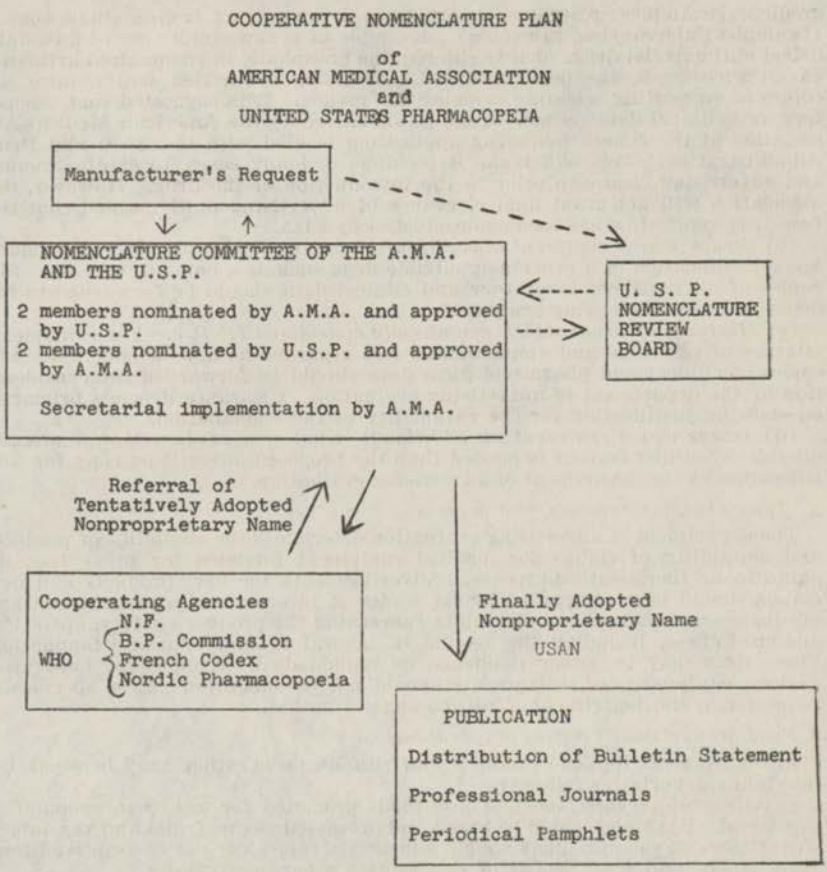
In keeping with its avowed purposes, the association will do all it reasonably can to insure the accuracy, comprehensiveness, timeliness, and relevancy of the advertising content of these publications. The evaluation of advertising copy will be based on the consideration of available data concerning the product or service. It will not be based on tests conducted by the AMA.

The appearance of advertising in AMA publications should not be construed as a guarantee or endorsement of the product by the association. The fact that an advertisement for a product, service, or company has appeared in an AMA publication sholl not be referred to in collateral advertising without specific authorization from the American Medical Association.

As a matter of policy, the AMA will sell advertising space in its publications when (1) the buyer believes purchase of such space represents a sound expenditure; (2) the inclusion of advertising material does not interfere with or seriously detract from the purpose of the publication; and (3) the advertising copy meets the standards established for that publication.

General Principles Governing Advertising in AMA Scientific Publications

The following general principles set forth the criteria which the American Medical Association will follow in screening advertising to be carried in the AMA scientific publications (The Journal and 10 specialty journals). The association reserves the right to change these principles in the light of developments in medicine or in industry.



U.S.P. also will publicize program itself and seek out recognition of these activities from both F.D.A. and F.T.C.

Eligibility for advertising

1. Products or services eligible for advertising shall be germane to, effective in, and useful in the practice of medicine and shall be commercially available.
2. Pharmaceutical products will not be eligible for advertising until a new drug application from the Food and Drug Administration has become effective.
3. Institutional-type advertising germane to the practice of medicine and public service messages of interest to physicians may be considered eligible for appearance in the scientific publications.
4. Alcoholic beverage and tobacco products are not eligible for advertising.
5. The association may decide that certain products or services are not eligible for advertising in AMA's scientific journals if advertisements for these products or services in other media consistently, or significantly, depart from the standards set forth in the following section.

ADVERTISEMENTS FOR SPECIFIC TYPES AND CLASSES OF PRODUCTS AND SERVICES

1. Drugs

For convenience, advertisements for drugs (including vaccines and biologicals) may be separated into four categories, as follows:

(a) *New drugs or new claims for drugs which have not previously been advertised in AMA publications.*—A new drug is here defined as a single active in-

gredient (examples: reserpine, deserpidine) or an extract from a single source (examples: alseroxylon, rauwolfia). Example of a new claim: use of an established antimalarial drug, such as chloroquine phosphate, in rheumatoid arthritis. In all such cases, the department of advertising evaluation will require six copies of supporting scientific evidence for review. It is suggested that laboratory and clinical data on new drugs be submitted to the American Medical Association at the time a new drug application is filed with the Food and Drug Administration. This will make it possible, in many cases, to obtain product and advertising clearance prior to the introduction of the drug. However, the association will not grant final clearance of advertising until notified that the new drug application has been made effective by FDA.

(b) *Drugs which represent a modification of an eligible product.*—Example: Some modification of a previously eligible drug such as a new salt or ester. Six copies of all pertinent laboratory and clinical data should be forwarded to the department of advertising evaluation.

(c) *Mixtures of drugs which are already considered eligible.*—For example, a mixture of reserpine and amphetamine was regarded as new at one time. Six copies of clinical and pharmacological data should be forwarded for consideration by the department of advertising evaluation. Clearance depends primarily on showing justification for the rationality of the combination.

(d) *Drugs which represent an additional brand of a product that is already eligible.*—Nothing further is needed than the proposed advertising copy for consideration by the department of advertising evaluation.

2. Apparatus, instruments, and devices

The department of advertising evaluation determines the eligibility of products and suitability of claims for medical equipment intended for preventive, diagnostic, or therapeutic purposes. Advertisements for new products and new claims should be accompanied by six copies of information presenting full and adequate scientific and technical data concerning the product's safety, operation, and usefulness, including the results of laboratory and clinical examination. These data may be either published or unpublished. Samples of apparatus, devices, equipment, or instruments should not be submitted unless specifically requested by the department of advertising evaluation.

3. Food products and vitamin preparations

Advertisements for food products and vitamin preparations may be separated into four categories, as follows:

(a) *General-purpose foods.*—Those foods promoted for use by the population in general. Examples would be bread and processed meats, fruits and vegetables. Advertisers of such products should submit six copies each of descriptive literature, labels, and a statement of composition where pertinent.

(b) *Special-purpose foods.*—These are foods for special dietary uses subject to the labeling conditions imposed by section 403j of the Federal Food, Drug, and Cosmetic Act. Examples are foods manufactured and promoted for use by certain specific segments of the population, such as infants, invalids, as well as others requiring foods with certain properties, i.e., foods for carbohydrate-restricted diets, sodium-restricted diets, and other therapeutic diets. Advertisers of such products should submit six copies of labels, statement of composition, and analytical data. When pertinent they should be supported with data demonstrating the effectiveness of the product for its intended use. If new claims are made for a previously advertised product, six copies of clinical data substantiating such new claims must be submitted.

(c) Supplemental vitamin preparations: Rational mixtures of the vitamins recognized to be essential in human nutrition or metabolism in amounts not differing greatly from the recommended dietary allowances of the Food and Nutrition Board of the National Research Council are eligible. However, with the exception of iron-containing and calcium-containing preparations that are intended for use during pregnancy, vitamin mixtures to which minerals are added (as contrasted to trace minerals which are inherent in the manufacturing process) are not eligible for advertising.

(d) *Therapeutic vitamin preparations.*—Rational mixtures of the vitamins recognized to be essential in the amounts not greater than five times the recommended dietary allowances are eligible. However, preparations containing a mixture of all or most of the following antianemic factors—vitamin B_{12}, folic acid, intrinsic factor, iron, ascorbic acid, and copper—are not eligible for advertising. If claims not generally recognized are made for any of the vitamins,

or mixtures of vitamins, such claims shall be substantiated with six copies of clinical studies in support of such claims.

4. Cosmetics

For cosmetics with acknowledged sound health claims, only the qualitative formula need be given. In the event that a question of safety arises, quantitative data on the one or more ingredients in question are necessary. In the case of a new cosmetic, or a cosmetic to which new ingredients have been added, six copies of supporting data for the product's safety and ability to perform as claimed should be forwarded to the department of advertising evaluation for review. Since relevancy to medical practice is one of the prerequisite for eligibility, it should be emphasized in each advertisement.

5. Books

A book may be requested for review so that its eligibility for advertising may be determined.

6. Miscellaneous products and services

Products or services not in the above classification may be eligible for advertising if they satisfy the criteria for eligibility and suitability.

SUITABILITY OF ADVERTISING COPY

After a product or service has been declared eligible to be advertised in the scientific publications of the AMA, the department of advertising evaluation must approve each advertisement. As in the case of eligibility, the AMA makes the final decision regarding the suitability of copy, layout, and artwork. The AMA's decisions on these matters will be guided in all cases by the following principles:

1. The advertisement should clarify identify the advertiser and the product or service being offered. In the case of drug advertisements, the full generic name, including salt and ester designation, of each active ingredient must be shown in appropriate type size If the generic name of a drug appears in close juxtaposition to the trade name, it should not be unduly subordinated, and under no circumstances appear in less than 8-point type. If the generic name does not appear in close juxtaposition to the trade name, it should not be unduly subordinated and under no circumstances appear in less than 10-point type.

2. Advertisements should not be deceptive or misleading. Layout, artwork, and format should be such as to avoid confusion with the editorial content of the publication.

3. Unfair comparisons of the blatant and unwarranted disparagement of a competitior's products or services will not be allowed.

4. Sweeping superlatives or extravagantly worded copy will not be allowed. Any claims for superiority must be supported by evidence acceptable to the association.

5. Quotations or excerpts from a published paper are acceptable only if they do not distort the meaning intended by the author. Claims made within quotations must conform to the same standards as unquoted claims.

6. Advertisements will not be accepted if they appear to conflict with the principles of medical ethics.

PROCEDURES OF THE AMA DEPARTMENT OF ADVERTISING EVALUATION (SCIENTIFIC JOURNAL)

The AMA Department of Advertising Evaluation is responsible for applying the foregoing principles and standards to advertising copy submitted for publication in AMA scientific journals. It will do so in acocrdance with the following procedures:

1. *Submission of data.*—The department of advertising evaluation requires that scientific data be submitted to substantiate claims made for new products (such as drugs, devices, or foods) or new claims for products which have previously appeared in AMA scientific journals.

2. *Type of data needed.*—Data should include pertinent reports published and unpublished, favorable and unfavorable, of laboratory and clinical investigations covering the efficacy and relative safety of the product (drug, device, or food) under consideration. These data should be based upon sound studies and should be sufficiently comprehensive to permit a critical evaluation of the

subject matter. While the quantity of the scientific data required will depend on the type of product, the nature of the medical problem involved, and the claims made in the advertising copy, the quality of the evidence is regarded as highly important; in this respect, the importance of suitable controls is emphasized. Compilations of individual case reports are ordinarily not considered acceptable evidence. The unpublished portion of all submitted data will be regarded by the department of advertising evaluation as confidential, and consultants will be requested to treat it accordingly.

3. *Consultation.*—The AMA Department of Advertising Evaluation frequently seeks the opinions of consultants and recognizes the statements formulated by AMA councils and committees in determining the eligibility of products and the suitability of claims. The consultants for the department of advertising evaluation are persons who have been selected for their competence in the field involved. Names and affiliations of the consultants are not made available.

Time requirements for department of advertising evaluation

Although the department of advertising evaluation cannot guarantee adherence, in all cases, to a fixed time schedule, every effort will be made to expedite completion of AMA consideration in the following time intervals:

Advertisements for eligible products with no new claims.—From the time copy is received, 5 working days should be allowed for AMA consideration.

Advertisements involving new claims for or modifications of currently eligible products, or both.—From the time copy and, if necessary, supporting data are received, 15 working days should be allowed for AMA consideration.

Advertisements for new products.—From the time copy and supporting data are received, 20 working days should be allowed for AMA consideration.

In those cases in which AMA consideration cannot be completed prior to the expiration of the foregoing time intervals, the advertiser or agency will be so informed.

As a matter of policy, the AMA will periodically review its principles of advertising with the view of keeping pace with changes that may occur in the industry and the profession. It is hoped by this policy of continuous review and reevaluation to insure and improve the timeliness, relevancy, and appropriateness of the advertising content of AMA scientific publications.

AMERICAN MEDICAL ASSOCIATION,
Chicago, Ill., August 31, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: The purpose of this letter is to supplement the association's comments on H.R. 11581 and S. 1552 submitted to the committee on August 29, 1962.

The American Medical Association is also concerned with those provisions of section 7 of S. 1552 which would give discretionary authority to the Secretary of Health, Education, and Welfare to include in regulations, governing exemptions from the law for drugs used for investigational purposes, provisions for requiring (1) adequate animal tests, and (2) registration with the Secretary of "scientific experts" who would be required to keep records of tests performed and "to furnish to the Secretary simultaneous copies of their reports to the manufacturer and, upon request of the Secretary, reports at other times." We are opposed, at this time, to action with respect to these provisions of S. 1552 inasmuch as there are proposed regulations on these subjects which were published in the Federal Register by the Food and Drug Administration on August 10, 1962. The notice of the proposed regulations invited comments from interested parties.

In view of this fact and the fact that neither the Senate Judiciary Committee nor your committee had an opportunity to receive testimony and to study these provisions in all their effects, we urge that they be deleted from the legislation. Favorable consideration by Congress on provisions of this nature would have the effects of prejudging the validity of the proposed regulation and negating comments on the proposed regulation by interested parties.

The American Medical Association is equally concerned and opposed to favorable action on the remaining provisions of section 7 of S. 1552 and sections 102(b)(5), 103(b), and 106(b) of H.R. 11581, which would require reports on

effectiveness or efficacy of drugs used for investigational purposes. Our reasons for this position are stated fully in our previously submitted statement.

I appreciate this opportunity to submit these additional comments and would request if possible that they be made part of the record of your hearings.

Sincerely yours,

F. J. L. BLASINGAME.

STATEMENT OF AMERICAN PHARMACEUTICAL ASSOCIATION ON H.R. 11581, BY DR. WILLIAM S. APPLE, EXECUTIVE DIRECTOR

As the professional society representing individual pharmacists in all facets of professional practice, the American Pharmaceutical Association (A. Ph. A.) is aware of the intense interest of Congress in proper health care for the people. We assure you that pharmacists share this interest and wish to cooperate to the fullest extent in all activities which best serve public health, safety, and welfare.

Since its inception in 1852, the American Pharmaceutical Association (A. Ph. A.) has never had a financial interest in any drug product, drug manufacturer, drug wholesaler, or drugstore. The first objective of our members, as stated in our constitution, is: "To improve and promote the public health by aiding in the establishment of satisfactory standards for drugs, and to aid in the detection and prevention of adulteration and misbranding of drugs and medicines, and to take such steps as an association and in cooperation with other organizations as will assure the production and distribution of drugs and medicines of the highest quality."

It is for this reason that we presented extensive testimony on S. 1552 and H.R. 6245, as they were originally proposed, on December 19, 1961, and May 24, 1962, respectively.

Because the basic objective of the profession of pharmacy is serving and safeguarding public health, we endorse the objectives of H.R. 11581. Because we recognize that this committee is making its appraisal in the public interest—present and future—the American Pharmaceutical Association (A. Ph. A.) believes that this committee will be interested in our opinions regarding specific sections of H.R. 11581.

ADVERTISING PRESCRIPTION-LEGEND DRUGS

H.R. 11581 would amend the section of the Federal Trade Commission Act concerned with definitions and, in particular, the term "False advertisement" as used in the act. In effect, the bill would require every advertisement to the medical profession to carry full information on side effects and contraindications as well as the common or usual name of each ingredient.

Another advertising matter to which committee attention is invited is the promotion of prescription-legend drugs to the public. Such advertising disregards the inherently dangerous nature of drugs and results from a misunderstanding of the professional services involved in prescribing and dispensing prescription medication. Our profession is gravely concerned by the advertising and trading of prescription-legend drugs as commodities in commerce.

As expressed in the regulations proposed by the Food and Drug Administration in the Federal Register of August 10, 1962, the American Pharmaceutical Association (A. Ph. A.) endorses the position of the Federal Government proscribing the advertising or promotion of investigational drugs. It now appears only logical for the Federal Government to similarly proscribe th advertising or promotion of prescription-legend drugs to the public. Both the Federal Food, Drug, and Cosmetic Act and the Federal Trade Commission Act provide an appropriate means for the Federal Gorvernment to make known that it will not condone a practice many of our States, and numerous other nations, already condemn.

Because an investigational drug is not available to medical practitioners for general treatment, there is no valid reason for either a sponsor of the drug, or any person on his behalf, to disseminate advertising, public relations statements, or news releases representing the drug to be safe or useful for the purposes for which it is intended.

Similarly, because a prescription-legend drug is not available for general sale to the public, there is no valid reason for either a pharmacy, or any person on its behalf, to disseminate advertising, public relations statements, or news releases representing the drug to be available for the purpose for which it is intended.

If the drug is available for general treatment or general sale, the purpose of advertising or promoting it is to induce, directly or indirectly, the use or purchase of the drug. The advertising or promotion of a drug which is not available for general treatment or general sale—investigational or prescription-legend—is both false and misleading.

FEDERAL REGISTRATION AND "FACTORY" INSPECTION

A Federal registration of all interstate drug manufacturers has the obvious advantages of identifying sources of origin, inviting inspections, and fostering control of manufacturers in the public interest. However, we urge that any language incorporating a Federal registration and inspection for drug manufacturers provide that such Federal registration and inspection shall not prempt or preclude States from licensing, controlling, or otherwise regulating manufacturers doing business within such States. Nor should such Federal registration of drug manufacturers and factory inspection permit Federal invasion of confidential patient health files, including prescription records.

The dispensing of prescription medication by pharmacists in pharmacies is a matter of licensing and regulation which States exclusively control under their police power. Therefore, we want to be certain that any Federal registration is not intended to invade areas of authority heretofore exclusively exercised by States over professional activities which have always been intrastate in nature. These activities include:

(1) A doctor, licensed by a State, administering a drug to a patient in that State; and.

(2) A pharmacist, licensed by a State, compounding or dispensing a drug for a patient in that State.

The fact that the particular drug employed by these practitioners may have moved in interstate commerce should not be used as the entering wedge for Federal control of the professions.

We note that John L. Harvey, Deputy Commissioner, Food and Drug Administration, whose American Bar Association speech was entered in the August 13, 1962, Congressional Record, analyzed provisions of H.R. 11581. He stated: "These requirements, however, would not apply to licensed practitioners who dispense such drugs in the course of their professional practice." (Par. 1, col. 3, p. 15239.)

The pharmacist dispenses prescription-legend drugs only in the course of his professional practice. To clarify the intent of Congress, we urge the following language for appropriate inclusion within H.R. 11581:

"The provisions of this act shall not apply to persons who are lawfully entitled under State law to compound, dispense, prescribe, distribute, or administer drugs to patients within that State, nor shall the provisions of this section confer rights or privileges to conduct business or engage in professional pursuits contrary to State law."

This specific language embraces both the prescribing and the dispensing professions without affecting the intended registration and factory inspection of drug manufacturers, wholesalers, and others.

ANTIBIOTIC CERTIFICATION

In the earliest days of their preparation, penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin were concentrates of extractives from culture media containing micro-organisms. Variations in the strength, quality, and purity of these concentrates originally made it difficult or impossible to establish adequate standards under which identity, strength, quality, and purity could then be determined and assured.

However, through modern methods of production, synthesis, and purification, these substances which may be called antibiotics, are essentially pure substances, frequently recrystallized salts, possessing the same degree of purity as any other fine chemical. Existing certification procedures and proposals to extend such certification procedures do not take into account advances in analytical technics which can provide more accurate methods of analysis.

Under such conditions, where adequate standards can be set to assure the identity, strength, quality, and purity of a substance, we oppose continuing the certification process.

NOMENCLATURE—STANDARDIZATION OF DRUG NAMES

When a new compound is discovered or synthesized, it is important that the name assigned to the compound be informative, convenient and distinctive. This is necessary in the interest of advancing science, be it medical, pharmacal, chemical, or any other science. Such a determination in nomenclature, if it is to have maximum utility to those professional and scientific persons who must work with and use the article, must be determined in relation to all other compounds available and the informative, convenient, and distinctive considerations mentioned above.

It is both scientifically and economically important to one who has synthesized a new chemical entity to establish a permanent, useful, official, nonproprietary name at an early date. In so doing, clinical and scientific reports and other pertinent data are more easily followed and the potentialities of the accomplishment, therefore, are more easily assessed.

The general principles of nomenclature followed in the revisions of the United States Pharmacopeia and the National Formulary are consistent with sound scientific principles and provide that the primary title of each drug monograph shall be in English and shall be, as far as possible, convenient for prescribing and dispensing and in harmony with general usage.

These guiding principles further provide that short titles wherever needed shall be coined for synthetic organic chemicals with cumbersome names, and shall be based upon rational chemical names.

Commonly used names may be inserted in the United States Pharmacopiea and the National Formulary as synonyms in the official monograph after the official title. Botanical and zoological names conform to the rules of the International Botanical Congress and the International Zoological Congress. This system of nomenclature is designed to be most useful to practitioners who must rely upon and work with these compounds. It has proved most satisfactory for over three quarters of a century.

Further, drum name standardization can be achieved under H.R. 11581 by employing the specific procedures described in addendum II.

UTILIZATION OF EXISTING AUTHORITY

The thalidomide incident has resulted in proposed regulations strengthening controls over investigational drugs. These regulations afford additional safeguards and are being promulgated by FDA pursuant to its existing authority under the Federal Food, Drug, and Cosmetic Act.

Unfortunately, the proposed regulations only concern new, investigational drugs. They do not relate to drugs which have been approved by FDA for general use by physicians, dentists, veterinarians, and other related practitioners. For this reason, the American Pharmaceutical Association (APA) cautions against the illusion that the proposed regulations will give the degree of patient or consumer protection necessary with drugs.

A drug which may be investigational today may be marketed tomorrow. The investigational legend is soon replaced by the prescription legend. This can be hazardous because a defect in drug distribution exists. Frequently, drugs bearing the legend "Caution: Federal law prohibits dispensing without prescription" are made available through persons other than pharmacists and from places other than pharmacies. The health of our citizens is fully protected only when all drugs are distributed to the pharmacist and personally dispensed by him.

All drugs today are more potent than ever, and the consequences from misuse, or abusive use, are more serious than ever. In drug matters, the knowledge, skill, caution, responsibility, and ethics of a pharmacist are more important than ever before. As the FDA stated in FDA Leaflet No. 12 (1960):

"A pharmacist is more than a purveyor of drugs—he is a member of the team of experts who have been scientifically trained to provide medical care to the people. As a consultant to the prescriber and the custodian of drugs for the community, he is licensed by law to dispense them according to the prescriber's instructions and the requirements of law.

"If we did not have the pharmacist, it would be necessary to invent him."

But the pharmacist does exist and he does not need to be invented. The pharmacist only seeks the opportunity to serve through the legitimate practice of his profession.

STATEMENT BY FRANK T. DIERSON, GENERAL COUNSEL, ON BEHALF OF GROCERY MANUFACTURERS OF AMERICA, INC., ON H.R. 11581, DRUG AND FACTORY INSPECTION AMENDMENTS OF 1962

1. OPPOSITION TO UNLIMITED INSPECTION

The bill H.R. 11581 would amend the Federal Food, Drug, and Cosmetic Act by adding an unlimited power of factory inspection which is unnecessary, detrimental to public interest, and probably unconstitutional. Therefore, Grocery Manufacturers of America, Inc., a national, nonprofit trade association representing some 300 food and grocery product manufacturers, urges the House Committee on Interstate and Foreign Commerce to drop title II of the bill, which proposes the objectionable grant of additional inspection power.

2. GMA—A SUPPORTER OF MANDATORY FACTORY INSPECTION

Ten years ago the Supreme Court of the United States ruled in the *Cardiff* case (344 U.S. 174, 1952) that the Federal Food, Drug, and Cosmetic Act did not authorize the Food and Drug Administration to inspect a factory except by voluntary permission of the owner. At that time Grocery Manufacturers of America, Inc., appeared before this congressional committee and supported the enactment of legislation for compulsory factory inspection; such enabling legislation was urged as required by the public interest, and appropriate congressional limits on the inspection power were approved to assure its fairness and constitutional validity. Both Houses of Congress subsequently passed a bill to enact what House Report No. 708 (83d Cong., 1st sess.) described as "compulsory, but limited inspection authority." The authoritative House report explained that addition of the new statutory language "within reasonable limits and in a reasonable manner" was intended "for the purpose of confining the scope of inspection to 'factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, containers and labeling therein.'" The Food and Drug Administration has successfully administered the act in this form since that time, and we are aware of no development in the food industry which calls for the extraordinary expansion of factory inspection now proposed.

3. TITLE II OF THE PENDING BILL

In contrast to the foregoing congressional definition of a "reasonable" factory inspection power, title II of H.R. 11581 would expand such power beyond anything reasonably required for enforcement of the Federal Food, Drug, and Cosmetic Act. For it would amend section 704 of the act, first to reach a manufacturer's consulting laboratory, in addition to his own factory; and second, to permit inspectors of a factory to examine "all things therein (including records, files, papers, processes, controls, and facilities)" bearing on violations or even potential violations of the act.

4. CONGRESSIONAL RULE OF REASONABLE INSPECTION

The itemized scope of the proposed new inspection power is reminiscent of the record inspection cases which Congressman Hinshaw described as "obnoxious" in House debate on the 1953 Factory Inspection Amendment. Messrs. Wolverton, Harris, Bennett, Priest, and Younger were of a similar mind. In House Report No. 708, and in statements on the floor, they determined that the language of the 1953 amendment represented a reasonable rule of factory inspection, and in doing so, they specifically insisted that the scope of such inspection does not include formulas, methods, processes, shipping records, complaint files, qualification of technical personnel, and prescription files.

5. UNREASONABLE SCOPE OF PROPOSED INSPECTION

Apart from its specific enumeration of records, formulas, etc., subject to inspection, title II of the bill enlarges inspection power to reach "all things" in a factory "bearing on" violations or potential violations of the act. This language is so broad as to lend itself to unlimited application by administrative interpretation. It is unsuitable for use in the Federal Food, Drug, and Cosmetic Act, first, because the act is an unusually drastic penal law whose violation can be punished by personal criminal conviction of a corporate agent, even in

the absence of any guilty knowledge or intent on his part; second, because such broad language affords no intelligent basis for a manufacturer's resistance to excessive demands by a field inspector, and puts him to unjustified legal hazard where he attempts it. It may well be that by routinely invoking this broad grant of power inspectors could force disclosure of valuable private information about manufacturers' production, packaging, labeling, advertising, marketing, pricing, and financial position.

6. INDUSTRY OPPOSITION—PRIVATE CONSIDERATIONS

In this situation a food manufacturer opposes unlimited factory inspection, not because he has something to hide, but because he believes he has a constitutional right to protect from disclosure and loss his private property in patents, formulas, processes, and other trade secrets. His understandable fear of such disclosure is increased by knowledge of the fact that State and local officials may be commissioned by the Food and Drug Administration to supplement the inspection activities of Federal agents. As a practical matter he knows that inspectors frequently leave Government service to take employment in the food industry, perhaps with a rival processor. In all such cases it would be difficult if not impossible to prove an unlawful breach of official confidence, and the manufacturer is therefore reluctant to disclose information which is not clearly pertinent to the statutory purpose of public protection.

The foregoing considerations apply equally to the proposal for unrestricted inspection of a manufacturer's independent laboratory. Traditionally entrusted with secret information in a professional, consultant-client relationship, the independent laboratory, if subjected to such inspection, is even less able under the proposed authority to assert appropriate resistance to excessive demands of a field inspector. When it is remembered that independent laboratories are not producers or distributors of food products and that such professional testing, research and development organizations do, as a matter of policy, cooperate with the Food and Drug Administration and other Government scientific agencies, there appears to be no good reason for extending the proposed inspection controls to their operations and records.

7. OPPOSITION—PUBLIC CONSIDERATIONS

The keeping of accurate corporate records relating to manufacturing processess, quality controls, consumer complaints, personnel qualifications, etc., is a voluntary practice normally and faithfully observed by the food maufacturer. He follows these procedures in order to maintain and improve the quality of his product, to correct any deficiencies as quickly as he can discover them, and by experience and training to develop the finest professional staff to conduct skillful research, development, production, and distribution in the field of his food technology. It requires little more than a statement of the food manufacturer's reasons for keeping these records to demonstrate that they indirectly but importantly contribute to the welfare of consumers, and that anything which needlessly discourages the keeping of these records operates to the detriment of the public interest. Therefore Congress should carefully consider the possibility of progressive neglect of recordkeeping as an adverse and undesirable consequence of the unlimited factory inspection authority proposed.

Reference has already been made to the drastic criminal punishment which may be visited upon individuals for even inadvertent violations. In *U.S.* v. *Dotterweich* (320 U.S. 277, 1943), the Supreme Court of the United States noted the fact that under the Federal Food, Drug, and Cosmetic Act, penalties serve as effective means of regulation, and it spoke as follows of a prosecution under the act in which guilt was imputed to a defendant solely on the basis of his authority and responsibility as a corporate officer:

" * * * Such legislation dispenses with the conventional requirement of criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. * * * "

8. REGULATION VERSUS PROSECUTION

The food manufacturer sees in this inspection proposal a shift from traditional agency inspection practices to a system of search and seizure in which inspection becomes a "fishing expedition" designed to obtain evidence for civil

and criminal prosecutions. Who can say that even a reputable manufacturer will ignore this danger in deciding whether or to what extent he should make and keep records with respect to complicated problems he is working to solve within the letter and spirit of the act. The greatest incentive for production of wholesome and nutritious food in the United States is the competitive rivalry among manufacturers to produce the finest products by applying modern advances in food science and technology. Punitive provisions should not be permitted to overshadow a sound regulatory and educational administration of the Federal Food, Drug, and Cosmetic Act which maximizes voluntary compliance. Such administration of the act is to be preferred as a constructive enforcement policy which best assures the attainment of its great social and economic objectives.

9. ADEQUACY OF EXISTING POWER

It remains to emphasize that the Food and Drug Administration already possesses ample powers of inspection and investigation which are sufficient to protect the public interest. In addition to its authority for mandatory factory inspections under section 704, the Food and Drug Administration can, where necessary, take advantage of regular search warrant procedure upon showing evidence to a court that a violation is probably taking place. The agency may also invoke the subpena power of a grand jury. Furthermore, in bringing court action against a violator the agency can obtain all the information it requires by written interrogatories and other discovery procedures authorized by the Federal Rules of Civil Procedure.

10. CONCLUSION

For all of the foregoing reasons, Grocery Manufacturers of America, Inc., respectfully urges the House Committee on Interstate and Foreign Commerce to strike out title II of the bill, H.R. 11581, which proposes the objectionable grant of unlimited factory inspection power. The present language of section 704 of the Federal Food, Drug, and Cosmetic Act was, after careful congressional deliberation, designed to authorize a compulsory but reasonable form of factory inspection. Ten years of experience with that section have confirmed the soundness of its draftsmanship by this committee. Arguments for adoption of title II of this bill are substantially the same as those pressed upon Congress by earlier advocates of unrestricted inspection power. We hope that Congress will maintain its original position; namely, that the Food and Drug Administration should have authority for a reasonable factory inspection, and that section 704 of the act as now written, confers it.

STATEMENT OF NATIONAL ASSOCIATION OF REFRIGERATED WAREHOUSES RE H.R. 11581 TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBMITTED BY JOSEPH H. COLQUITT

The National Association of Refrigerated Warehouses consists of nearly 500 member plants throughout the United States representing approximately 80 percent of the public refrigerated warehouse space in the country.

Both this association and its members believe that a strong and effective Food, Drug, and Cosmetic Act—including adequate inspection authority—is necessary for the protection of the consuming public. We believe that the existing inspection authority is adequate to provide this protection. We are, therefore, strongly opposed to the provisions of section 201 of H.R. 11581 which would extend this inspection authority to include "all things * * * (including records, files, papers, processes, contracts, and facilities) * * *."

H.R. 11581 is concerned with the manufacture and marketing of drugs and antibiotics, not with foods. In fact, except as it appears in the name of the act which this bill would amend, the word "food" is never even mentioned in title I of the bill. Yet title II would amend the act so as to impose far more stringent inspection provisions on warehouses storing solely food as well as drug and cosmetic warehouses. It is grossly unfair to penalize perishable food warehouses with these almost limitless inspection provisions when it is not necessary.

Present provisions of the law covering warehouse inspection give FDA inspectors access to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

These provisions have proven completely adequate insofar as food inspection is concerned. This is attested by the food industry's excellent record in providing Americans with the greatest quantities of the most healthful foods in the world. In particular is the record of the public refrigerated warehousing industry an outstanding one in annually handling billions of pounds of perishables with a near perfect record.

Another reason we oppose such all-inclusive inspection authority as that provided by H.R. 11581 is its inherent dangers. It would open up to inspection confidential company files, personnel records, correspondence, and anything else which in the opinion of individual inspectors might be pertinent. Such authority could not possibly be exercised uniformly with fairness to all and the possibility of excesses would be substantially increased over that now existing.

Finally, an unusual situation exists with respect to public warehouses. The goods stored in public warehouses belong not to the warehousemen, but to his customers. The public warehouseman has no interest in the goods in his warehouse other than to give them proper care and protection. He is merely a custodian.

As agent for the owner of the goods, the public warehouseman can legally and morally act for him with respect to his goods only on his instructions. In addition there is a certain confidence between the public warehouseman and his customers similar to that between a banker and his depositors. An inspection authority which extends to "all things" in the warehouse is viewed by all conscientious warehousemen as a violation of these principles.

The present law under which inspectors may enter a public warehouse, inspect the goods stored, and take samples has proven effectve. Anything further is an infringement of personal or business privacy, is subject to excesses and is a violation of the public warehouse-customer relationships.

We emphatically urge that there be no further extension of inspection authority under the Food, Drug, and Cosmetic Act.

STATEMENT OF PERRY R. ELLSWORTH, ASSOCIATE DIRECTOR, MILK INDUSTRY FOUNDATION, WASHINGTON, D. C., REGARDING H.R. 11581, TITLE II, RELATIVE TO CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY OF FOOD AND DRUG ADMINISTRATION

The Milk Industry Foundation is opposed to title II of H.R. 11581, 87th Congress, 2d session, which is designed to broaden existing authority of the Food and Drug Administration, Department of Health, Education, and Welfare, to conduct inspection of food establishments. It is the position of the Milk Industry Foundation that existing authority of the Secretary of Health, Education, and Welfare in this area is already sufficient to enable him to fulfill his responsibilities.

This statement is submitted pursuant to authorization of the board of directors of the Milk Industry Foundation, which is a national trade association of fluid milk processors and distributors, with member companies in every State of the Union. These members range in size from the large national dairies to small local companies.

In submitting this statement, the Milk Industry Foundation is presenting the views of its members as processors and distributors of one of the most important foods of the Nation; namely, milk and milk products, which are considered basic to the health and diet of the people of this country.

As the "milkmen of the Nation," the industry represented by the Milk Industry Foundation has a vital personal stake in preserving the purity and wholesomeness of the products which it provides to the public. The industry takes this responsibility very seriously. No governmental agency, Federal or State, can possibly be more concerned with the wholesomeness and the purity of the product which the milk industry purveys than the milk industry itself.

This is mentioned because it is very pertinent to the issue of whether the Congress should enact title II of H.R. 11581. The need for external regulation is less where the enlightened self-interest of the industry is such that the industry, itself, assumes full responsibility for the distribution of wholesome products.

The keen responsibility felt by the members of the milk industry is a responsibility shared by the vast majority of American food manufacturers.

The living standard of this country is, of course, one of the highest in the world, and this is particularly true with respect to the diet of the American

people. This result could not have been achieved had the members of the food industry, including the milk industry, not taken a personal responsibility for the type of food products which are sold to American consumers.

It is also recognized that Government has played its part in the highly developed existing system for the production and distribution of food to the people of this Nation. Perhaps, however, more than in any other area of our national life, it can be said that the Government has not played the dominant role in this magnificent development.

The Federal Government already possesses ample authority in the present provisions of the Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 321 et seq.) to enter and inspect any place where food is kept or manufactured or held for shipment in interstate commerce. Section 704 of that act is the key provision of the present law which would be amended by title II of H.R. 11581. Section 704 is divided into four subdivisions. Each of these subdivisions is important, but subdivision (a) leads all the rest.

It permits an inspector of the Food and Drug Administration to enter, at reasonable times, any factory, warehouse, or establishment, and to inspect, at reasonable times and within reasonable limits, and in a reasonable manner, the establishment, itself, and any equipment, materials, and labeling which he finds therein.

Subdivision (b) provides that the FDA inspector must give the owner of the establishment a report of any practice observed by the agent which shows that, in his judgment, any food in the establishment consists, in whole or in part, of (1) any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under unsanitary conditions.

Subdivisions (c) and (d), respectively, provide that samples may be collected and that, if an analysis is made of the sample, the FDA inspector must give the person from whom the sample was taken a report of the analysis.

These are extremely broad powers. The Committee on Interstate and Foreign Commerce discussed them at length in a report which it filed during the 83d Congress when in 1953, it amended the factory inspection provision of the 1938 act to avoid the necessity of securing the permission of the owner of the establishment (report of the House Committee on Interstate and Foreign Commerce, House of Representatives, Report No. 708, 83d Congress, July 6, 1953). In that report, the committee noted that almost every person in the food industry voluntarily permitted inspections to take place but, in view of the fact that there were a few who refused, and in view of the then recent decision of the Supreme Court of the United States in *United States* v. *Cardiff*, 344 U.S. 174 (1952), holding that it was not unlawful for a factory owner to refuse to give permission to enter and to inspect, it was decided by the Congress to amend the law so as to remove the necessity of securing the permission of the owner of the establishment.

But the Congress did more than this in the 1953 amendment. The committee report, referred to above, shows that the Congress gave careful and detailed consideration to the whole philosophy upon which inspections by FDA inspectors are based.

The Committee on Interstate and Foreign Commerce, in the report cited, took the view that the purposes of these inspections are not based on any prior suspicion or notion that the law has been or is being violated, but that the inspections contemplated are a matter of routine checking to determine sanitary conditions and to assist regulated persons by advising them of legal requirements. In the light of these purposes, it was concluded that the Congress should not then limit FDA inspectors to the use of a search warrant type of procedure.

The committee report upon which the 1953 amendment is based reveals clearly that the Congress felt that it was giving the Food and Drug Administration the utmost authority which it needed to perform the job which was assigned to it; namely, to see that food is processed under the sanitary conditions and properly labeled as required by law. It is equally clear that the Congress did not then feel that it would be warranted in giving FDA agents the type of authority to inspect which would now be conferred upon them by title II of H.R. 11581.

There can be no doubt that if the amendments to section 704 of the act proposed by title II of H.R. 11581 are adopted, it will turn that section of the law into a license to permit an unrestrained attempt by FDA inspectors to ferret out violations of law upon the basis of mere suspicion and without the safeguards of a search warrant type of procedure.

H.R. 11581 would convert this provision of the law from a mechanism for conducting routine investigations to spot check on sanitary conditions and for assist-

ing the food industry in its compliance with the act into a provision which would authorize FDA inspectors to operate as a kind of roving grand jury, a concept which is at total variance with our system of law and with the established sense of justice and fairplay.

H.R. 11581 would do this by amending section 704 so as not only to permit FDA inspectors to do what they now may do; namely, to enter factories, warehouses, and establishments at reasonable times and to conduct reasonable investigations of the sanitary conditions in such establishments, as well as the equipment and materials found therein, but also to permit FDA to look at all the "records, files, papers, processes, controls, and facilities" bearing on whether articles are possibly adulterated or misbranded within the meaning of the act. This particular provision of the amendment frankly states that such investigations may be made to determine "violations or potential violations" of the act.

Furthermore, for the first time, FDA inspectors would be permitted to extend their search to "consulting laboratories" and to the records, files, papers, processes, controls, and facilities of such "consulting laboratories" performing services for food manufacturers.

One of the remarkable features of the food industry to which frequent reference has been made over the years—including a reference by the committee in its 1953 report, referred to above—is that over 95 percent of the industry has voluntarily permitted inspection of its facilities. This was true even prior to the 1953 amendment which, for the first time, clearly permitted compulsory inspection. In view of this impressive record, it is difficult to grasp why more inspection power is now needed.

A roving inquiry into all records, files, papers, processes, controls and facilities to determine potential violations of the law will endanger valuable trade secrets and processes.

Many members of the American business community have their own trade secrets, processes, controls, and facilities. These are trade secrets because they are not disclosed. In many cases, special processes have been patented, which means that, in return for disclosure, a limited monopoly has been conferred by the Government for a limited period of time. The Government, however, has no inherent right to force the business community to divulge its trade secrets and processes, especially where such disclosure is not necessary in order to perform public purposes.

If FDA inspectors are permitted to have free access to all of the files of the company, including its secret processes, these will cease to be "secret" in an absolute sense the minute they are disclosed. An ex-FDA employee later employed by a food company can hardly be expected to forget what he had picked up under the protection of his badge.

This proposed legislation poses the question whether it is necessary, in the public interest, to require the business community to give up its trade secrets and processes to FDA inspectors.

The answer to this question is clearly that there is no such overwhelming public interest, and for a very simple reason which derives from the basic purpose of the Federal Food, Drug, and Cosmetic Act of 1938, as amended.

The purpose of inspections under that act is primarily to make certain that the food which is distributed to the consumers is pure and wholesome and is not misbranded and to assist companies in compliance with the law. These facts can be determined by examination of the food and labels, and it is unnecessary to go into the secret processes underlying the manufacture of food.

FDA inspectors already have the authority to inspect food for sanitary conditions and, of course, to examine labeling. They have authority to inspect the equipment and the finished and unfinished materials used in the manufacture of the food as well as the containers and labeling of the food. What more authority does FDA need to carry out its functions? It is submitted that it needs no further authority and that all of its responsibilities may be accomplished by inspecting the product before it leaves the plant.

The fear of the business community over the divulging of its trade secrets is not exaggerated. Section 202 of title II of H.R. 11581 would amend section 301(j) of the act which at present provides that the following acts are prohibited: (in the following quotation, the underscored language would be added by H.R. 11581, sec. 202, and the material in brackets would be omitted:)

"SEC. 301(j). The following acts and the causing thereof are hereby prohibited:

* * * * * * *

"(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this act, *or as authorized by law*, any information acquired under authority of section 404, 409, 505, 506, 507, or 704 (concerning any method or process which as a trade secret is entitled to protection)."

In other words, the bill would eliminate from the above-quoted section the very language concerning trade secrets which is found in the present law and, at the same time, would, by the underscored language, open up the possibility of revealing any type of information secured by FDA inspectors, not only in judicial proceedings under the Food and Drug Act, but in any other instance "authorized by law."

No one knows what this would lead to. It would certainly seem to open the way to subpena FDA officials in private litigation brought by competitors if they could convince courts that secret information in the possession of FDA inspectors was pertinent to the issues involved in the litigation.

Also, this very provision involves the point, earlier made, that a trade secret once divulged is no longer a trade secret. The statute just quoted shows clearly that the FDA inspector could legitimately reveal any secret obtained by him to the Secretary of the Department of Health, Education, and Welfare or to any of the thousands of officers and employees of that Department. And this is before one reaches the provision which authorizes the divulging of these secrets in judicial proceedings involving the act or, if the amendment is to be adopted, in any other manner "authorized by law."

This proposed legislation, in short, would sound the death knell to trade secrets in this Nation. Small wonder, therefore, that the business community is alarmed at this grab for power in an area where this very committee, less than 10 years ago, said that such power was not necessary. Nothing has happened during the intervening years since 1953 to render these broader powers necessary.

On the contrary, the passage of the 1960 color additives amendments render such power even less arguably necessary than it was in 1953. Both of these amendments are based upon the philosophy that before a substance may be added to a food—either as a food additive or as a color additive—the safety of the ingredient must have been established by a regulation of the Food and Drug Administration. This shifts the burden of proving the safety of the food supply from the Food and Drug Administration to the food industry itself—a responsibility which the food industry has always willingly received. Therefore, if the Food and Drug Administration is executing its responsibilities effectively under the basic 1938 act, as well as under the 1958 and 1960 amendments, there can be no serious argument that it needs these broader powers.

Another circumstance which renders added powers even more ludicrous is the extraordinary power which the FDA already possesses to seize and condemn food which it determines to be misbranded or adulterated. These seizures may be made in advance of judicial determinations as to legality of the seizure. The history of the enforcement of the Food and Drug Act shows that FDA has not been timid in using these powers. At any moment that FDA has reason to believe that any food is adulterated or misbranded, it can take a sample of that food, make a spot check determination and, if necessary, order its seizure.

Why, therefore, does FDA need to have the power to dig into the files of a company and to turn its normal task of routine sanitation investigations into a search warrant type of investigation without the benefit of search warrant type procedures?

Furthermore, in a search warrant type of procedure, an agency exercising such power is limited in the scope of the examination which can be made to specific places and things which may be investigated. The pending bill, however, would permit these FDA inspectors, as has been said, to roam at large. They would only need to say that they wanted to see something because they thought it might potentially have a bearing on a violation of the act. They would not necessarily have to say they wanted to look at a particular place or at a particular thing. They would have the right to come in and say "We want to look around, because we think we might find something in violation of the Federal Food, Drug, and Cosmetic Act of 1938, as amended. Where are your files?"

Insofar as the milk industry is concerned, it should also be pointed out to this committee that, in addition to the Federal Food, Drug, and Cosmetic Act of 1938, as amended, the dairy processing industy complies with a variety of State

and local laws and ordinances dealing with sanitation and related matters. It can be said with utter confidence that there is absolutely no need for additional legislation in order to assure a wholesome and pure supply of milk for the people of this Nation.

In this statement on behalf of the Milk Industry Foundation, a frank presentation of the views on this proposal has been made because we feel that the proposed legislation is absolutely unnecessary in order to protect consumers. Anyone who feels otherwise simply does not understand the facts and the existing law.

One of the quickest ways to destroy the confidence of business in Government is by the passage of unnecessary and burdensome laws which serve no purpose other than to increase the powers of Government agencies. Already, in our day and age, the Government has assumed a dominant role and frequently a necessary role in the business life of this Nation; but we must never forget that the principal role is that played by the business community itself. The quickest way to destroy the kind of Government which we want and cherish is to undermine the confidence of the business community in the Government. The proposed legislation would do just that.

The Milk Industry Foundation urges that title II of H.R. 11581 be disapproved.

STATEMENT OF FLAVORING EXTRACT MANUFACTURERS' ASSOCIATION

My name is Charles P. McCormick, Jr. I am chairman of the legislative committee of the Flavoring Extract Manufacturers' Association of the United States. Our association was organized in 1909. It consists of more than 175 firms concerned with, or engaged in, the manufacture of flavors, extracts, flavoring extracts, essences, bases, mixes, and related products which are sold both to manufacturers of foods, drugs or cosmetics, and to the general public for household use.

The flavor industry wishes to take this opportunity to express its views on this proposed legislation. We have long supported the work of the Food and Drug Administration and worked closely with the Administration in the development of analytical methods relating to our products. We testified before this committee in support of the food additives amendment, and, in that testimony, recommended certain provisions, such as ad hoc scientific advisory committees which, although not included in the food additives amendment, have been a part of later similar legislation. We share with the Food and Drug Administration, and with the great majority of industrial concerns and the consuming public, the desire to see the Food and Drug Act thoroughly, fairly, and effectively administered.

We wish, however, to register our strong opposition to some of the features and implications of the proposed legislation. We are primarily concerned by the fact that this bill would give inspectors of the Food and Drug Administration access to many company records which they now can view only by permission of the company involved, or by showing sufficient cause to warrant the issuance of a court order. As others have pointed out, the proposed bill would authorize "fishing expeditions" on which Congress and the courts have always frowned. Product formulas are of minor concern to some companies, while to other companies, they are important. But to firms in the flavoring industry, formulas are absolutely vital. They are their whole stock in trade; they are all they have to sell; they are their sole reason for existence.

Even a small flavoring house will have several thousand formulas, and a large company may have in its active files between 50,000 and 100,000. Some of these represent only minor variations from other formulas, and are arrived at quickly with little cost in time or effort. Other formulas or groups of formulas represent the expenditure of literally hundreds of thousands of dollars of research and development work.

It is standard policy for the flavoring industry to take extreme precautions to safeguard the confidential nature of these records. Many of them are complex mixtures made up of subassemblies, so arranged that only a few of the most responsible employees can possibly know the entire composition. The only case in which disclosure of flavoring formulas to the Food and Drug Administration is now legally required, is in the case of new drug applications. While flavor manufacturers certainly use formulas adequate for this purpose, no manufacturer would use a formula he considers of particular value, simply because of the hazards involved in the disclosure.

Our attitude here is based on concern, both for the possibility of inadvertent revealing of confidential material, and also for the possibility of deliberate abuse of such confidential information. In some cases, the key to a particularly valuable formula may involve the use of only one or two unusual or unexpected substances. A premeditated attempt to gain such information is not necessarily implied, but one cannot wipe out key recollections from a man's brain. Officials of the Food and Drug Administration have occasionally pointed out, in justifying this request for information, that no known case of the release or abuse of confidentially submitted information has even occurred. Such a statement, however, merely serves to illustrate the difficulty of proving such an occurrence, rather than the fact that the event has not occurred. We are not imputing any bad faith, past or present, to Food and Drug Administration employees. We are merely saying that they are human. Many former employees of the Food and Drug Administration have left Government service for industrial and academic posts. Others have established themselves in consulting firms or in private legal practice. The opportunity for abuses exists, and we are simply concerned to see that that opportunity is kept to the absolute minimum unavoidable in effective administration of the act.

One of the bases cited by the Food and Drug Administration in support of their request for this legislation is that such extensive inspection powers are necessary to police the use of food additives. While there are many different flavoring ingredients in use, their usages, with few exceptions, are, in the words of the food additives amendment, "generally recognized as safe." Because of this, they are legally not food additives, and they do not come under the specific regulatory provisions of the food additives amendment. Hence, no regulations involving tolerances apply. Their use is governed instead by other provisions of the basic Food and Drug Act. Since there are no tolerances, there has been no necessity to develop analytical methods.

On the other hand, when a food additive, in the legal sense, is involved, the Food and Drug Administration issues a food-additive regulation. This states how a substance may safely be used, and usually contains a tolerance or limitation on maximum use. The regulation and the petition for the regulation must also include a practicable analytical method, so that the Food and Drug Administration may be certain that the tolerance is not being exceeded. It is apparent that the results of an analysis are vastly more useful than the self-serving records of a company. If the Food and Drug Administration were concerned about the use of a specific substance, they certainly would not be so easily satisfied as to stop with consideration of a company's formula, but would analyze the product in any event. That is, and must remain the only effective determination of whether the provisions of the food additives amendment have been fulfilled. The important point concerns what is in the final food as eaten. The composition of an intermediate product, such as a flavor formulation, may be relevant, but certainly is not final. Thus, when a food additive is not involved, there is no tolerance because there is no significant hazard, and formula inspection is unnecessary. Where a tolerance and analytical method for a food additive are involved, analysis is needed in any case. Formula inspection is unnecessary because it is superfluous.

We are further concerned at the provision which would permit inspectors to inquire about the qualifications of technical and production employees. There are no standards in this field, and even professional associations have not been able to arrive at effective standards. In the absence of standards, such judgments would be personal and arbitrary at best, and it is appropriate for us to ask, and to doubt the qualifications of Food and Drug inspectors who would make such judgments.

Finally, we wish to join in the views of others who have opposed the inclusion of the records of consulting laboratories in this legislation. We agree, of course, that the files of consulting laboratories, dealing with quality control and product characteristics, are pertinent to the enforcement of the act, and should be available through normal judicial processes, just as are the records of the company itself. But the proposed legislation even fails to distinguish between records dealing with research and development on new products and quality control on present ones. We feel that this is so patent a flaw that it could not intentionally have been included in the proposed legislation.

We have dealt in this statement with those aspects of H.R. 11581 of particular interest and concern to the flavor industry. In general, however, we wish to associate ourselves with the views expressed by Mr. Samuel A. McCain in

articles in the March 1962, issue of Food Processing and the April 1962, issue of The Business Lawyer. We are grateful for this opportunity of presenting our position.

STATEMENT OF THE NATIONAL HAIRDRESSERS AND COSMETOLOGISTS ASSOCIATION IN OPPOSITION TO SECTION 201(a) OF H.R. 11581, SUBMITTED BY ROBERT A. COLLIER, COUNSEL

This statement is submitted by the National Hairdressers and Cosmetologists Association, Inc., in opposition to section 201(a) of H.R. 11581, the "Drug and Factory Inspection Amendments of 1962." The association represents more than 65,000 beauty salon owners and operators with a total employment of more than 150,000 trained and licensed cosmetologists.

The present inspection provisions of section 704 of the Food, Drug, and Cosmetic Act authorize Government agents to enter any establishment, including beauty salons, in which cosmetics are held. Section 201 of H.R. 11581 would expand this authority to permit inspection of "all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of the act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations of this act." The effect of this section of the bill is to provide carte blanche inspection. Under such broad language, it would not be possible for anyone to refuse inspection of anything.

We are not opposed to inspection per se. However, we do feel that any statute which imposes criminal penalties upon an unknowing violator, as does the Food, Drug, and Cosmetic Act, should provide for limitation upon unwarranted Government fishing expeditions. Not only does this proposal authorize an invasion of the business privacy of beauty salon operators, but it would also raise serious questions as to whether it is unconstitutional under the fourth amendment as an unlimited, and therefore unreasonable search and seizure.

We recognize that some legislation may be necessary to permit inspection of those few businesses who have been able to successfully evade it. However, we respectfully submit that any such need is not based upon any alleged violations of the Food, Drug, and Cosmetic Act by NHCA members. To include these beauty shop owners within the coverage of this bill would be an unjustified and unwise extension of governmental inspection authority.

STATEMENT OF PINEAPPLE GROWERS ASSOCIATION OF HAWAII ON H.R. 11581, SUBMITTED BY R. L. CUSHING, PRESIDENT

This statement is submitted on behalf of the Pineapple Growers Association of Hawaii, the members of the association being Baldwin Packers, Ltd., California Packing Corp., Dole Corp., Hawaiian Fruit Packers, Ltd., Kauai Pineapple Co., Libby, McNeill & Libby and Maui Pineapple Co., Ltd.

The member companies operate eight pineapple canneries in Hawaii. An affiliated company of one of the members operates a pineapple cannery in Puerto Rico. The companies produce all but a small part of the U.S. annual production of approximately 18.5 million cases of canned pineapple and 12.3 million cases of canned pineapple juice, a total of 30.8 million cases. The canned pineapple pack is approximately 15 percent of the total U.S. canned fruit pack and the canned pineapple juice pack is approximately 23 percent of the total U.S. canned fruit juice pack.

As producers of a major canned fruit product, the pineapple canners are concerned over the additional, and, we believe, unwarranted factory inspection authority proposed for the Food and Drug Administration under title II of H.R. 11581.

We are advised that Commissioner Larrick of the Food and Drug Administration stated before the Senate Appropriations Subcommittee:

"A few years ago the Food and Drug Administration submitted a bill to the Congress which was believed to provide for inspection authority permitting FDA to make complete studies of the production procedures and controls employed by firms, the complaints received concerning their products, and the

qualifications of their employees (especially scientists) * * * . However, the legislative history of the bill indicated that it was not the intention of the law to give FDA access to this type of information. Consequently, FDA has had to operate with rather serious limitations ever since."

The pineapple canning industry in Hawaii has a long history of cooperation with the Food and Drug Administration and has consistently supported legislation which appeared to be reasonable and necessary for that Administration to discharge its responsibilities.

The Food and Drug Administration now has authority to inspect food factories, warehouses, establishments, and vehicles used in transporting the products of such factories, and to inspect all pertinent equipment, finished and unfinished materials, containers and labeling, and to take samples of products for analysis. The Secretary of Health, Education, and Welfare, under whose jurisdiction the Food and Drug Administration operates, has power of seizure of adulterated or misbranded products. The Secretary may publicize the facts in any case in which he believes there is danger to the public health, as was done in the cranberry incident. Furthermore, there is available the search warrant procedure whereby the Food and Drug Administration, upon presentation of reasonable evidence of a violation in a food-making establishment, may obtain a search warrant which will enable the FDA to obtain all files, records, documents, formulas, and anything else relating to the violation which FDA believes is being committed. After the search, FDA could have the factory padlocked if it can convince the judge this is a proper procedure.

The additional authority which would be granted FDA under title II of H.R. 11581 would empower it to have access, on a routine basis, to all things in a food factory, including records, files, papers, processes, controls, and facilities.

We do not believe there is any demonstrated need for such unrestricted governmental access to food plant files and records of production procedures and quality controls. Existing authority of the FDA to inspect plants, to draw random samples of the product, to subject such samples to any analyses seen fit, and to seize products it determines do not meet the standards, provides sufficient authority for the FDA to insure the purity and conformity with standards of quality of canned goods.

Commissioner Larrick cites the greatly increased use of food additives as a new argument for the increased factory inspection authority. The safeguards of the additive law itself and the FDA regulations on its administration reveal no need for additional legislation to protect the public health.

The preservation of competition between companies manufacturing canned goods depends upon the maintenance of competitive advantages based on production methods, production equipment, and product formulae. Unrestricted access by the FDA to the confidential records covering these matters could result in, although possibly inadvertently, the disclosure of proprietary production methods and could thereby lessen competition.

Access to personnel records would be, presumably, to determine the qualifications of a food processor's employees as Commissioner Larrick had indicated that the FDA inspectors should be able to determine that an employee is qualified to do his job. The specialized skills and knowledge required in the food-processing business are such that only those directly and finally responsible for operation of the business can evaluate the qualifications and day-by-day performance of their employees.

As food manufacturers we object to the proposal which would subject our confidential records to search under inquisitorial powers just as, as individuals, we would not want to be denied the benefits of the fourth amendment to the Constitution which insures us protection in our persons, houses, papers, and effects against unreasonable searches and seizures.

STATEMENT OF THE U.S. TRADEMARK ASSOCIATION IN OPPOSITION TO THE TRADEMARK ASPECTS OF H.R. 11581, SUBMITTED BY MR. THACHER H. FISK

The U.S. Trademark Association opposes H.R. 11581 insofar as its provisions have some impact upon the entire field of trademark law and practice.

The association is a membership corporation organized under the laws of the State of New York, with offices located at 6 East 45th Street in the city of New York. Its membership comprises regular (or voting) members, who are owners of trademarks, and associate members, who are lawyers, advertising firms, pub-

lishers, and others interested in trademark law, trademark protection, and trademark practice. A printed list of members as of August 1, 1961, is attached.

The association now has 264 regular (or voting) members. Thirty-one of them are pharmaceutical manufacturers; and of the 33 members of the board of directors under whose direction the association operates, 5 are executives of pharmaceutical manufacturers. These data are given because of the short title of the bill under consideration, the "Drug and Factory Inspection Amendments of 1962."

The association is 84 years old, having been founded in 1878. Its purpose, generally stated, is to aid in the dissemination of information pertaining to trademarks and to afford a means of cooperative activity in protecting them. It publishes the Trademark Reporter®, a monthly journal containing judicial opinions in litigated cases and articles of research and commentary. The association has worked for uniform State trademark legislation, which has been adopted in many States.

Although the position of the association as presented here is limited to what might be termed the trademark aspects of H.R. 11581, failure to comment upon other aspects of the bill is not to be construed as approving or disapproving such other aspects.

Specifically, the U.S. Trademark Association is opposed to section 112(a)(4) of H.R. 11581. The section, if enacted, would require the manufacturer of a drug to use the drug's "established name" in a position of precedence over and in type of equal size and prominence as the drug's trademark on labels and in informational and promotional material. This subordination of the trademark, if accomplished, would profoundly alter and seriously abridge the fundamental legal and economic principles upon which the trademark system of product identification is founded.

The trademark system, possessing both a rich history and a great contemporary importance, enables merchants and manufacturers to compete vigorously and encourages them to endeavor to earn the fair competitive advantages that stem from creativity and quality. Therefore, the association strongly urges that the system be preserved from the dangerous sort of incursion embodied in H.R. 11581, and to support its position presents these reasons:

In the first place, the trademark-related provisions of H.R. 11581 discriminate against the pharmaceutical industry. No other industry is subject to comparable restrictions having to do with product identification. And the association believes that the splendid achievements of drug manufacturers deserves congratulation and not discrimination. Moreover, the precedence in position and equal prominence requirements appear to be outside the ambit of the Federal Food, Drug, and Cosmetic Act. The act properly deals with important matters of public health and safety, but its focus should not be made less clear by seeking also to deal with independent commercial practices.

Shifting to broader considerations, however, and apart from the possible particular consequences for the one industry, the association is genuinely concerned that the trademark-related provisions of H.R. 11581 might establish a perilous legislative precedent. They contain the genesis of the erroneous notion that trademarks are superfluous or inappropriate whereas experience and commonsense show the contrary to be true. Indeed, by identifying and distinguishing the worthy product, a trademark provides a true form of protection for the public. The precedence in position and equal prominence requirements would emphasize the generic name every time the trademark for the worthy product is promoted. The result will be at least as much public acceptance for the generic name as for the trademark. Thus, the requirements of H.R. 11581 with respect to use of the generic name will provide a means by which the marketer of an inferior product may confuse and deceive the public as to the quality and source of his product.

Then, too, any legislation of this character would dilute or discount the important identificatory values that established trademarks represent. In a very real sense there would be effected an uncompensated taking of the valuable goodwill that resides in these business assets.

If the product identification theory of H.R. 11581 were generally accepted, an incentive to promote a superior product and inform the public of its availability would be destroyed. Two consequences would be the reduction of quality of products to the lowest common denominator and the discouragement of new product development.

The association realizes, of course, that nonproprietary nonmenclature can and does fulfill an important function and that, in the pharmaceutical industry as is true for nearly all industries, the disclosure of generic or common descriptive names is legally sound and advisable. It is not, however, in the best interest of the general purchasing public or trademark owners for the Government to coerce its citizens against the use of trademarks or brand names either with respect to drugs or any other commodity.

STATEMENT OF JAMES F. FORT, COUNSEL, PUBLIC AFFAIRS, AMERICAN TRUCKING ASSOCIATIONS, INC., ON H.R. 11581

Mr. Chairman and gentlemen of the committee, my name is James F. Fort. I am counsel, public affairs, of the American Trucking Associations, Inc., with offices at 1616 P. Street, NW., Washington, D.C. The association, as most of you know, is a national federation representing all forms of motor carriers, both private and for hire, and having affiliated associations in 49 States and the District of Columbia.

We appear today in support of part C of title I of H.R. 11581 which relates to the control of amphetamine and other stimulant habit-forming drugs.

In 1954 the trucking industry first obtained concrete evidence that amphetamine drugs were being sold illegally at highway stops and establishments near highways. Since that time we have cooperated with the Food and Drug Administration, we have conducted extensive educational campaigns among our employees, and we have for a number of years sought legislation similar to that before you today to effectively control these drugs.

The committee has already heard testimony as to the detailed provisions of the bill and as to the improper uses which are made of stimulant drugs, so it is not our purpose today to review these technical points. Rather, we think that the committee would be more interested in a brief description of the problems which we have had in this area.

It is our wish initially to make it clear to the committee that the use of amphetamines by truckdrivers is far more of a health problem than it is a safety problem. We have followed closely over the years the Interstate Commerce Commission's investigations of motor-vehicle accidents, and of their many, many investigations we are able to find less than 10 Commission proceedings in which the use of amphetamines has been held to be the cause of a highway accident. This is not to minimize the problem, for it is a problem and it has been our effort for a number of years to educate our drivers on the dangers to their overall health, as well as to educate them as to the driving hazard which may result from unsupervised or excessive use of these drugs.

According to published reports, the Food and Drug Administration estimates that production of amphetamine drugs annually is sufficient to produce about 5 billion pills or capsules. Commissioner Larrick has stated that a large proportion of these go into illicit channels. Against this background it is obviously illogical to assume that the truckdrivers of the Nation's approximately 700,000 tractor-semitrailer trucks could conceivably be the prime users. Further, National Safety Council and ICC statistics substantiate the fact that truckdrivers, as a group, have the finest safety record of any type of drivers. This record is steadily improving. Let me cite just one statistic to verify this: Trucks constitute a little over 16 percent of all registered motor vehicles. However, they comprise only 11 percent of vehicles involved in accidents. This is involvement, not necessarily fault. A major insurance company several years ago made a study of 100,000 truck-involved accidents and found that in 70 percent of the cases the truck was not at fault, so obviously our record is one of which we are very proud.

The committee knows that under the ICC's safety regulations all interstate drivers must meet, periodically, the strict physical qualifications established by the ICC. They must have in their possession at all times, when driving, a copy of the medical certificate issued by a doctor at the time of their most recent examination. Habitual use of amphetamines or related drugs obviously would keep any driver eventually from passing his physical examination. Also, as the committee knows, the ICC has very strict regulations which govern the amount of time which a driver may spend on the road. Currently this requirement is 10 hours of driving time between minimum 8-hour off-duty periods with

weekly maximum limitations. Further, every interstate driver must maintain a "driver's log" to record his hours. In addition to these stringent Government regulations most trucking companies schedule their drivers' runs so that they will be well within the maximum allowable driving time. Thus a driver complying with the ICC's safety regulations and his own company's policies should not need any "stay awake" type stimulus.

Our cooperation with the Food and Drug Administration goes back many years since shortly after we first became aware of the problem. The Enforcement Division of FDA has joined with us in our efforts to stamp out illegal sales. Their agents have been trained by our member companies as drivers and helpers in order that they could make purchases and subsequent arrests. Enforcement officers have ridden thousands of miles on our trucks and have made hundreds of arrests while they were posing as employees of trucking companies throughout the United States. This, of course, could only have been accomplished with the complete cooperation of the management of our companies. It is a truly exciting story which has been, to date, largely untold.

This mutual effort between the trucking industry and FDA has resulted in a large number of arrests being made at truck stops and other highway type installations, and at the same time it has resulted in a great deal of bad publicity for the trucking industry and its drivers. Our files are replete with lurid, sensational stories based upon suspicion, hearsay, and pure fiction which purport to relate that truckdrivers generally use these drugs and thus are responsible for a major traffic hazard. This, as I have stated, cannot be borne out by ICC records.

FDA has also worked with us in producing hundreds and thousands of pamphlets which have been distributed through our members across the country. Attached to this statement is the latest publication produced by the Food and Drug Administration with our cooperation. About 50,000 copies of this pamphlet have been distributed through our industry in the last month. A previous pamphlet produced by ATA several years ago was distributed to over 500,000 drivers throughout the country.

We are most hopeful that the committee will act favorably upon the pending legislation to the end that this problem will be eliminated both for our industry and for the public as a whole.

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DRUGS AND DRIVING—SOME PRECAUTIONS FOR HIGHWAY SAFETY

Drugs that produce no unusual symptoms in most people may cause abnormal reactions in some individuals, making it unsafe for those persons to drive. This is true regardless of whether the drug is self-administered or taken at the direction of a physician. No one should drive when taking drugs unless he is certain they will not impair his driving ability.

High on the list of highway killers and traffic safety violators is the drunken driver. But alcohol is no longer the only cause of "intoxication."

The Food and Drug Administration is concerned over the increasing threat to highway safety from drivers "under the influence" of drugs. The drugs involved range from true narcotics to stimulants, tranquilizers, sleeping pills, and even some cold remedies (e.g., anti-histamines). Some are widely used in such common ailments as nervousness, overweight, high blood pressure, and hay fever. Because of these common uses many people do not realize the effects drugs may have on driving ability. They may innocently contribute to the danger on the streets and highways.

And, because some dangerous drugs can be obtained without prescription—despite legal requirements to the contrary—some people use them for their "side effects" or for reasons other than their intended medical purpose. One example is the use of stimulant drugs to keep awake while driving.

Controlled use of drugs by a person under his doctor's care brings with it safeguards that avoid danger. Uncontrolled use of the drugs discussed here is a danger to the health and welfare of the user and the safety of others. Here are the facts about the dangers and precautions to be taken when driving.

AMPHETAMINES

Amphetamine drugs have many nicknames, some innocent sounding—"bennies," "pep pills," "thrill pills," "copilots"—which conceal the seriousness of uncontrolled use.

The amphetamines are useful in treating certain illnesses when used under medical supervision. Carelessly used they can be very harmful to the health of the user, and make it unsafe to operate a motor vehicle.

Legally, amphetamines can be sold only in drugstores and then only upon a doctor's prescription. This is for the protection of the user. Anyone who uses bootleg channels to avoid the prescription requirement not only contributes to a violation of the law, but also runs the risk of being "hooked" to habitual use, with all the degradation and misery that follow.

Common beliefs about amphetamines are: "They are no more harmful than a cup of coffee"; and "you can drive without sleep and never miss it." Both are false and both are dangerous.

Amphetamine may increase alertness and efficiency for a short time; but this effect may be followed by headache, dizziness, agitation, irritability, decreased ability to concentrate, and marked fatigue.

The most important fact for drivers to consider is that excessive, unsupervised use interferes with the body's normal protective symptoms of drowsiness and fatigue. The feeling of exhaustion is short-circuited, causing a driver to use up reserves of body energy until a total and sudden collapse may occur. But before collapse there may be a period of decreasing driving ability and alertness, even though the driver thinks he is driving very well.

Another often reported effect is that of seeing things in the road that are not really there—mirages or hallucinations similar to the delirium tremens of the alcoholic. Such "visions" may cause the driver to swerve into oncoming vehicles or off the road. Bennies can kill.

Truck drivers and many others who constantly use the highways are victimized by unscrupulous and illegal dealers in amphetamine drugs for the enormous profits involved. Such drug bootleggers promote the false belief that bennies are helpful to drivers. They place personal profit above human life.

Rest is the only safe remedy for fatigue. Reliance on stimulant drugs can result in anything from a badly overworked heart to sudden death.

BARBITURATES AND OTHER SEDATIVES

Barbiturates are very useful medicines to calm nervousness and produce sleep in persons with medical problems. However, they are habit forming and by law may be sold only upon prescription. Uncontrolled use can lead to addiction more serious in some respects than true narcotic addiction. Barbiturates are often "pushed" by underworld peddlers promoting experimentation knowing it may lead to habitual use, addiction to true narcotics, and another "hooked" customer.

Barbiturates also often follow excessive use of amphetamine drugs, in an effort to slow down and get off the "jag." Amphetamine-barbiturate use may thus become a vicious cycle causing serious emotional and physical damage.

The excessive use of barbiturates produces symptoms similar in some respects to alcoholic intoxication. The person affected becomes drowsy and confused. He cannot coordinate his muscular action when he walks or stands and sometimes reaches the point of collapse. He may experience tremor of his hands, lips, and tongue, and he has difficulty in thinking or talking clearly. A person so affected is obviously unfit to drive.

But even the occasional user of barbiturates will become drowsy and less alert. Effects vary greatly in different individuals. Even if the dose is small and the time under the medication is short, the person should make sure he knows how the drug will affect him before driving. Follow your doctor's advice in the use of these potent drugs. It is up to the doctor, of course, to give the necessary instructions where the drug is not identified to the patient.

TRANQUILIZERS

This descriptive term is applied to a group of preparations that are, generally speaking, muscle relaxants affecting some reflexes to relieve mental apprehension. While some of them are also used to reduce high blood pressure, their effect is largely on attitude and outlook.

However, in normal or larger doses, or with other drugs or alcohol, tranquilizers may result in sedation to the point of dizziness or drowsiness. Obviously, these preparations may also pose a danger to the driver and should be taken only under adequate medical supervision, with the doctor knowing that driving is contemplated.

ANTIHISTAMINES

These drugs are used for relief of nasal congestion due to colds, to combat allergies, and for other purposes. Some may be purchased without prescription; others are too dangerous for use without medical supervision.

These drugs may also cause side effects such as inattention, confusion, and drowsiness. In fact, some of them are available for use as an aid to sleep. If the drug produces such results in a particular individual, then that individual should not drive or operate machinery. Observe label directions carefully, or follow your doctor's advise about driving.

NARCOTICS

Since the true narcotics are used primarily by doctors in seriously ill, usually hospitalized patients, these patients are not likely to be driving at all. In the unusual situation where narcotic medication is indicated and the doctor permits driving, he will undoubtedly advise necessary precautions.

However, a narcotic addict—or a person "experimenting" with the wares of the dope peddler—is a real threat to highway safety. These drugs affect judgment, produce drowsiness, interfere with concentration, impair vision, and release inhibitions against reckless driving and other improper behavior.

DRUGS PLUS ALCOHOL ARE ESPECIALLY DANGEROUS

Everyone knows the dangers of driving while under the influence of alcohol. Not so many know how the drugs discussed above threaten driving safety. But still fewer know that the combined effects of these drugs and alcohol may be exceedingly dangerous.

The combined results may be much more dangerous to health and to highway safety than the effects of either the alcohol or the drugs alone. The scientific term for the reaction effect is "synergism."

The old adage, "If you drink, don't drive," is still good. But here are some additional rules that may save your life—or the other fellow's:

1. If you are ill, see your doctor.
2. If your doctor prescribes drugs, ask him about driving while on the medication.
3. If you drink, don't drive; but ask your doctor about the combined effects of alcohol and any medicine he prescribes.
4. Don't ask your druggist to violate the law by selling dangerous drugs without a prescription, and don't buy from one who will.
5. Don't allow filling station or truckstop operators to sell you any drugs. These operators may be good mechanics for your automobile or truck, but your body is a much more valuable—and delicate—machine.

The organizations of professional drivers and of persons serving the driving public endorse this policy as being in the best interest of the driver.

If you are offered any of these drugs under circumstances which arouse your suspicions, get in touch with the Food and Drug Administration office serving your area or the headquarters office at Washington 25, D.C.

STATEMENT OF ADOLPH K. SCHWARTZ ON BEHALF OF THE ASSOCIATED DRUG & CHEMICAL INDUSTRIES OF MISSOURI, INC., RE H.R. 11581 (AND S. 1552)

My name is Adolph K. Schwartz. I am a member of the bar of the State of Missouri. I am a native of St. Louis and have been engaged in the general practice of law there since 1939. My address is 721 Olive Street, St. Louis, Mo. My statement here is on behalf of the Associated Drug & Chemical Industries of Missouri, Inc.

The association was incorporated by pro forma decree under the laws of Missouri in 1930. It has 156 member companies, all of whom are engaged in the manufacture and distribution of drugs and chemicals and allied industries.

St. Louis is one of the larger drug centers and many of the association member companies manufacture and distribute nationally known products.

In the interest of brevity we adopt the statement of James F. Hoge made on behalf of the Proprietary Association before this committee on August 21, 1962, with the addition of a few points which we believe should be emphasized.

EFFICACY OF EFFECTIVENESS

The two bills use the words efficacy and effectiveness as though they were synonomous, in connection with new drug applications. Present law on this subject provides for safety of all such products. We do not believe that addition of efficacy or effectiveness to the definition of drugs requiring a new drug application, is either necessary or desirable. So long as the safety in a new drug application is established, the economics of the marketplace will, as it does at present, take care of any drugs that are not effective or efficacious. Moreover, under present law, if claims are made for a drug product which cannot be substantiated, the manufacturer is subject to sanctions for mislabeling or misbranding; and is also subject to prosecution by the Federal Trade Commission.

Finally, if such a requirement must be made, we urge that careful consideration be given to the difference in meaning between the words efficacy and effectiveness. Using common cold remedies as an example, effective would mean that the drug would relieve those common cold symptoms for which claims are made; but efficacy might be construed to mean that the product must cure a cold. We would, therefore, prefer the word effective as used in S. 1552 rather than efficacious as used in H.R. 11581.

GRANDFATHER CLAUSE

If the definition of "new drug" is changed to include effectiveness as efficacy, then it is essential that a "grandfather clause" be included so that old established drug products will be exempted and not have to go through elaborate and costly new drug procedure. S. 1552 contains such a grandfather clause but H.R. 11581 does not.

ADULTERATION

Section 101 of H.R. 11581 provides in effect that the FDA, by regulation, can establish methods of manufacture and qualifications of personnel, and then if a company or a product does not, in the opinion of an inspector comply, FDA could find that the product was "adulterated" notwithstanding that the purity or safety or quality were unquestioned, and the labeling was proper. We think this amounts almost to licensing by the FDA, is the concentration of too much authority in an administrative agency, and places an unfair burden upon industry. The provisions in S. 1552 are less stringent and are adequate.

TRADEMARKS AND ESTABLISHED NAMES

Section 112 of H.R. 11581 provides that FDA may require all products to use an "established" or "official" name on a given product. Proprietary drugs, sold over the counter without a prescription, are known by their trademarks. They are mostly compounds of several ingredients and could not sensibly have a "generic name." Proprietary medicines should be exempted from this provision.

LABELING

Section 112 of H.R. 11581 also requires that the label contain quantitative listing of all active ingredients in type the same size as the trademark, and requires that they be given a position of precedence on the label. Quantities of each ingredient in a compounded medicine, in other words the formula, is a trade secret. To require this on the label serves no purpose of safety to the public, yet it would destroy many small medicine manufacturers who depend upon secret formulas which they have developed and marketed for many years. It would, of course, also destroy the value of a trademark, without any accompanying benefit to the public. Furthermore, the requirement in this section that the names of the ingredients be printed in type of the same size as the trademark (or in type of at least 50 percent the size of the trademark as provided in S. 1552) imposes an impossible condition for many products. For example, the product Anacin, marketed in a small tin of 12 tablets (and in other packages) contains, as shown

on the label, acetophenetidin, aspirin, caffeine. Certainly these ingredients could not be printed in the same size type as the trademark Anacin. Another example is mentholatum which contains, according to its label, menthol, camphor, boric acid, petrolatum, oils of sweet birch, pine, and eucalyptus. Still another example is murine which contains, according to its label, potassium borate, berberine hydrochloride, boric acid, glycerin, hydrastine hydrochloride, merthiolate and sterilized water.

FACTORY INSPECTION

Section 201 of H.R. 11581 authorizes an almost unlimited inspection which would include not only plant and personnel, but also all records, financial reports, trade secrets, manufacturing processes and "know-how," and anything else. Under the existing law it is a criminal offense to refuse "to permit entry or inspection." There is no need for these broad vague powers of inspection of things which have no bearing on the safety, or purity, or effectiveness of a drug or medicine. Its constitutionality is questionable and it would constitute another unnecessary and unfair interference with and burden upon industry. We see no need for amendment of inspection powers under existing law, however, if they are to be broadened, they should be clearly defined and be limited to items bearing upon the safety and purity, and perhaps the effectiveness, of drugs and medicines.

CONCLUSIONS

It is hoped that the foregoing will be of assistance to this committee in understanding the broad scope and unnecessarily burdensome nature of some of the provisions in H.R. 11581, and that the committee will amend these provisions as we have suggested.

STATEMENT BY SIERT F. RIEPMA, PRESIDENT AND TREASURER OF NATIONAL ASSOCIATION OF MARGARINE MANUFACTURERS

The National Association of Margarine Manufacturers respectfully opposes those provisions of H.R. 11581, 87th Congress, 2d session, which seek to broaden the existing statutory authority of the Food and Drug Administration, Department of Health, Education, and Welfare, to make inspections of factories and other food establishments, including "consulting laboratories." Specifically, the opposition of the National Association of Margarine Manufacturers is directed to those amendments contained in title II of H.R. 11581, as to which the association requests this committee to report unfavorably.

The National Association of Margarine Manufacturers is a nonprofit trade association organized under the Illinois Not-For-Profit Corporation Act and composed of most of the margarine manufacturers in the United States. Margarine manufactured by the members of the association is produced and distributed in accordance with the provisions of Federal and State laws, including the Federal Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. 321, et seq. Under this act, the Food and Drug Administration of the Department of Health, Education, and Welfare has issued a Federal definition and standard of identity for margarine (17 F.R. 4613 and 21 F.R. 6566).

In those instances in which animal fat is used in the production of margarine, the product is also produced and distributed in accordance with the meat inspection regulations of the Secretary of Agriculture issued pursuant to the Meat Inspection Act, as amended (21 U.S.C. 71-91), and section 306 of the Tariff Act of 1930 (19 U.S.C. 1306). The Secretary of Agriculture has also issued a Federal definition and standard of identity for margarine similar to that issued by the Food and Drug Administration of the Department of Health, Education, and Welfare.

It is the position of the National Association of Margarine Manufacturers that the various Federal and State laws, including the present provisions of section 704 of the Federal Food, Drug, and Cosmetic Act of 1938, as amended—the so-called "factory inspection provision"—afford ample authority to governmental officials, including officials of the Food and Drug Administration of the Department of Health, Education, and Welfare, to inspect adequately the premises of any food establishment for sanitary and related conditions and that no satisfactory need has been demonstrated for expanding the factory inspection powers of the Food and Drug Administration in the manner proposed by title II of H.R. 11581.

At the present time section 704(a) authorizes the Secretary of Health, Education, and Welfare, through such officials or employees as he may duly designate, to enter, upon presentation of proper credentials to the owner, operator or agent, at reasonable times, "any factory, warehouse or establishment" in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in interstate commerce. Therefore, the present law already authorizes Food and Drug inspectors to enter into any place where food is kept or held for shipment in commerce.

For what purposes may such entry be made?

Section 704 provides specifically that the purpose of such entry is to permit inspection at reasonable times within reasonable limits and within a reasonable manner, such factory, warehouse, establishment, or vehicle and pertinent equipment, finished and unfinished materials, containers, and labeling therein. This is an extremely broad power as it now stands. Food and Drug inspectors have, under this provision, ample power to inspect all material and equipment used in connection with the production of food as well as the food itself.

Section 704(b) provides that, upon completion of any such inspection of a "factory, warehouse, or other establishment," the inspection official must give to the owner, operator, or agent in charge of the premises a report in writing "setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device, or cosmetic in such establishment, (1) consists in whole or in part of any filthy, putrid, or decomposed substance or (2) has been prepared, packed, or held under insanitary conditions." It also provides that a copy of such report will be sent to the Secretary of Health, Education, and Welfare.

But the present law does not end here. Under section 704(c) the inspecting officer is permitted to take a sample obtained in the course of the inspection for which he must give a receipt to the person from whom the sample was taken.

Under section 704(d), if an analysis is made of the food sample taken, a copy of such analysis must also be furnished to the person from whom it was taken.

Certainly these powers, already in the hands of the Food and Drug Administration of the Department of Health, Education, and Welfare, individually and in combination, constitute a powerful enforcement weapon which enables that Agency to deal with any conceivable situation in which the wholesomeness of the food supply of the Nation is involved.

The present inspection powers, just described, did not come about overnight but rather are the product of a long evolutionary history in the development of adequate legislation in the food and drug field on the Federal front.

The 1906 Food and Drug Act, the first major legislation in this field, contained no provision authorizing so-called "factory inspection." Even in the absence of compulsory inspection powers, the Nation's food industry cooperated by voluntarily permitting inspection by the persons charged with the administration of the early Food and Drug Act. It has been stated that more than 95 percent of the food and drug manufacturers invariably gave permission to inspect their premises.

In 1938 when the law was changed, there were included provisions which permitted inspection of premises where food is manufactured "after first making request and obtaining permission" of the owner of the factory. These provisions did not prove entirely satisfactory in operation because of the necessity of Food and Drug inspectors first obtaining permission of the owner before undertaking to inspect his premises.

In *U.S.* v. *Cardiff*, 344 U.S. 174 (1952), the Supreme Court held that the provisions in the 1938 act dealing with this question were fatally inconsistent and did not clearly provide that refusal to admit a Food and Drug inspector constituted a violation of the act. Accordingly, in 1953 the Congress amended section 704 to its present form, eliminating the necessity for obtaining permission of the owner before inspection of his premises.

The controversy and litigation, to which allusion has just been made, concerned only those provisions requiring preinspection permission of the owner of the premises to be inspected. There has never been any question until now but that the 1938 act gave ample authority to Food and Drug inspectors to carry out their enforcement responsibilities. An examination of the legislative history of the 1953 amendment, for example, reveals that the overriding concern of the

Congress was the necessity of clarifying the ambiguity in the law resulting from the *Cardiff* decision (see report of the House Committee on Interstate and Foreign Commerce, House of Representatives, Report No. 708, 83d Cong., July 6, 1953). Significantly, in this committee report, recognition was again given to the fact that the great majority of the food industry voluntarily permitted inspections to take place and that there was only a small minority group which refused to cooperate, making it necessary for the Food and Drug Administration to exercise its compulsory authority to conduct such inspections.

The committee report pointed out that the inspections were normally a matter of routine checking, primarily as to sanitary conditions, and that they were not necessarily based upon any suspicion or determination that any law had been or was being violated. Accordingly, it was concluded by the Congress that a search warrant type of procedure would be inappropriate.

The report cited is a most careful exposition of the views of the Congress upon this point. It emphasized that the bill which subsequently became the present law was not intended to authorize fishing expeditions into private papers such as financial accounts, personnel records, and payrolls. This is particularly significant in light of the amendments which are now being proposed by title II of H.R. 11581.

The committee report stated that the bill was intended to provide the Food and Drug Administration with sufficient inspection authority to protect the public by providing a means of knowing the composition of finished and unfinished materials whenever the composition of such articles is relevant to compliance with the law. It was stated that "inspection" means "to examine critically," and that the words of the proposed statute should be given a meaning with the overall purpose of protecting the public. It was stated, for example, that a food and drug inspector should have authority to inquire whether a person in charge of safety controls is qualified by training and experienced but that this should furnish no basis for insistence that a person's entire life history be exposed to inspection through examination of his personnel records.

The foregoing discussion justifies the conclusion that the Food and Drug Administration was given in 1953—and still possesses—ample authority to inspect food establishments in order to carry out the responsibilities imposed upon it and there is no need at this time for expanding this authority in a manner which in 1953 the Congress did not deem desirable.

I now request the committeee's consideration of the proposed amendment.

At the heart of H.R. 11581 is section 201(a) of title II which would amend the first sentence of section 704(a) of the Federal Food, Drug, and Cosmetic Act so as to retain most of its present provisions but would add provisions which would give inspectors of the Food and Drug Administration a license to conduct what can only be called fishing expeditions into any and all matters which may directly or indirectly relate to the sanitation of the food processes at the establishment or to the wholesomeness and proper labeling of the food resulting from those processes.

The broad power thus proposed incorporates the possibility of FDA agents examining all documents and processes in order to consider those documents or processes which are relevant. Not only would FDA inspectors be permitted to enter and inspect factories, warehouses, or establishments where food, drugs, devices or cosmetics are manufactured or held but they would in addition be permitted to inspect any "consulting laboratory," its records, files, papers, processes, controls and facilities bearing on whether articles which are adulterated or misbranded within the meaning of the act or which may not be manufactured by reason of the act, have been or are being kept in violation or potential violation of the act. A "consulting laboratory" is defined as any laboratory or other establishment which, for a fee, performs or agrees to perform assays or other services, laboratory services for a food, drug, or cosmetic manufacturer if such manufacturer owns or has under his control an establishment which is subject to inspection.

In effect these provisions would give food and drug inspectors the power to conduct a roving search with undefined specific objectives, and without having to comply with even the most elementary form of search warrant procedure. Such power to investigate law violations is one jealously and wisely guarded by the common law.

All-pervasive investigatory power of this sort was one of the very things which the report of the Committee on Interstate and Foreign Commerce, referred to above, considered and refused to confer in 1953. In short, that

committee, after carefully reviewing the various types of inspection statutes which Congress enacted into law, and after considering the type of inspection necessary and desirable in the food and drug field, concluded that, since Food and Drug inspectors should primarily inspect as to sanitary conditions, and not necessarily on the basis of a prior suspicion of a law violation, that a search warrant type of procedure would be inappropriate. Now, however, the provisions of H.R. 11581 bluntly state that Food and Drug inspectors may be permitted to inspect, among other things, records, files, papers, processes, controls, and facilities bearing on potential violations of the law. Yet no effort at all is made to provide a search warrant type of procedure which is the normal and expected procedure employed by law enforcement officers.

The National Association of Margarine Manufacturers feels that the provisions of title II of H.R. 11581—designed to broaden the factory inspection powers of the Food and Drug Administration—are (a) ill-conceived, (b) are at variance with the fundamental philosophy carefully enunciated in 1953 referred to above, (c) are inconsistent with accepted principles dealing with search warrant types of procedure, and (d)—most important of all—are wholly unnecessary.

The 1958 food additives law is also highly pertinent. It changed the whole regulatory philosophy in this subject area. As this committee knows, the rationale of that law was that before an ingredient may be used in a food its safety must have been established by regulations issued by the Food and Drug Administration, thus passing in large part the burden of determining safety from the Food and Drug Administration to the industry.

Prior to 1958 it was necessary for the Food and Drug Administration to develop information to show that a food was adulterated or misbranded. Thus there is less need today than before for the broad inspection authority provisions of title II of H.R. 11581. The business community properly fears that if inspectors of the Food and Drug Administration are to be given a roving authority to make examinations of their records, files, papers, processes, etc., on the basis of mere suspecion, important trade secrets and processes may be revealed. This is particularly true when consideration is given to some of the related amendments also proposed by title II of H.R. 11581.

Thus, section 202 of the bill amends section 301(j) of the act. Section 301(j) of the act now provides that it shall be unlawful for any person to use to his own advantage or to reveal to anyone other than to the Secretary, or officers, or employees of the Department, or to the courts, any information acquired under authority of section 704 *concerning any method or processes which, as a trade secret, is entitled to protection.* But section 202 of the pending bill would strike the language above emphasized and would at the same time make it lawful to reveal any information obtained pursuant to amended section 704, not only when relative to any judicial procedure under the Federal Food, Drug, and Cosmetic Act, but also to reveal such secrets and processes as authorized by law. What does this mean? The bill does not say.

The way may be opened for inspectors to be subpenaed in purely private litigation by competitors to reveal information given to them in confidence. Certainly the Federal Rules of Civil Procedure authorize the issuance of subpenas in appropriate cases. If a trade secret became relevant in a private suit, the proposed amendments would open the way to get at these secrets through the subpena route. This is but one of the striking defects in the bill.

The business comunity, of which the margarine industry is a part, is keenly concerned over any disclosure of trade secrets because a secret once revealed is no longer valuable to its owner. Food and Drug inspectors are not necessarily permanent Government employees. There is nothing effectively to prevent them from using information obtained in subtle and difficult-to-detect ways once they leave their Government positions, even though they religiously lived up to their obligations under the law so long as they remained Government employees. No satisfactory remedy exists in law to repair the damage caused by the wrongful disclosure of a valuable trade secret.

The same objections as have been made regarding the involuntary disclosure of trade secrets apply with respect to other private and personal, business matters which have no legitimate relation to the performance of the statutory functions of the Food and Drug Administration. Included in this category are such matters as financial data, pricing data, sales data, personnel data, and data pertaining to research programs in all stages of development. Although information contained in each of the above categories has no relationship to whether

a given food product is misbranded, mislabeled or unwholesome, such information where improperly disclosed could wreak irreparable havoc upon business ventures and individuals associated with a food establishment. Businessmen cannot feel secure knowing that individuals outside the corporate family are possessed of the company's most vital operating data, and the public interest cannot be served where an important segment of the business community must operate under such insecure conditions.

Attention is called to fact that section 704(c) of the present law would be left unchanged by section 201 of H.R. 11581 but even this poses a problem for, as stated earlier, section 704(c) provides that, if a Food and Drug inspector takes a sample in the course of his inspection of a factory, warehouse or other establishment, he must give the person in charge a receipt describing the samples obtained. What if he obtains a sample from a consulting laboratory which the bill would authorize him to inspect. Is he to give the person in charge of the consulting laboratory a receipt?

Everyone in the food industry is mindful of the necessity for reasonable enforcement provisions, including inspection provisions. In amending the law to its present form in 1953, the Congress gave the Food and Drug Administration the utmost power which it needs to perform its task. To go beyond that is to burden unnecessarily the majority of the business community for the recalcitrance of a few. This is out of all proportion to the advantages to be gained by the Government.

The Food and Drug Administration has not, in the course of its administration of this important law, revealed any reticence to exercise fully the powers given to it in the most effective manner. Bearing in mind that the Food and Drug Administration has the power of seizure, it is almost inconceivable, with existing inspection powers, that it cannot adequately protect the food supply of the Nation. To permit it to do more is to destroy the confidence of the business community in the agency and to give it an authority out of all balance with its needs.

For the foregoing reasons the National Association of Margarine Manufacturers respectfully urges this committee to not recommend the passage of title II of H.R. 11581.

STATEMENT OF ELSIE NAOMI JONES, ATTORNEY, RE H.R. 11581

My name is Elsie Naomi Jones. I am an attorney engaged in the private practice of law in the District of Columbia with offices at 1047 31st Street NW., Washington, D.C. I am a member of the bars of the District of Columbia and the State of Tennessee. Prior to entering private practice in 1960 I was employed as an atorney in the Federal Government for 26 years with assignments in several departments. I file this statement with the committee only as an attorney who is interested in the food and drug field and who has had occasion to spend some time in study and research in such field.

Last week I attended the public hearings on H.R. 11581 and was impressed by the concern of some witnesses and committee members over placing in one man authority to determine (1) whether a new drug is efficacious before allowing it to be marketed, and (2) whether a drug already on the market presents an imminent hazard and if so, summarily remove it from the market. The proposed House bill, of course, would place this responsibility in the Secretary of the Department of Health, Education, and Welfare. As clearly brought out by the testimony and questioning, however, many drugs are admitted to be effective only as to a small percentage of users. In addition, experts do not always agree as to the degree of efficacy or the hazards posed.

In connection with the doubt expressed as to the wisdom of endowing one public official with such far-reaching authority to be exercised in areas where much conflict of expert opinion exists I would like to call to the committee's attention the existing authority of the Food and Drug Administration to achieve the removal of a food, drug, device, or cosmetic from the market by obtaining a permanent injunction in which judicial proceedings the manufacturer of the product has no right to trial by jury.

Of the three types of actions which the present Federal Food, Drug, and Cosmetic Act authorizes the FDA to institute, i.e., criminal, seizure, and injunctive, the right to trial by jury is afforded the accused in the criminal and seizure actions. However, with respect to proceedings seeking to perpetually enjoin the accused, the Supreme Court of the United States has recently denied cer-

tiorari in a permanent injunction proceeding instituted by the FDA where the failure of the court to grant a trial by jury as requested by the accused was in issue. This is the case of *United States of America* v. *Ellis Research Laboratories, Inc. et al.*[1] This proceeding involved a diagnostic aid device which had been on the market for some 30 years and sold only to doctors of medicine, chiropractors, and other persons licensed by the several States to practice in the healing arts. The record shows marked conflict in expert testimony as to the device's efficacy. Expert opinion, however, seemed unanimous that the device was harmless. The Court's ruling granting the permanent injunction has the effect of putting the manufacturer out of business and depriving diagnosticians of the device without the manufacturer having had the jury trial which he requested.

I submit that the right to trial by jury should be afforded the accused when the FDA elects to seek to perpetually enjoin as well as when it elects to proceed by the institution of a criminal action or by a seizure action. Accordingly, I respectfully suggest that an appropriate amendment is in order to H.R. 11581 so as to provide for amending section 302(*a*) of the Federal Food, Drug, and Cosmetic Act[2] by adding at the close of that section the following language: "When a permanent injunction is sought, trial shall be by the court, or, upon demand by the accused, by jury."

I thank the committee for this opportunity to file my above statement for inclusion in the record of the committee's hearings on H.R. 11581.

STATEMENT OF JACOB RECK ON BEHALF OF THE NATIONAL BEAUTY & BARBER MANUFACTURERS ASSOCIATION IN OPPOSITION TO SECTION 201 OF H.R. 11581

My name is Jacob Reck. I am counsel for the National Beauty & Barber Manufacturers Association, and herewith present its opposition to section 201 of H.R. 11581, which would expand FDA's factory inspection authority by removing restrictions and limitations in the existing law and, thus, enable FDA agents to conduct the broadest kind of search of cosmetic plants and beauty salons or barbershops in which cosmetics are held after entry into interstate commerce.

We oppose the unprecedented, unrestricted, and unlimited search authority provided for in section 201 of this bill which would subject retail and wholesale establishments where cosmetics are held after entry into interstate commerce, such as drugstores, grocery stores, beauty salons or barbershops, to an inspection of their records, files, and papers bearing on potential violations of the Federal Food, Drug, and Cosmetic Act, which means anything and everything on the premises, because the fine safety record of cosmetics during the past decade demonstrates there is no need for this broad and unreasonable inquisitorial power.

FDA's published reports of legal actions instituted against cosmetics show that in the past decade only two cosmetic products out of $15 billion worth of cosmetics sold during that period were removed from the market by FDA court action because of adulteration with a poisonous or deleterious substance. Anyone familiar with the cosmetic enforcement picture knows that a drive by FDA immediately following the enactment of the cosmetic provisions in the act of 1938 cleared the market of unsafe cosmetics more than two decades ago and that since then, for the purpose of self-preservation and to expand consumer acceptance, cosmetic firms adequately inform themselves concerning the safety of their products before putting them on the market. An increasing consumer acceptance bears out this fine record of safety.

In view of this lack of need, we contend it would be just as unreasonable at the present time to authorize FDA to inspect the formulas, complaint and personnel files of cosmetic producers and resellers as it was in July 1953 when

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[1] *United States of America* v. *Ellis Research Laboratories, Inc., et al.*, U.S. District Court, Northern Division of Illinois, Eastern Division, civil action No. 60C578, permanent injunction decree entered June 14, 1961; affirmed, U.S. Court of Appeals for the Seventh Circuit, No. 13471, by opinion entered Mar. 22, 1962; certiorari denied, Supreme Court of the United States, No. 929, October term, 1961, on June 11, 1962.

Should it suit the convenience of the committee I should be glad to supply the committee with names and addresses of the defendant's attorneys of record.

[2] 21 U.S.C. 332(a).

this committee, through its present chairman and ranking minority member, in the House floor debate on the compulsory factory inspection amendment, emphasized that it was the congressional intent to provide for inspection within a reasonable manner and within reasonable limits which did not include authority to inspect the formulas, profit-and-loss statements, complaint or personnel files and many other similar documents. This emphasis on the intent to limit the inspection authority was made necessary by the grave constitutional questions inherent in an unlimited, compulsory factory inspection. These difficult constitutional questions have been raised anew in the expanded inspection authority requested in section 201 of this bill. We submit that these questions require a limitation on the inspection authority now just as they did in July 1953 when your committee inserted in the factory inspection amendment a requirement that the inspection be "within reasonable limits and in a reasonable manner" for the purpose of confining the scope of inspection to "factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." (See H. Rept. No. 708, 83d Cong., 1st sess. (1953), p. 7.)

Accordingly, we respectfully request your committee to withhold approval of section 201 of H.R. 11581 with respect to cosmetics and consulting laboratories.

STATEMENT OF JOHN S. HALL, SECRETARY OF AND IN BEHALF OF NATIONAL MANUFACTURERS OF BEVERAGE FLAVORS IN OPPOSITION TO H.R. 11581, PROPOSED AMENDMENT TO SECTION 704(a), FACTORY INSPECTION

On behalf of the National Manufacturers of Beverage Flavors, we are anxious that the views of that industry regarding House Resolution 11581 be clearly stated and understood. We appreciate the opportunity to state our position.

We agree that if a previously accepted substance or flavoring is proven to be unsafe, that prompt steps must be taken to prevent its use. However, we do not agree that the ultimate goal, protection of the consumer, is served by giving inspectors complete liberty to enter a factory with unrestricted access to "all things therein." To the contrary, our courts have consistently ruled in favor of protection of fundamental rights—which would be violated by the delegation of such strong powers for purposes of factory inspection.

We must emphasize our alarm after reading the proposed broadened authority. No personal business records, no secret formula papers would be denied access to the inspector. The proposal speaks of "all things * * * bearing on violations or potential violations * * *." To our way of thinking, this invites unlimited inspection, it invites adjudication of guilt or even presumption or suspicion of guilt by a field inspector—a man suddenly called upon to serve in the capacity of judge and jury.

Historically, the inspector's prime concern has been sanitation and general conditions of the factory premises, as related to health problems. Progress is being made and more progress will be made. The inspector's role should adapt to the desired functions. However the fundamental rights of the producer and of owners of secret formulas should not be surrendered to the inspector who, without statutory guides, can merely suspect a potential violation and use such a key to any factory and to all things therein. What policeman protecting against dire crimes is vested with this authority? What grand jury is empowered to act on such a basis? Where does this power fit in the pattern of lawful search and seizure?

To our deep concern over damage to the rights of our industry members and the value of the formulas and industrial properties they have built up, we must reiterate the concern expressed by other industries. Additional objections have been adequately expressed.

This request for unlimited power has been injected into proposed amendments dealing primarily with that section of the law covering the manufacture of drugs. Our interests are not in that field, but if any greater factory inspection authority is needed in the administration of the drug law, proposed amendments should be directed to that purpose and not to the food section of the law.

We stand willing to cooperate with the Food and Drug Administration in the mutually desired goal of protecting the consumer. But we must object to proposed legislation which, in the guise of serving that goal, destroys basic rights. If the administration can provide evidence that the present legislative authority is inadequate for a specific purpose, they should come forth so that that problem

would be fairly analyzed. Our industry will have no objection to any reasonable approach on the basis of a showing that a change is necessary. A vague expression that more power is needed is not in keeping with sound legislative growth. Thank you for permitting us to add our expressions of opposition to the proposed legislation.

STATEMENT OF JAMES B. CAREY, SECRETARY-TREASURER, INDUSTRIAL UNION DEPARTMENT, AFL–CIO, ON H.R. 11581, THE DRUG AND FACTORY INSPECTION AMENDMENTS

My name is James B. Carey. I am the secretary-treasurer of the Industrial Union Department, AFL–CIO, and president of the International Union of Electrical, Radio, and Machine Workers, AFL–CIO.

The Industrial Union Department, AFL–CIO, has come before committees of the Congress several times to testify on behalf of strong legislation to insure drug safety and efficacy, and fair prices. We have consistently taken the position that strong legislation is needed. We have done so in the interest of the 6 million industrial workers represented through the IUD and of all the American people.

It would be easy enough to say, "We told you so," in the light of the recent thalidomide tragedy. But nothing is to be gained from finger pointing and there is little that can be done for the victims of this drug "progress." It is a sad commentary upon our civilized society that we must wait until such tragedy strikes before there is corrective action.

Pressures from the drug industry prove the need for a well-armed cop to patrol the drug industry beat. Dr. Kelsey was subjected to strong and constant pressures from a company intent upon marketing its product, regardless of whether or not there was adequate proof of safety. What has happened to the Food and Drug Administration under present circumstance is worthy of congressional investigation.

Charges against FDA are outlined in the September Saturday Review by John Lear, who broke the drug industry scandals that resulted in congressional investigations. Similar charges were made in testimony of Dr. Barbara Moulton, who vainly sought to accomplish what Dr. Kelsey heroically achieved. Dr. Moulton charged in testimony that the Food and Drug Administration had become "in many areas a service bureau" for the drug industry.

Legislation cannot of itself guarantee that such circumstances will not arise again, that there will be no new scandals like that involving Dr. Henry A. Welch, who headed the Antibiotics Division of FDA until it was revealed that he had used that position for personal gain. But legislation giving the Secretary of Health, Education, and Welfare adequate police power can change the entire orientation of our Food and Drug Agency.

The people must be guarded against any "buyer beware" philosophy in drug merchandising. They have little choice in the matter except to believe the label, or take what the doctor prescribed. In no other industry is there such urgent need for strong legislation.

The thalidomide tragedy is only the latest in a long series of drug mishaps due to lack of adequate safeguards. The case of MER–29 was nearly as serious. Here, too, the chief concern of the drug industry was to get the compound to market regardless of proof of safety.

FDA Deputy Commissioner John L. Harvey now agrees that the drug should never have gone on the market. It seems probable that had there been adequate safety requirements the drug would have been withheld.

In this case too, the FDA doctor who cleared the drug was subjected to strong industry pressures. And even if these had not been applied, the law is such that MER–29 would have soon been on the market. Current law permits applicants to market new drugs if they have not been disapproved by the FDA within 60 days.

MER–29 resulted in cataracts, skin problems and other injurious side effects. Yet, even after the side effects were reported, the drug continued to be prescribed. Over 300,000 patients had used the drug before it was withdrawn. Even while efforts were being made to force withdrawal, an ad in the American Medical Association Journal claimed that there were "few toxic or side effects reported."

The age of miracle medicines has made it more important than ever that we proceed with care. These medicines have made wonderful cures possible, but

they have also brought us to new thresholds of body chemistry. Unless there are adequate precautions, the cure may prove as dangerous as the illness.

Rheumatic arthritis is a merciless affliction. It was no wonder that when decadron was introduced in 1956, thousands turned to it for relief. Side effects ranging from simple rounding of the face to severe mental disorders were soon evident. Yet, 2 years later, advertisements continued to proclaim: "No worrisome side effects contributable to decadron have occurred as yet."

The drug industry has failed to learn from experience. Voluntary restraint has proved woefully inadequate. The drive has been for the quick (profit) kill with the quick pill. It is a miracle that there have been no worse tragedies.

H.R. 11581 goes a long way toward correcting the situation now prevalent. It does not, in our view, go as far as it should. However, we urge quick passage of the measure as a decisive step forward on the road to sanity in drug manufacture and marketing. The bill will protect patients, doctors, and even the drug industry against itself. It will provide means to combat the manufacture of drugs under unclean or unsafe conditions. In itself, this will be beneficial to the responsible drug company because it will help to eliminate the drug bootlegger who is now able to prevent plant inspection, and who now does not even have the legal obligation to register as a drug manufacturer.

H.R. 11581 would require drug manufacturers to register with the HEW Secretary. Only those who have something to hide need fear this provision. And certainly, those with something to hide have no place in the drug industry.

In our view, the drug registration provision does not go far enough. While we are in favor of passage of the measure as written, we shall continue to push for a law requiring that drug manufacturers be licensed by the Federal Government. The ability to grant, withdraw, or withhold license is essential for adequate policing of the industry and for the enforcement of proper standards of safety and efficacy.

The bill would require each applicant seeking approval to market a drug to establish and maintain records of its effectiveness and its side effects and make these records available to the Government. This will be of significant help in keeping useless and—more importanly—harmful drugs off the market. We are in full agreement with the requirement.

The provisions covering factory inspection are long overdue. Such inspection will insure cleanliness in plant operation, protection from adulteration, and the proper branding of products. It will give Federal inspectors access to papers, records, files, processes, controls, and facilities. This will make inspection meaningful.

The IUD is not impressed with arguments that factory inspection will result in invasion of industrial privacy, or the pirating of business secrets. In the first place, the public health and safety is more important than business secrets. In the second place, there is adequate protection within H.R. 11581. The law proclaims that information obtained by inspectors is confidential. Certainly, trade secrets will be as confidential as they are now, in view of advanced chemical analysis and electronic snooping.

The law, as presently written, permits FDA only very limited rights in checking qualifications of drug personnel. These rights will be broadened under the proposed law. This will be a step forward since the safety of the consumer is intimately tied up with the qualifications of key personnel.

We are especially pleased with that section of the law which gives the HEW Secretary the right to order a drug off the market if he finds that clinical, or other experience, or tests show the new compound unsafe or of no medical value. Too often, the consumer must wait for tragedy before a drug is withdrawn under present circumstances. The consumer will be significantly safer if this provision becomes law.

Testimony before this committee and in the other body of the Congress has attested to the exorbitant prices of drugs, and to the fantastic profits of the industry. Certainly, under such circumstances, the consumer has the right to expect efficacy and relief from the medicines he is offered. This, in far too many cases, has not eventuated. Drugs often are not injurious but neither are they effective. The scandal of RDX and of safflower oil capsules illustrates the point. Power to remove useless drugs from the market will be an effective tool in calming down exaggerated claims for drug efficacy.

No drug should be permitted on the market if it represents a hazard to the public at large. H.R. 11581 would remedy this situation. The IUD is of the view that the bill's section, which authorizes the HEW Secretary to withdraw such drugs, is indispensable.

The argument has been raised that the law will place the HEW Secretary in the position of a czar. Nothing could be further from the truth. The law requires that withdrawal orders shall be accompanied by detailed findings. Court review is also provided. The honest manufacturer who seeks to serve the sick will have nothing to fear.

The batch testing requirement in the case of antibiotic represents consumer protection of a vital kind. It will insure better quality control, as well as added safety. It is difficult to understand industry objections to this provision. In view of promotional and pricing policies of the industry, its sudden concern about added costs is hardly impressive.

We are gratified to note that H.R. 11581 requires the truth in advertising claims for prescription drugs, together with a listing of side effects, active ingredients by usual name and contraindications of the drugs. Exaggerated claims made in drug advertising have been shameful. They have cruelly raised the hopes of the sick, the aged, and the infirm. It is time that the truth should be made an elementary requirement of this advertising. It is inhumane to permit this industry to take advantage of people who grasp at almost any straw in the hope of cure or relief from pain. Here, too, there is an area of confusion and massive misinformation. The cost of patent medicines reaches into the billions. Certainly, as RDX proved, there is a need for truth in advertising in this area, equal to that in prescription drugs.

The general tightening up in the area of barbiturates and other habit-forming stimulant drugs provided in the bill should have the approval of the drug industry itself. The expanded use of such stimulants has exacted a toll reflected in prison records, delinquency, and brutal crimes. The public welfare demands the bill's regulation, and the IUD gives its full endorsement.

H.R. 11581 would extend the time in which the Government could examine a new drug application. This should aid materially in relieving unwarranted pressures on FDA doctors. With a maximum of 180 days for study and investibation, instead of the present 60 days, the probability of decisions in the interests of public safety will be greater.

We strongly favor the granting of power to the HEW Secretary, permitting him to keep a new drug from the market until it is proven safe and effective. This right cannot be exercised arbitrarily, as some have alleged. The right of review and recourse to the courts is clearly available.

The Industrial Union Department hails as a step forward, the provision in H.R. 11581 that gives the HEW Secretary the right to standardize drug names. This will help to eliminate much confusion and will facilitate prescription by generic name. This is an essential step toward fairer drug prices.

The requirement that the standard or generic name shall appear on the drug label, and that the quantity of each ingredient—if there is more than one—shall also be stated, is another welcome step in this direction. The need for consumer protection in this area is greater today than ever. The wonder drugs of our day grow increasingly expensive, and the most expensive way of obtaining them is by brand name. It is our hope that these requirements will influence pricing policy in the drug industry so that the consumer will finally get a break.

We are disappointed by one major lack in H.R. 11581, which we feel is essential if drug prices are to be held down. Badly needed is modification of the patent laws as applied to drugs.

It is our belief that no patent should be granted on any new drug unless there is a substantive change and improvement. As things stand, a slight alteration of the formula is sufficient for a new patent. Drug research, as a result, has stressed changes sufficient to enable rival firms to come up with duplicate products. Research has been geared to promotion, and the stress is on the new, rather than the better.

In the decade ending with 1959, some 3,500 new products hit the ethical drug market and another 1,100 new dosages of existing products were also marketed. Of the new products, 88 percent were combinations of drugs already on the market or duplications of existing products. Such practices have added to the confusion and costs in the drug field.

Patent monopoly in the area of new discovery has permitted the drug industry to charge what the traffic will bear. Truly competitive pricing policies will not be established until the patent laws are changed to permit true competition in the manufacture of the same product. Exclusive patents should be granted for not more than 3 years, after which provision should be made to require the licensing on fair terms, of all who want to enter the field.

The Industrial Union Department, AFL–CIO, recognizes that H.R. 11581 represents a long step forward. While it is of the view that patent reform is fundamental in drug policy, it takes the position that its exclusion should not be reason to hold up the bill before this committee.

The IUD will continue to work for improved drug legislation in line with the Nation's needs. It will continue to press for patent reform. Such reform is essential if the price gouging made possible by the ills and the suffering of millions of us is to be ended.

At the present time, patients have no knowledge that they are sometimes used as guinea pigs when new drugs are introduced. Patients should have the right to reject such drugs and doctors should be required to inform patients that they are being treated with trial drugs. We urge the inclusion of such a provision in the measure before you.

The IUD applauds the work of this committee in the field of drug legislation and commends its chairman for introducing this bill. It is our hope that it will soon be reported to the House floor. New drug legislation that will protect the public can be a major accomplishment of the second session of this Congress. We are gratified at the unanimous vote for similar legislation that came in the Senate last week.

In view of what has been revealed in more than 2½ years of drug hearings, it is difficult to understand the position taken by some industry spokesmen. We are, in fact, appalled by the views of some, who last week came before your committee.

We refer the committee to the NAM News of August 24. A front page story there is headed, "Drug Industry Fears Effect of Emotional Congress Action." The NAM, indeed, and the drug industry, show little respect for the judgment of the Congress.

The pharmaceutical industry takes the position that H.R. 11581 represents over regulation. The representative of the Pharmaceutical Manufacturers Association testified that "careful" study is required and that there should be no "drastic changes" in the law. He termed the efficacy requirement of H.R. 11581 "nebulous." It would seem that the manufacturers want to maintain "flexibility" on this matter.

Let us look at the "flexibility" that now exists. FDA Deputy Director Kenneth L. Milstead, in a speech to the Yonkers Academy of Medicine a few months ago, was reported as saying that FDA would crack down on doctors who—

> Arrange for tailored studies to permit a drug promoter to advertise that a product has been clinically tested, although only a few uncontrolled observations on a few patients have been made.
>
> Rent themselves out as "consultants" to drug firms and then agree to rig drug test procedures so that the results will be as predetermined.
>
> Use as treatment-for-pay-medicine drugs labeled "for investigational use" without submitting proper clinical reports necessary for the evaluation of the drug's benefits or harmful effects.

How many more thalidomide tragedies does the drug industry need?

It is interesting to note that the drug industry would now try to point to the thalidomide tragedy as proof that new legislation is not required because the drug wasn't actually marketed. Yet, thalidomide would have been marketed had it not been for a conscientious FDA employee upon whom the industry brought heavy pressure to release the drug. It is also strange that the lack of law in other nations should be used to justify inadequate law here. Yet, this has been done in testimony before this committee.

The big question is whether the "quick kill with the quick pill" outlook shall go unchallenged. It is a question of whether profits or public safety shall come first. We take the position that reasonable profits coming from service to the Nation are the kind America needs, while profits resulting from denial of the public welfare are harmful.

The New York Times of August 26 carried a front-page story headed, "Scientists Fear New Laws May Curb Drug Research." A reading of the article shows that those most concerned are representatives of the industry.

The fear is that tight restrictions on clinical testing will result from new legislation. Yet, we find no such restrictions in H.R. 11581. True, the Senate legislation would give the HEW Secretary the right to require animal tests, but there is nothing in the proposed legislation that would halt clinical testing. We feel that the industry and others are building a strawman.

It has been proposed that a qualified advisory committee of scientists be named to help draft sensible proposals to insure safeguards for the people, especially in the area of clinical testing. This may help to supply an answer and is worthy of the consideration of FDA. We find no reason, however, to believe that either the proposed legislation or newly announced HEW regulations will result in the hampering of clinical testing. We cannot believe that the HEW Secretary would act against clinical testing in any specific case, unless there were good reason to doubt the safety for human use of the drug in question.

We take this occasion to remind the Congress that the best of laws can become meaningless without adequate funds for enforcement. Funds granted up to now have been inadequate for the FDA to carry out its functions as it should. FDA has a tremendous responsibility in an increasingly vital area. This responsibility must not be abused nor should there be any excuse for neglect.

STATEMENT FOR CONSUMERS RESEARCH, INC., SUBMITTED BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11581, SECTION 202

The proposed amendment to section 301(j) of the Food, Drug, and Cosmetic Act concerning confidentiality of information is apparently intended to protect from disclosure and from improper use such private information as might be obtained from inspections of premises and examinations of records found in such premises.

We can understand the need or some such provision in conjunction with the extended powers of inspection provided by section 201 of H.R. 11581. However, section 202 goes far beyond any needs which would be created by enactment of section 201. The proposed new rule about confidentiality would not only protect from disclosure such information as might be obtained from inspections, but the amendment as set forth in section 202 would also throw an unwarranted and highly improper statutory blanket of secrecy over a wide range of other matters which ought to be open to public scrutiny.

For example (and this may be the most important single example), section 202 would make it a matter of law that the entire contents of food-additive petitions be held in confidence. These would include petitioners' reports about tests as to the safety of such additives. We believe it is beyond question that the reports of such investigations should be freely available to the public, and especially that they should be available for examination and study by the scientific community. It is through the wide dissemination of scientific reports that the asserted findings are tested against the expert knowledge and opinions of all those other scientists who are informed in a special field of knowledge and who should have the opportunity to read and consider published reports, freely available to all who are interested.

Section 202 would require the withholding from the public of much other vital information. The list is too long and varied to give here; it would include just about every piece of information required to be submitted by manufacturers under many important sections of the Food, Drug, and Cosmetic Act. Under some circumstances, it would perhaps become possible for a manufacturer to seal the lips of the Food and Drug Administration as to a grave danger to the public welfare simply by including certain information in a report or petition to that agency.

The provisions of the Food, Drug, and Cosmetic Act are in many respects a patchwork of amendments upon amendments. Each of several chapters of the act now has more or less appropriate requirements as to confidentiality of information. These separate rules were established by the Congress with careful consideration as to their effects. The change proposed by section 202 of H.R. 11581 would have a widespread disruptive effect on established rules in a way which we do not believe the Congress could possibly intend.

We recommend that section 202 of H.R. 11581 be entirely rewritten. It should provide for appropriate confidentiality of such information as is obtained through factory inspections and is properly to be withheld from competitors, and should be severely limited to that purpose. We believe that section 301(j) of the act need not be amended at all in this connection, but that the necessary provisions should be included as a subsection of section 704, which deals with factory inspections.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington D.C., June 22, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: In testifying before your committee on June 22, 1962, Mr. Thomas Austern, representing the National Canners Association, commented on testimony presented on June 19 by Secretary Abraham Ribicoff.

The portion of Secretary Ribicoff's testimony to which Mr. Austern referred was:

"Evidence obtained during inspections over a number of years have shown that some of the tomatoes of the King's Creek Canning Co. operating five canneries on Maryland's Eastern Shore were unfit for food. The firm has consistently refused to furnish full information about interstate shipments. Many shipments are made by the manufacturer's own trucks. In 1959 gross insantiary conditions were encountered during inspection of the plants. We found fly eggs and maggots in the canned tomatoes. We were able to locate and seize only three shipments which probably represented less than 5 percent of the firm's output.

"Thus the refusal of this canner to furnish complete shipping records resulted in the marketing and consumer consumption of large quantities of filthy, maggoty canned tomatoes."

Mr. Austern indicated that one of the lots of filthy tomatoes referred to by the Secretary was released to a charitable institution for consumption following Federal seizure. Mr. Austern indicated that this was reported in our Food Notice of Judgement No. 27381.

Each of the three lots of filthy tomatoes referred to in the Secretary's testimony was seized in 1959, condemned and destroyed. The Food Notice of Judgement No. 27381, to which Mr. Austern referred, has to do with a seizure made 2 years later in 1961; it was not seized because of the presence of filth but rather because the tomatoes did not meet the requirements of the applicable food standard by reason of excessive liquid, and it was, as Mr. Austern indicated, delivered to a charitable institution.

May I ask that the record be amended by inclusion of a copy of this letter? I am sending a copy of this letter to Mr. Austern.

Sincerely yours,

JOHN L. HARVEY, *Deputy Commissioner.*

NATIONAL CANNERS ASSOCIATION,
Washington, D.C., June 28, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Deputy Commissioner John L. Harvey of the Federal Food and Drug Administration has forwarded to me a copy of his letter of June 22, 1962, in which he comments on a portion of my testimony on that day on behalf of the National Canners Association before your committee.

In his letter, the Deputy Commissioner states that I "indicated that one of the lots of filthy tomatoes referred to by the Secretary was released to a charitable institution for consumption following Federal seizure." Mr. Harvey also quotes what he believes to be the part of Secretary Ribicoff's testimony to which I was referring in my testimony.

An examination of the official transcript of my testimony will readily make it clear that there was no "indication" on my part that I was referring to the 1959 shipments.

On the contrary, I specifically said "Now, there was a third seizure of 600 cases in June 1961. That is FDA Notice 27-381" (transcript, p. 184). Both the date and the citation were given.

In addition, my references to the Secretary's testimony were not limited to the portions quoted in Mr. Harvey's letter.

The Secretary (transcript, pp. 36–37) made it clear that he was not talking about the year 1959 alone in describing the operations of the named processor. He referred to "evidence obtained during inspections over a number of years."

He talked about a consistent refusal to furnish information about interstate shipments. He then continued by talking about "case after case" in which foods that went "distributively all over the United States," to "thousands and thousands of retail outlets," were "adulterated and unsafe goods."

His apparent point was that the departmental proposal for authority to search through all of the files was supported by this example of a processor's refusal to furnish shipping records of the movement by his own trucks of what was called "adulterated and unsafe goods" (transcript, p. 37). It would be difficult indeed to read all of the Secretary's observations without concluding that the entire packing operation of the particular canner was implicated by his statements.

As the transcript of my testimony makes perfectly clear, I did not refer to the Secretary's animadversions on this packer in pointing to the existing FDA authority to get shipping records and its other powers presently authorized on the facts reported by the Secretary (transcript, pp. 177–179).

Instead, I did so later in discussing the possibility of what I called "casual publicity" being damaging to a particular company. As I put it, the committee had "heard that man's pack talked about in most derogatory terms" (transcript p. 184).

My reference to the later 1961 seizure was intended to rebut the clear implication of Secretary Ribicoff's testimony that everything the named canner packed was unfit. In fact, our search revealed only three notices involving the packer whose name had been so unhappily used in the hearings.

It occurred to us that the best refutation of the Secretary's implication concerning this canner's entire pack was that another lot of this packer's tomatoes had been subjected to intensive examination by the FDA and that no evidence was found that the packer's tomatoes were unfit for food. This June 1961 seizure was based solely on the ground that under the applicable regulations the goods were not properly labeled under section 403(h)(1). The notice of judgment specified that after default the tomatoes were delivered to charitable institutions.

It is our view that the charge and disposition in this seizure make it clear that the 1959 charges were in all likelihood confined to a particular period in that packing season, and that since that time this packer's product has been free of the alleged conditions so unhappily described by the Secretary.

We are confident, however, that the committee will appreciate that the specific reference to a named canner by the Secretary in his testimony, which is somewhat unusual in itself, was offered to support the FDA's contention that the proposed amendments to section 704, authorizing their inspectors to have access to food plant files and records, are necessary to enable the FDA, to carry out its enforcement responsibilities under the act.

Reference to an earlier part of the transcript, dealing not with casual unfortunate publicity, but with the specific existing powers of the FDA under the provisions of the present act (transcript, pp. 178–180) will indicate that I offered four specific reasons why the particular example offered would on the asserted facts in no way support the proposed amendments in title II:

If the "evidence obtained during inspections over a number of years" was as reported, the emergency permit control provisions of section 404 of the law might have been brought into play. The provisions of section 302 providing for injunctions, which have been utilized by the FDA in the past, were also applicable. And if the evidence was as cogent as suggested, a criminal prosecution under sections 301(a), 303, and 402(a)(4) was also available.

But more important, I suggested that if the processor was using his own trucks, section 703 of the law would require the production of shipping records. That section now authorizes the FDA to "have access to and to copy all records showing the movement in interstate commerce of any food." It applies to all carriers engaged in interstate commerce, which in our view includes those delivering in their own trucks. But a specific written request is required, and the congressional prohibition against the use of these records in a criminal prosecution becomes applicable.

Accordingly, in this earlier portion of my testimony, an effort was made to demonstrate that the report of prevailing operating conditions yielding unfit food, coupled with the refusal to furnish shipping records, could abundantly have been dealt with under the existing act, and hence offered no support for the requested authorization for a sweeping and recurrent examination of all records and files.

I am confident that on a full reading, the transcript, both of the Secretary's and of my testimony, will speak for itself. In order that no misunderstanding may exist, I would appreciate your including in the record a copy of this letter along with that of Mr. Harvey.

Very truly yours,

H. THOMAS AUSTERN, *Counsel.*

NATIONAL ASSOCIATION OF FOOD CHAINS,
Washington, D.C., August 28, 1962.

Mr. W. E. WILLIAMSON,
Clerk, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. WILLIAMSON: This statement is submitted by the National Association of Food Chains, Inc., in opposition to section 201(a) of H.R. 11581, the "Drug and Factory Inspection Amendments of 1962." The association is composed of approximately 250 corporate food chains, ranging in size from as small as 2 store operations to organizations distributing through more than 2,000 stores.

Section 201(a) of H.R. 11581 would greatly expand the present inspection provisions of section 704 of the Food, Drug, and Cosmetic Act to authorize carte blanche inspection of "all things" in any establishment, including food stores, which bears on any violation of the act. The practical effect of this section of the bill is to make it impossible for anyone to refuse Government inspection of anything, including all business records.

NAFC recognizes that Government inspection is necessary in some instances to uncover violations of Federal law. This inspection authority should, however, contain some limitations to protect the legitimate interests of law-abiding businesses. Section 201(a) ignores this important principle. It eliminates any protection against unwarranted Government fishing expeditions, it invades the business privacy of food store operators, and it raises serious questions as to whether it permits unconstitutional search and seizure.

Moreover, the costs to a company's operations of such a widespread and detailed inspection may well be considerable. These costs, in turn, must be passed on to the consumer.

No attempt has been made in these hearings to demonstrate why such broad inspection authority would further the remedial purposes of the law. Certainly, no such need is based upon any alleged violations by NAFC members.

The Food, Drug, and Cosmetic Act can impose criminal penalties upon unknowing violators. To include food store operators within the coverage of this bill is therefore not only unjustified but is also a dangerous extension of governmental inspection authority.

Respectfully submitted.

CLARENCE G. ADAMY,
Executive Vice President, National Association of Food Chains.

VIENNA, VA., *August 21, 1962.*

DEAR SIR: During your committees deliberations on the drug mess I thought perhaps the enclosed might be of interest to you. It is not directly related but since some of the ingredients mentioned are also drugs there is a direct tie-in. I am generally unalterably opposed to Federal meddling in controls but recognize some are absolutely essential. This is one area that needs bolstering to combat the commercialism involved.

Do your children or grandchildren consume quantities of ice cream?

Sincerely,

N. D. EPPLY.

[From Prevention, August 1962]

ADDITIVES BY THE HALF-GALLON—IF YOU EVER THOUGHT ICE CREAM WHOLESOME FOOD, YOU WILL BE STARTLED AT THE REVELATIONS ABOUT WHAT EACH DELICIOUS SPOONFUL REALLY CONTAINS

The kids this year have over 200 flavors of ice cream to pick from though chances are that they'll choose one of the old standbys—chocolate, vanilla, or strawberry. For the more adventurous, there are rhubarb, mango, and coconut caramel to try.

The mango is described as "intensely lemon-colored," so it should meet with great success. Color is very important in the ice cream business, and an ice cream flavor whose color is "intense" is the most likely to get its fair share of a market which has every American licking or spooning over 15 pounds of ice cream per year.

Ice cream manufacturers have also discovered that ice cream which holds its expected texture longer sells better. The customer enjoys eating it more and the salesman in the store finds it nicer to work with.

In the course of his education the ice cream manufacturer soon becomes aware that to make a full-flavored ice cream takes a lot of flavoring. A lot of berries, chocolate, bananas, peaches, etc., cost a lot of money. So the manufacturer is usually graduated into a new approach—synthetic flavorings.

It is easy to see how the pattern of modern ice cream has developed. It is the story of the development of most modern food industries, whose aim is to make more cheaper, with no regard for food value, and little for safety. This is what has caused the gravest danger to us, in our food supply. Prevention finds this heedless profiteering cause for great alarm.

NO PROTECTION IN THE LAW

It took until 1958 for the United States Government to do anything at all about regulating by law the standards under which ice cream is produced. What went on in the industry before that was unspeakable. Now there is some control, but still one cannot help being astounded at the many dangerous additives that continue to be used in ice cream. Furthermore, Federal law does not control many aspects of manufacture in products which are sold exclusively within a single State—as most ice creams are. The States themselves are inconsistent in what they require in an ice cream. By and large, the ice cream industry has a fairly free hand in what it sells to the consumer as a final product.

All of this information became quite apparent as we read through a recently published book, "Ice Cream and Related Products," by J. H. Frandsen and W. S. Arbuckle. The book is intended as a basic handbook on the manufacture and selling of ice cream. As such, it gives a pretty full picture of what one is getting when one takes a half-gallon of ice cream home from the supermarket. Of course, Prevention's objections to commercially sold ice cream start with the most basic ingredient: the milk. Milk is no better for the body when it appears creamy and frozen than when it is poured from a bottle. The milks and creams in ice cream contain the same excessive tallness factor, the same butterfat, the same objectionable antibiotics and the same allergenic properties that Prevention has warned against for years.

But milk is only one of the drawbacks in ice cream. Sugar, for another, presents an even greater hazard to the body, and sugar constitutes up to 20 percent of what is sold to you as ice cream. Sugar is the one item in our diets that robs us most freely of valuable B vitamins, and sets our blood sugar to doing roller-coaster climbs and plunges. If there is any nutritive merit in the milk products in ice cream, the sugar quickly snuffs out any advantage. As "Ice Cream and Related Products" evaluates sugar's part in ice cream, "The main function of sugar is to increase the acceptance of the product, not only by making it sweeter, but more especially by enhancing the pleasing creamy flavor and the desired delicate true fruit flavors."

We doubt that parents who disallow their children candy and do allow them to eat ice cream are aware that every dish of ice cream a child eats contains two or three tablespoons of sugar. And if your family goes through the popular half-gallon package every week, as many families do, they're adding an extra pint of pure sugar to their already unimpressive diet.

CHEMICALS AND MORE CHEMICALS

Have you noticed that the ice cream in late years is notably free of ice crystals and has a smooth creaminess about it? That's no accident. It's the result of stabilizers, and emulsifiers. The stabilizers used to be of gelatin animal sources such as the skins and bones of calves and pork, or of vegetable sources: agar-agar, certain types of seaweed, etc. Today there has been a general switch to a cheaper synthetic chemical, sodium carboxymethylcellulose (CMC) is the basic stabilizer being used by the ice cream industry of the present day.

Emulsifiers are another of the strange things that have happened since making ice cream moved from the back porch to the factory. These are described as valuable for "the improved whipping quality of the mix, the production of a drier ice cream with a smoother body and texture having superior drawing qualities at the freezer, and more exact control which can be maintained in the various manufacturing processes." Natural emulsifiers such as eggs, milk proteins, fat lecithin, etc., have given way to the monoglycerides and diglycerides and to compounds known collectively as the poly compounds. The glycerides are artificial fats, which Prevention condemns for several reasons, not the least of which is their propensity as with all processed fats, to open the way to cancer and raise the natural cholesterol level of the blood.

The polyglycerides, of which polyoxyethylene monostearate is a commonly encountered example, have been used in breads, salad dressings, and ice cream. Federal law prohibited their use in these products, because, as one former Food and Drug Commissioner put it, they would make "good paint removers." Some are used for this purpose, as well as for antifreeze in cars and coolants in airplane engines. An elixir sold in the 1940's, and guaranteed to cure kidney disease, strep throat, or gonorrhea, contained diethyl glycol. After 105 men and women had died as the result of taking the elixir it was recalled from the market. Is diethyl glycol in your ice cream? The Federal law which outlaws the use of polyglycerides covers interstate commerce, but many ice cream manufacturers have designed their products for local consumption only. Unless the specific State has a law which prohibits polyglycols, chances are that local manufacturers will use it.

However, an even more offensive area of additives in ice cream is that of artificial flavoring and coloring. There are Federal laws against the use of artificial colorings or flavorings in ice cream. How well do you think they are observed on the State level?

SOME TASTY POISONS

Sales figures bear out the fact that vanilla is the most popular ice cream flavor of all. "Ice cream and Related Products" gives a run-down of the compounds now used to give ice cream that popular vanilla taste. You can be old fashioned—and extravagant—and use real vanilla beans. (Even these don't sound too appetizing when we learn that the extractions are prepared from finely cut vanilla beans in a solution of not less than 35 percent alcohol.) You can get vanilla concentrates, vanilla pastes, blends that contain true vanilla extracts mixed with synthetic, and preparations which "contain no vanilla bean extractives."

As the flavor desired gets more specialized, so does the method of acquiring it. Commercial ice creams almost never use the natural substance to attain the bulk of the flavor intended. In the book, "Food Flavorings," by Merory, we came across a chapter entitled "Imitation Flavors." Many of these formulae are the ones used to flavor the ice cream we are offered. Here is the recipe for banana flavorings:

	Grams
Imitation violet-formula MF 140	7.2
Benzyl propionate	22.0
Ethyl caproate	24.0
Heliotropin	24.0
Vanillin	24.0
Coumarin substitute	24.0
Linalaol	40.0
Amyl valerate	60.0
Amyl butyrate	120.0
Acetaldehyde	120.0
Amyl acetate	534.8

We investigated these ingredients in the Merck Index and came up with some surprising and disconcerting background on some of those that were listed. Heliotropin was found to be a drug, which if used in large amounts, will cause depression of the central nervous system. Amyl valerate is a substance that has been used as a sedative for hysteria. Amyl acetate is used to perfume shoe polish and in the manufacture of artificial silk, leather and in dyeing and finishing textiles. It is also known to cause headache, fatigue, and irritation of mucus membranes upon continuous exposure. Acetaldehyde is used, among other things, in the manufacture of plastics. It irritates the mucus membranes, and

has a general narcotic action. Large doses may cause death through respiratory paralysis. Its toxicity symptoms are similar to those of chronic paralysis.

This formula for banana flavoring was chosen at random from a listing of dozens of similar ones offering common flavors such as butterscotch, tutti-frutti, and blueberry in Mr. Merory's book. Banana ice cream is just one of many whose flavoring ingredients would give one reason to be concerned.

Other flavorings containing specific undesirable ingredients are: cherry-piperonal, a substance used to kill lice; aldehyde C-17, an inflammable liquid used in aniline dyes, plastics and synthetic rubber; pineapple-ethyl acetate, a chemical used for cleaning textiles, whose vapors may be irritating to the mucus membranes, and may damage the heart, the kidneys and the liver; nut flavor—butyraldehyde, used in rubber cement, rubber accelerators and synthetic resins; strawberry-benzyl acetate, a substance that can cause vomiting and diarrhea; black walnut-ammonium valerate, a medical sedative.

COLORS PRETTY BUT DEADLY

In coloring techniques, the additives men have had a field day, and ice cream manufacturers are right there waiting to make use of any new development. A technical book entitled "Synthetic Food Adjuncts" by Morris B. Jacobs, Ph.D., carried an interesting page on color association as it is understood by most food manufacturers, especially those who make confections such as ice cream. In the listings we saw such recommendations as "blackberry-dark, bluish-red; nut-walnut to golden brown; pistachio-bright green; strawberry-bright, bluish pink."

The author thoughfully lists a grouping of various shades of the primary colors, with the formulae for the different dyes to be mixed to achieve them.

BLACKBERRY

Dark

Amaranth: Caution: consult latest Government regulations before using this dye in foods, drugs, and cosmetics.

Indigotine: Dark blue dye.

Glycerol: Used as solvent, humestant, emollient, sweetener, in cosmetics, liquid soaps, confectionery, blacking, printing and copying inks, also in the manufacture of nitroglycerol. Medical use: vehicle for antitussines.

Blush-red

Ponceau 3r: Caution: consult latest Government regulations before using this dye in foods, drugs, and cosmetics.

Tartrazine: Caution: consult latest Government regulations, etc.

Indigotine: Dark blue dye.

Glycerol: See above.

NUT

Walnut

Amaranth: Caution, see above.

Tartrazine: Caution, see above.

Orange I: Orange dye.

Ponceau 3R: Caution, see above.

Indigotine: Blue dye.

Glycerol: See above.

Fast green: Dyeing silk, wool, jute, leather.

Medical use: Antiseptic for bacterial and mycotic infections.

GOLDEN BROWN

Amaranth: Caution, see above.

Orange I: Orange dye.

Tartrazine: Caution, see above.

Erythrosine: Brown color; caution, consult latest government regulations before using in food, dyes, and cosmetics.

Ponceau 3R: Caution, see above.

Brilliant blue: Dye for cotton and silks. Medical use: has been used as an antiseptic.

PISTACHIO

Bright green: Tartrazine. Caution, see above.
Brilliant blue: Dye, see above.
Light green: SF yellowish dye.

STRAWBERRY

Bright—amaranth: Caution, see above.
Tartrazine: Caution, see above.
Bluish pink: Indigotine—dye.
Glycerol: See above.
Frythrosine: Caution, see above.

As you can readily see, what one ordinarily thinks of as ice cream—milk, sugar (even that is often a synthetic sweetener), eggs and fruit, or real vanilla or powdered real chocolate—is not what we buy at the store nowadays. Probably an ice cream manufacturer with ideals of purity and honesty of product could not exist in his competitive industry.

And this conglomeration of chemical filth is what they have the nerve to offer to the public as a pure and nutritious food, especially good for children! We have even seen its use advocated as a breakfast food, atop dry cereal!

Ice cream is as jazzed-up a product as one can buy. Every trick in the book has been employed to make its appearance attractive, if deadly, and its manufacture as cheap as irresponsible methods permit. It is difficult to believe that intelligent people would permit their children to eat it, even occasionally, if they understood the chemical garbage it contains.

Show this article to your friends, for the sake of their little ones if for no other reason. And please, as you value your health don't ever succumb yourself to those pretty colors and sweet flavors achieved with deadly chemicals.

THE AMERICAN PUBLIC HEALTH ASSOCIATION, INC.,
Washington, D.C., August 21, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, New House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: The American Public Health Association has, for several years, been concerned with the problems resulting from the manufacture and sale of an increasing number of drugs. In the opinion of the APHA, serious defects have become apparent during recent years relative to the clinical investigation, distribution, promotion and advertising of hundreds of new drugs which are marketed in the United States annually. These inadequacies are evidenced by the fact that since 1957 at least 19 drugs have had to be recalled or withdrawn. The following is a list of 15 of these drugs and manufacturers, and the reason for recall or withdrawal follows:

Manufacturer	Drug	Reason for recall or withdrawal
Lederle Laboratory	Lederle liver injection with folic acid.	Mislabeled—contained epinephrine injection.
Sandoz, Inc.	Landostene	Agranulocytosis.
Blair Laboratories	Kerid	Swelling and soreness of the ear.
G. F. Harvey	Cerulav	Do.
Purdue Frederick Co.	Cerumenex	Do.
Eaton Laboratories	Furadantin oral suspension	Subpotent.
Pfizer Laboratories	Syngesterone aqueous suspension.	Potency variations.
Hoffman LaRoche	Marsalid	Liver damage.
McNeil Laboratories	Flexin	Hepatitis.
White Laboratories	Entoquel	Severe atropine-like reaction in infants.
Upjohn	H.F.C. albamycin	Labeling error.
Eaton Laboratories	Altafur	Dangerous side effects.
Upjohn	Monase	Agranulocytosis.
E. R. Squibb & Sons	Pentids "400"	Mixed in error with pentids sulfa syrup.
Wm. S. Merrell Co.	MER/29	Caused cataracts, baldness, etc.

The severity of this situation has recently been brought to the attention of all through the tragic experience in thousands of pregnant women abroad following their use of thalidomide. In this instance one of the most serious defects in the problem of drug control was clearly indicated—that is the lack of adequate preliminary research before clinical investigation is permitted. Investigation of new drugs does not regularly include careful research of the drug on pregnant animals. Also, clinical investigators are not always fully apprised of possible and dangerous side effects. This, it seems to us, was demonstrated in the use of thalidomide resulting in congenital malformations in thousands of newborn babies.

In the light of these problems relating to the multiplicity of new drugs and the tragic experience with thalidomide, the executive board of the APHA on August 14, 1962, approved the attached statement and has requested that it be made available to your committee in order that you may know the position of our association relative to this matter. Additional information which may be of assistance to your committee will be provided at your request.

Respectfully yours,

NOBLE J. SWEARINGEN,
Director, Washington Office.

STATEMENT OF THE EXECUTIVE BOARD, AMERICAN PUBLIC HEALTH ASSOCIATION, AUGUST 14, 1962

The American Public Health Association expresses deep concern occasioned by reports of the occurrence of large numbers of congenital anomalies in several countries from the prescription for pregnant women of an insufficiently tested drug marketed under a number of different proprietary names.

We strongly commend the work of Dr. Kelsey, a member of the staff of the FDA who prevented the release of the drug for sale in the United States. At the same time in order further to diminish the possibility of the promotion and sale of harmful drugs in the United States, the American Public Health Association—

(1) Reaffirms the importance of its resolution on drugs adopted in 1960 urging on welfare, health, and other public agencies limitation of public expenditures for drugs to those prescribed by nonproprietary generic names included in United States Pharmacopoeia or National Formulary (accepted dental remedies) or if not included approved by a qualified formulary committee.

(2) Emphasizes the importance of strengthening the power of the Food and Drug Administration to require satisfactory evidence of safety before any drug is released for general use, both by legislation and by increased appropriations to permit expansion of qualified professional and technical staff.

(3) Requests that the FDA require that generic names be printed on labels and in advertising in equal prominence with proprietary names.

(4) Recommends that by legislation or regulation release of drugs for trial in human patients be conducted according to protocols which meet the standards to be established by the FDA in consulation with the PHS and which conforms to principles of ethics in clinical research established by the AMA.

(5) Particularly calls attention to the risk of congenital anomalies resulting from use of inadequately tested drugs and urges that drugs which may be used during pregnancy be subjected to suitable tests as to teratogenic effect prior to their approval by FDA.

(6) Recommends that the appropriate authorities of the Federal Government establish restrictions upon the import into the United States of drugs not approved for sale in the United States except for clinical trials under protocols to be established by the FDA.

(7) Calls upon the pharmaceutical industry to hasten the implementation of these measures of protection for the public by initiating voluntary action to these ends pending the development of new regulations and the enactment of needed legislation by the Federal Government.

THE UNITED STATES PHARMACOPOEIA,
New York, N.Y., August 24, 1962.

Re H.R. 11581, antibiotics certification.

HON. OREN HARRIS,
Chairman, Committee on Interstate Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: This will convey the information on antibiotics certification that I promised to provide in response to a request made by Congressman Roberts during my appearance as a witness on August 22.

Of the hundreds of substances discovered in the past 20 years that may be classed as antibiotics by virtue of the fact that they are produced by living organisms, relatively few have been introduced for use as drugs. These latter constitute only slightly more than a dozen different basic molecular structures. I have compiled a list of them, together with certain information that bears on the need for their being subject to batch certification.

During my appearance on the stand, Congressman Moss read from an address recently delivered by Mr. John L. Harvey, Deputy Commissioner of FDA, in support of the legislation now before Congress. With respect to batch-by-batch certification, Mr. Harvey stated that certification of all antibiotics is needed because (*a*) "antibiotics are the first choice in treating life-threatening infectious conditions"; (*b*) most antibiotics are produced by processes that are complex and yield "undesirable byproducts"; and (*c*) "the potency of antibiotics must be determined by biological assay procedures, the interpretation of which requires unusual competence."

I regret that, not having seen a copy of the address earlier, I was not in a position to comment on it adequately during the questioning period. Hence I wish now to offer some remarks.

With respect to point (*a*), there is no disputing that antibiotics are the first choice in treating many infectious conditions but this blanket statement requires considerable qualification. In the view of the outstanding physicians who serve on the U.S.P. Committee of Revision, it is best to use one of the newer sulfa drugs in many cases in preference to antibiotics. However, infectious diseases make up only part of the medical emergencies that physicians face daily so that the role of antibiotics in medicine is not so different that, as a class, they should be given different status under the law.

The statement (item (*b*)) that antibiotics are produced by complex processes which sometimes lead to undesirable products also does not distinguish this group from other drugs for which the same thing may be said. One of our most important groups of drugs are those which produce relaxation of muscles so as to facilitate the work of the surgeon. The first of these, tubocurarine chloride, is the poisonous ingredient of what is popularly known as "arrow poison" and is obtained from crude materials collected by South American tribesmen. The best methods of extracting tubocurarine yield a product that contains other substances having undesirable activity. With respect to synthetic muscle relaxants, the chemical manufacturing process is such as to require great care in eliminating harmful byproducts. Hence an argument based on complexity or undesirable byproducts is scarcely moving in putting the antibiotics in a class by themselves as requiring special FDA handling.

With respect to item (*c*), it is simply not true that the potency of antibiotics must be determined by biological assay, because chemical assays are used for many of them, as is indicated in the enclosed table. The FDA itself uses these chemical assays. Furthermore, this again does not place the antibiotics in a separate class because there are many drugs which are not subject to certification that can be tested only by biological assay. I need mention only digitalis, the indispensable heart drug; posterior pituitary, the drug used in childbirth; or heparin, which is used in the emergency of acute heart attacks to prevent further clotting of the blood in the coronary artery. Other less important drugs also require biological standardization. Insulin-containing products also require biological standardization, but these of course are subject to a type of batch certification that works less hardship on producers and does not require duplicate

testing on the part of the Government. Indeed, if the certification of antibiotics were put on the same basis as that of insulin, the present proposals would be less objectionable.

The ultimate destination of the fees paid the Government for the antibiotics program was the subject of a regrettable misunderstanding between me and Congressman Moss. The point I wanted to make is simply that once a Government agency has built up a testing unit for which it charges fees, it is unrealistic to expect that unit to recommend its own abolishment. If we cannot depend upon the Congress to look carefully into the continued need for such services, I am sure that citizens will have a right to feel that they are not being adequately represented.

With respect to the statement that antibiotics certification costs only one-twentieth of a cent per dose, the fact should be brought out that this is an overall average for the industry, and is made up of widely disparate figures. For the large manufacturer who submits a large batch of antibiotics, the testing fee is not much larger than that charged for a small batch submitted by a small manufacturer so that the latter's cost per dose is much larger. This will tend to drive the small producers of antibiotics completely out of business. A trend in this direction is already indicated in the pharmaceutical business for other reasons as shown by a recent survey completed for and published by the Pharmaceutical Manufacturers Association. This shows that during the past 20 years, 544 new basic drugs were introduced. One-third of these were developed by 5 firms alone and three-fourths of them were developed by only 19 firms. With respect to the role played by the antibiotics in this picture and the trend to concentration in the industry, the record shows that nearly one-fifth of the total of 544 drugs were antibiotics or closely related drugs also used to treat infections.

There is a further aspect of the true and full cost of the FDA certification program that bears examination. This is the immense cost in technical manpower which, as estimated by the Comptroller General in his 1960 report to Congress, amounted to 128 man-years in 1959. An estimate given by another witness this week put it at 150 man-years for 1961. Skilled technicians are too scarce and FDA needs them elsewhere too much for it to continue devoting such a huge effort to the duplication of testing already done.

It is of interest to note that the above-cited Comptroller General report states, on page 10, in respect to the fees paid for the FDA testing of antibiotics, insulin, and colors:

"In the fiscal year 1960, about $13.5 million was obligated for the enforcement program and $1.3 million was obligated for the certification program. The certification program was financed by fees received from users of the service."

For the reasons cited in my statement and above, we feel that your committee will do a great service to the public welfare by limiting batch certification to the antibiotics that really need it.

In order to expedite delivery of this letter I am sending it only in triplicate. Additional copies will be sent next week.

I thank you again for the courtesy of your attention last Wednesday.

Sincerely yours,

LLOYD C. MILLER, Ph. D.,
Director of Revision.

Antibiotics in current use, with estimate of need for FDA batch certification on basis of state of purity, and the kind of assay required

[Legend: U.S.P., Official in United States Pharmacopeia; N.F., Official in National Formulary]

Antibiotic	Present official status	Number of therapeutically useful variants [1]	General state of purity and stability	Biologic assay required	Suggested need for batch certification
Amphotericin			Good	Yes	Probable.
Bacitracin [2]	U.S.P.		do	Yes	Do.
Chloramphenicol [2]	U.S.P.	3	Excellent	No	None.
Colistimethate			Fair	Yes	Definite.
Erythromycin	U.S.P.	6	Excellent	No	None.
Fumagillin			Fair	Yes	Probable.
Gramicidin	N.F.		Excellent	Yes	None.
Griseofulvin			Good	Yes	Probable.
Kanamycin	U.S.P.		Excellent	Yes	None.
Neomycin	U.S.P.		Good	Yes	Do.
Novobiocin	U.S.P.		do	Yes	Do.
Nystatin	U.S.P.		do	Yes	Do.
Oleandomycin		2	do	Yes	Probable.
Penicillin [2]	U.S.P.	13	Excellent	No	None.
Polymyxin	U.S.P.		Good	Yes	Probable.
Ristocetin			Excellent	Yes	Do.
Streptomycin [2]	U.S.P.	2	do	Yes	None.
Tetracycline [2]	U.S.P.	5	do	No	Do.
Tyrothricin	N.F.		Good	Yes	Do.
Vancomycin			do	Yes	Probable.
Viomycin			Fair	Yes	Do.

[1] If more than 1 form is useful.
[2] FDA certification now required for most batches.

NATIONAL FRUIT & SYRUP MANUFACTURERS ASSOCIATION, INC.,
New York, N.Y., July 18, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The purpose of this communication is to reaffirm the position which our members have taken with respect to H.R. 11581 opposing, without reservation, those provisions of the said bill with regard to factory inspection that would enlarge the authority of Food and Drug inspectors so as to allow the invasion of the files and records, including such confidential material as formulas and processes of a manufacturer.

Our members rightly feel that such enlargement of authority would not in any way prevent adulterated or mislabeled food from reaching the public but would expose the manufacturers' private and confidential formulas to the danger of falling into the wrong, unauthorized hands.

We further feel that the present laws covering factory inspection adequately protect the consuming public by insuring shipments of wholesome foods prepared under sanitary conditions.

For the foregoing reasons, we again place ourselves on record as being definitely opposed to the legislation in question on which the public hearings which have been held before your committee are being continued.

While we do not ask for leave to appear before the committee personally, at the continued hearings, we respectfully urge that our opposition to this bill appear on the record.

Respectfully yours,

ROBERT M. RUBENSTEIN,
Executive Director and Counsel.

HILLS BROS. COFFEE, INC.,
San Francisco, Calif., June 14, 1962.

Subject: H.R. 11581.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: As a part of the U.S. food industry, we are deeply concerned over the ultimate effect of this bill presently under consideration.

The food industry fully subscribes to the principle of consumer protection as provided for under the basic laws with respect to the Food and Drug Administration and particularly the compulsory factory inspection amendment of 1953, which confined this power to matters of sanitation and specifically prohibited burdensome investigations not pertinent to the basic principles involved.

We take particular exception to "Title II: Clarification of and Strengthening of Factory Inspection Authority," which should be deleted in its entirety insofar as it applies to the food industry.

Some basic reasons for opposition

(1) Unlimited inspection authority is contrary to basic American principles.

(*a*) Since the public has not suffered under present law, it is not necessary to sacrifice principle for unproven gain.

(2) Research and development will be retarded, since trade secrets and processes would be subject to disclosure by Government inspectors whether deliberate or inadvertent.

(*a*) To counter this, manufacturers would tend to switch their research and development activities to foreign countries at the expense of American industry and labor.

(3) The cost of these types of inspections (Government and industry expense) will ultimately be passed along in the form of taxes and cost of goods to consumers.

(4) Foreign-produced goods are not subject to the same regulations and consequently enjoy a competitive advantage at a time when American industry is being hard pressed.

We believe that under present law the American consumer is adequately protected on foods processed in the United States. Furthermore, the consumer will gain the benefits of improved products at lower cost through research and development and fostering of competitive home industry.

Since the U.S. food industry is at a competitive disadvantage and the consumer is not protected in the same manner or to the same degree with foreign food products, we feel that a real service could be rendered by reviewing that particular phase of consumer protection.

Yours very truly.

REUBIN W. HILLS III, *President.*

THE R. T. FRENCH CO.,
Rochester, N.Y., June 13, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: We understand your committee will begin hearings on H.R. 11581 (drug and factory inspection amendments to the Federal Food, Drug, and Cosmetic Act) within a very short time. Although we are not able to send a corporate officer to these hearings, we nevertheless feel our position on this amendment might be of interest to you.

The relationship between reputable grocery manufacturers and the Food and Drug Administration has been marked for a long time by a cordial and mutual respect. This is due to a number of reasons, among them the recognition that the activities of the FDA benefit the industry as well as consumers. There has also been close contact between FDA and the industry at numerous conferences and through the independent Food Law Institute. We are at a total loss to see how the enforcement of the Food and Drug Act will in any way be benefited by H.R. 11581.

We have FDA inspectors on our premises at various times. We know of no instance when there was any difference of opinion over what they could or should look at. They go about their business most capably, assisted by members of our staff whenever necessary.

The unlimited powers of inspection into personnel records, complaint files, secret formulas, etc., appear to use to be an unnecessary and conceivably hostile invasion of privacy by the Federal Government. This great authority could be abused by inexperienced inspectors or by ones with a grudge against a particular grocery manufacturer. Moreover, it would adversely affect the beneficial climate in which the grocery manufacturing industry and the FDA operate.

Most manufacturers have the impression, warranted or not, that H.R. 11581 was written more for its political salability as a supposed consumer aid than for any practical purpose of improving the efficiency of FDA enforcement or food product quality.

Sincerely,

C. R. YOUNG, *Secretary.*

LIBBY, MCNEILL & LIBBY,
Chicago, Ill., July 10, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Libby, McNeill & Libby has been engaged in the processing of canned foods for almost 100 years and now also operates facilities in the Northwest, Florida, and on the east coast for the freezing of fruits and vegetables. It is one of the world's largest suppliers of a diversified line of canned and frozen foods, with processing facilities located throughout the mainland and in Hawaii, and with extensive plant facilities in foreign countries. Its domestic and foreign-produced products are marketed throughout the free world.

This company has over its long history consistently supported the 1906 Food and Drug Act, the enactment of the Food, Drug, and Cosmetic Act in 1938, and the several amendments to that act, through the National Canners Association, representing substantially all of the Nation's producers of canned fruits, vegetables, meats, specialties, and seafoods.

We wish to voice our vigorous objections to the enactment of title II of H.R. 11581 and strongly endorse the detailed statement of opposition submitted by the National Canners Association on behalf of its membership on June 21, 1962, and the oral presentation made by the association's general counsel, Mr. H. Thomas Austern. The NCA statement sets out in great detail the many substantial reasons for our opposition to this unwarranted demand for increased authority on the part of the Food and Drug Administration over canners and freezers. There is no country in the world supporting a higher standard of esthetic values than the United States, and nowhere is there such a plentiful supply of wholesome, quality food products than is prepared in this country. It is our firm conviction that the increased inspection authority sought under this bill is wholly unnecessary and no reasonable explanation has been advanced to support the suggested amendment of section 704 of the present Food, Drug, and Cosmetic Act.

The unprecedented authority granted under this proposed bill to search the property and records of the canners and freezers raises, in our view, serious and substantial doubts as to its constitutionality.

Furthermore, we believe it is certain to follow that broadened authority will be accompanied subsequently by demands for more inspectors and increased budgets for FDA—all at a time when we have long since reached the point where the vesting of additional controls in Washington which are patently unnecessary exceeds both good judgment and sound practice and the people's ability to meet the increasing tax burden. The hearings before the committee, we are confident, will not produce testimony in support of any demonstrated need for such further control and, in the absence of concrete evidence to the contrary, the request for broadened inspection authority should be defeated.

The Food and Drug Administration, as has been pointed out for the record, already possesses ample powers of inspection and investigation which are in every way adequate for the protection of the public interest. The present language in section 704 providing for mandatory factory inspection was carefully considered and adopted only after extended congressional deliberation. The intervening years of long experience with that section has served to amply confirm the decision made at that time.

The request for broadened inspection authority over foods will neither serve the purposes and objectives of the Food, Drug, and Cosmetic Act, nor make any constructive contribution to the progress the food industry has shown under the present act. We stanchly support the statement submitted by the National Canners Association and ask that our views likewise be made a part of the record.

Sincerely,

ROBERT L. GIBSON, Jr.

KALAMAZOO SPICE EXTRACTION CO.,
Kalamazoo, Mich., July 5, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: This letter concerns provisions in H.R. 11581 now pending before your committee concerning permission granted to inspectors of the Food and Drug Administration to examine all records, papers, etc., of food manufacturers. In particular, my letter is addressed to chapter 7, section 704(a), entitled "Factory Inspection." This is on page 15 of the Ramseyer print.

My company is actively engaged in the processing of spices and other condiments for use in the food industry in the United States. We have supported insofar as we could the food additive and color additive amendments, and were one of the first firms to have a food additive amendment issued. We are in sympathy with the objectives of the food and drug regulations, which are now in existence, as well as with the objectives of H.R. 11581.

We feel, however, that before the broad powers of examining records, papers, research work, etc., are granted to inspectors of the Food and Drug Administration, an overwhelming case should be made for the unsatisfactory operation of the present provisions for factory inspection. Needless to say, violations of the law are now taking place which would be prevented if these powers were granted to food and drug inspectors, but I think it better to allow these violations to continue through difficulty with enforcement of the present act, provided there is not serious danger to the public health, than to increase the authority of the Federal Government to invade hitherto private areas of personal and business life.

It is my opinion, based on experience with the controls and objectives of major food manufacturers in this country, that products are not incorporated into foods which are injurious to the public health on a significant scale, and never knowingly by responsible food manufacturers. I do not believe that the factory inspection provisions would significantly impair the operation of most food manufacturers, but would make it more difficult for some of the marginal operators to do what they are now doing. The danger of revealing processes and secret formulas can well be overemphasized, as it has been my experience that little is very secret in food industry. Particularly, secrets are usually lost within a period of a few years.

The important issue, therefore, in our opinion, is whether or not further incursion by the Federal Government into what has here been considered private affairs of individuals or corporations should be encouraged. It is my understanding that it is possible for Congress to subpena any papers of any corporation if they so desire, in connection with an investigation, and it is my belief that similar seizure of papers could be effected by agents of the Government under court warrant. Although this would be too cumbersome a procedure for day-to-day regulatory control, it nevertheless provides an avenue for investigation by your committee as to whether or not the inspection powers are necessary and in the public interest.

It is always easy to attempt to control an alleged evil by enacting a restrictive law, and such a law may indeed eliminate some of the evil. In our free society, we must decide how far we should restrict the freedoms of individuals to prevent the unethical person from taking advantage of others. I should prefer to have us err on the side of too much freedom, rather than too much restriction, and this is why I believe that modifications of section 704 should not be made unless an overwhelming case has been prepared indicating the absolute necessity.

I should appreciate your incorporating these remarks in the record of the committee if possible.

Very truly yours,

PAUL H. TODD, JR.,
President.

ASSOCIATION OF NATIONAL ADVERTISERS, INC.,
OFFICE OF THE PRESIDENT,
New York, N.Y., August 28, 1962.

Congressman OREN HARRIS,
U.S. House of Representatives,
Washington, D.C.

DEAR CHAIRMAN HARRIS: I am writing concerning H.R. 11581 and specifically to express the serious reservations this association has about section 131 of the bill which involves advertising.

ANA does not have a primary interest in the prescription drug, or any other vertical industry as such. Its concern is to preserve and advance sound, effective, and wholesome employment of national advertising processes for all American business.

ANA is strongly opposed to the principle inherent in section 131 of H.R. 11581 of automatically requiring by legislative or agency mandate the incorporation of any lengthy statement into the advertising of a given product.

Advertisements are, by their nature, unavoidably limited in the space or time available for communicating their messages. The smaller the advertiser, and the less money he can devote to advertising, the more curtailed will be the physical boundaries within which he must operate.

There simply is not the time or space in print or broadcast media for an advertiser to set forth extensive dissertations concerning his product or service.

To require that he do so is, in effect, to forbid him from advertising at all. The smaller the company, and the less its ability to invest in long commercials or large space advertisements, the more effectively would it be barred, by regulatory requirements for affirmative disclosures, from using advertising in its competitive efforts.

The law in its present state already protects the public against an advertiser's failure to disclose those additional matters which need to be stated in order to prevent deception from arising out of his claim and no further legislation is needed for that purpose.

In this connection our attorney reminds me of the following section of Wheeler-Lea Act: "* * * in determining whether any advertisement (of a food, drug, device, or cosmetic) is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisements, or under such conditions as are customary or usual" (Wheeler-Lea Act of March 21, 1938, 52 Stat. 111, 15 U.S.C. 55(a)(1)).

These illustrative cases, brought under present law, prohibited deception created by the advertisers' failures to disclose important matters in connection with their advertised claims (*Ward Laboratories, Inc.* v. *F.T.C.*, 276 F. 2d 952 (2 Cir. 1960)), (*Wybrant System Products Corp.* v. *F.T.C.*, 266 F. 2d 571 (2 Cir. 1959)), (*L. Heller & Son, Inc.* v. *F.T.C.*, 191 F. 2d 954 (7 Cir. 1951)), *American Medicinal Products* v. *F.T.C.*, 136 F. 2d 426 (9 Cir. 1943)).

Section 131 would go further, however. It would impose upon an advertiser, even one who might wish to publish no more than the brand name of his product, the obligation to set forth in his advertisement virtually a textbook chaper describing all the conditions for which it will (and will not) be efficacious, its side effects and its contraindications including, we suppose ("full and accurate"), all exceptional, variant and qualifying circumstances and influencing factors.

Administered as written, this would, as a practical matter, make impossible all small space prescription drug advertisements, and almost all large ones.

Extended to nonprescription drugs, or to virtually any other products, arbitrarily compelled recital of detailed product specifications within the four corners of a print advertisement, or in the 10, 20, 30 or (at most) 60 seconds of a broadcast commercial, would fatally restrict the use of the advertising process as such.

Advertisements are physically not equipped to serve as product manuals. Legislative or administrative efforts to impose that function upon advertising could not be complied with and, hence, ultimately could only force its abandonment.

For these reasons the ANA is deeply disturbed over the underlying concept which, so far as it knows, appears for serious legislative consideration for the first time in section 131.

If advertising space and time can be preserved for the communication of brief messages, designed to engage the interest or stimulate the recollection of potential customers in the advertiser's product, and if detailed specifications, as desired by the purchaser, are available through labeling, product brochures, or other more suitable media, the public will be adequately protected, and advertising's indispensable stimulant effect upon American commerce, and its competitive aid to the users of the small print advertisements and spot commercials in entering and remaining in the national marketplace, will not be put into a straitjacket.

Sincerely yours,

PETER W. ALLPORT.

MANUFACTURING CHEMISTS' ASSOCIATION, INC.,
Washington, D.C., August 29, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The Manufacturing Chemists' Association, Inc., a trade association with a membership representing more than 90 percent of the Nation's chemical productivity, is concerned with the sweeping new factory inspection provisons of H.R. 11581 now pending before your committee. These provisions are found in sections 201 and 202 of the bill which would extend the existing factory inspection authority in the Food, Drug, and Cosmetic Act to include records and all other things in affected factories bearing on violations or potential violations of the act.

Our analysis of these provisions has been conducted solely in terms of their impact on our member companies who manufacture food and food additives. As to their impact on manufacturers of drugs, we defer to the views expressed by the Pharmaceutical Manufacturers Association and others more intimately concerned with that aspect of the matter. Thus, our interest involves the new factory inspection proposals as they related to food or, more particularly, to food additives.

Our concern centers on two aspects of the proposed additional inspection authority:

(*a*) The threat to confidentiality of trade secrets, research, pricing and sales data, and personnel records of individual employees.

(*b*) The constitutionality of such authorization of unlimited inspection for purpose of uncovering evidence of violations or "potential violations," in possible derogation of rights against unreasonable searches and seizures guaranteed by the fourth amendment.

In the absence of a clear showing that the Food and Drug Administration must be given such sweeping authority to protect the public health, the wisdom of granting such broad inspection powers should be open to serious doubt. We believe that review of the testimony in these hearings and, in fact, of all events since the 1953 amendments to the Food, Drug, and Cosmetic Act, would demonstrate no such need.

In view of the passage by the Senate of S. 1552 restricting these new inspection powers, with appropriate limitations, to manufacturers of prescription drugs, it would seem appropriate to modify sections 201 and 202 of H.R. 11581 in a similar pattern. Certainly, the imposition of the proposed unlimited inspection authority without adequate demonstration of need, at least insofar as manufacturers of food additives are concerned, seems unwise and unjustified.

On behalf of the Manufacturing Chemists' Association, I, therefore, strongly urge that food and food additives be excluded from the factory inspection provisions of H.R. 11581 and would appreciate your placing this letter in the record of the hearings so that our views can be given most careful consideration by all members of your committee and of the Congress.

Sincerely,

J. E. HULL.

THE WINIFRED MASTERSON BURKE RELIEF FOUNDATION,
THE BURKE FOUNDATION REHABILITATION CENTER,
White Plains, N.Y., August 28, 1962.

Hon. OREN HARRIS,
House of Representatives,
Washington, D.C.

DEAR MR. HARRIS: I have just sent you a wire regarding impending legislation aimed at restricting clinical and scientific appraisal of drugs in an effort to reduce incidental hazards. Although the aim of such legislation may be laudable, there is great concern on my part, as well as that of fellow scientists, that such restrictions may unduly hamper medical progress and have the ultimate effect of impeding the attack of medicine on many diseases. The restrictions imposed by the present legislation, had they been in effect 20 years ago, would have reduced or made impossible the availability of antibiotics and cortisone-like substances.

Accordingly, it is requested that these matters be considered in action upon this bill (S. 1552).

Very truly yours,

ANTHONY A. ALBANESE.

NOVILLE ESSENTIAL OIL CO., INC.,
North Bergen, N.J., August 28, 1962.

Congressman OREN HARRIS,
Chairman, House Interstate and Foreign Commerce Committee
House Office Building, Washington, D.C.

DEAR MR. HARRIS: Please permit us to go on record that we emphatically support and agree with the statement made by Mr. Frank F. Dittrich, president of the Essential Oil Association of U.S.A., before the House Committee on Interstate and Foreign Commerce, relating to H.R. 11581, which is now being reviewed by your committee.

It is our candid opinion that there is no historical or valid reason to support the need for factory inspection of perfume oils used in products for external application only.

The lifeblood of our business is the formulas for the making of fragrances developed by us continuously, and having their roots in traditions going back for centuries. We have not a single case on record, having been in business for over 20 years, where the perfume oil which we supplied to our many customers, even remotely could be blamed for harm to the human body. On the other hand, being exposed to a possible violation of secrecy through factory inspection, could jeopardize the very basis of our business to which we have dedicated our whole life, and on which depend innumerable numbers of people for their livelihood.

We feel this is the essence of our objection to H.R. 11581, and the more elaborate exposition by Mr. Dittrich before your committee, should surely convince you of the justification of our stand.

Respectfully submitted.

A. G. NICKSTADT, *President.*

BLAIRSTOWN, N.J., *August 28, 1962.*

Mr. W. E. WILLIAMSON,
Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

MY DEAR MR. WILLIAMSON: The Food and Drug Administration's grasp for added authority to inspect papers, files, books, and records in food plant offices as contained in H.R. 11581 should be rejected.

The requested expansion of so-called factory inspection authority to permit FDA inspectors to rummage through business records in food plants has nothing to do with current problems in the drug field. Efforts are being made to ride the unhappy results of the thalidomide episode to secure enactment of unnecessary and unwise legislation having to do with papers, books, and records in dairy and other food establishments.

Title II of H.R. 11581 which has to do with factory inspection should be disapproved by the House Committee on Interstate and Foreign Commerce because it is unnecessary and unwise.

Authority to inspect business papers and records of food establishments is not necessary because the food supplies of the United States are the purest, safest, and most nutritious in the world.

Added authority is unnecessary because under existing law food and drug inspectors:

(1) May inspect the food plant and all machinery and equipment bearing on sanitation;

(2) May inspect all ingredients and finished products, manufactured in the plant;

(3) May take samples of raw materials and finished products for analytical purposes;

(4) May inspect all containers and packaging material used;

(5) May inspect all of the labels and labeling material;

(6) May demand shipping records from carriers or from persons holding products in question in civil proceedings and may use time-honored court processes in criminal prosecutions.

Added authority to the Food and Drug Administration to inspect papers, files, books, and records is unwise. Congress itself, in enacting compulsory factory inspection in 1953 stopped at factory inspection, and the House committee explicitly did not authorize business records inspection.

Added authority to inspect papers and files in food establishments is unwise because:

(1) Based upon "potential" violations it constitutes a "fishing license."

(2) Under the language of the legislation private, company formulations (trade secrets) are not protected.

(3) It will fail of its purpose because fly-by-night operators who would engage in willful adulteration would not be expected to keep records.

(4) It is believed that the provisions of title II cannot be reconciled with the prohibitions against unreasonable searches contained in the fourth amendment to the Constitution.

(5) And finally, even though title II was held unexpectedly to be constitutional, the legislation sanctions an erosion of the rights of citizens which have been enjoyed since the founding of the Republic.

Respectfully submitted.

T. O. HOFMAN.

ALBERT EINSTEIN COLLEGE OF MEDICINE,
YESHIVA UNIVERSITY,
DEPARTMENT OF PHARMACOLOGY,
New York, N.Y., August 28, 1962.

Hon. OREN HARRIS,
House of Representatives,
Washington, D.C.

MY DEAR MR. HARRIS: I have deliberated a long time before addressing myself to your committee, as the lateness of this communication testifies. I am most confident of the wisdom of decisions reached by a carefully conducted investigation of a congressional committee. However, I am apprehensive of amendments to proposed legislation which may arise from emotional reactions that have little basis in fact. I would therefore like to outline to you some of my thoughts that relate to procedures for the control of the introduction of new drugs.

Before proceeding, let me state my qualifications for the opinions I am about to express. I have been an academic pharmacologist for 30 years. During that time I have been on the faculty of Yale and Columbia and presently am chairman of the department of pharmacology at the Albert Einstein College of Medicine. During the war years I was a major in the Army, United States and served as chief of the pharmacology section of the Medical Division of the Chemical Warfare Service. I was a member of the investigating team that introduced the use of the highly toxic chemical warfare agents, the nitrogen mustards, for the treatment of human cancer. I was a member of the first pharmacology and experimental therapeutics study section of the U.S. Public Health Service and subsequently served two additional terms, one as chairman. I am coauthor of a widely used textbook of pharmacology and am a past president of the American Society for Pharmacology and Experimental Therapeutics. I am presently a member of the Pharmacology Training Committee of the U.S. Public Health Service and a member of the executive committee

of the Division of Medical Sciences of the National Research Council. During the past decade I have also had close contacts with pharmaceutical industry as a consultant.

Lastly, before proceeding, may I say that although I respectfully request that my opinions be incorporated in the record of the hearings of your committee on H.R. 11581, they are being addressed solely to you in your official capacity. Indeed, I do not ask to appear to testify for there is little that I can add to my following remarks.

One of the greatest achievements of modern medicine has been the progressive increase in life expectancy. This has often been confused with a change in life span. Nothing could be further from the truth. The potential span of life is little or no different than in biblical times. It requires millenniums to change the genetic characteristics which inevitably result in death.

However, life expectancy has increased tremendously and more and more of our population can look forward to the enjoyment of their full life span. Many factors have contributed. One of the most significant relates to improved prenatal and early postnatal care. Advances in nutrition have also been of primary importance. The science of immunology has made outstanding contributions to public health. In recent years, however, the major influence in the increase in life expectancy has resulted from drug therapy. The greatest advances have occurred in the field of infectious disease but it is becoming more and more obvious that metabolic diseases, degenerative diseases, mental diseases, and even malignant diseases may soon be treated with equal success.

This achievement is a matter of record. It has been accomplished by the combined efforts of basic and applied research in the environment of academic and clinical medicine and pharmaceutical industry. According to the testimony of some, we are rashly decimating our population by the hasty introduction into therapy of new drugs that have been inadequately studied in laboratory animals. Nothing could be further from the truth and actuarial statistics belie it.

During the course of any major medical advance there is a small minority that may take advantage. But this does not apply to the ethical pharmaceutical laboratories that have made such important contributions to current progress. I could cite many examples from my personal experience where the cautious and conservative attitude of pharmaceutical industry has delayed the clinical trial of drugs by months to years. These responsible members of pharmaceutical industry would welcome reasonable legislation to protect them from the onus created by those who are less dedicated. However, legislation which imposes restrictions on an area of medical research which has made such a major contribution to public health cannot be constructive if hastily considered under circumstances when emotion conquers reason.

The problems relating to the clinical trial of drugs are legion and cannot be adequately met by blanket legislation. Permit me to cite just a few examples. Preliminary investigations in a few selected patients by experienced clinical pharmacologists represent an early stage of drug development. Most drugs fail to pass these early tests, occasionally because of unexpected untoward effects, but more commonly because of lack of efficacy in man. To impose severe restrictions on the early testing of candidate therapeutic agents by experienced investigators in a research environment could halt progress in the field of drug therapy. Of course, precauctions must be taken and careful animal testing must be performed before these initial clinical trials, but they need not and indeed cannot be as elaborate as those necessary when more extensive clinical testing is contemplated. Finally, when a drug is to be given to thousands of patients, but still on a trail basis, the precautions must be just as great as those exercised before the release of a drug for general use. No ethical pharmaceutical company would take exception to such restrictions since they are already self-imposed.

Another problem which must be carefully considered before blanket restrictions are placed on the clinical testing of drugs relates to the seriousness of the disease which is being treated. A drug to be tested in the treatment of cancer may have serious toxic effects in animals and yet be acceptable for clinical trial in man. On the other hand, no serious toxicity can be tolerated in drugs that are employed for minor symptomatic therapy.

It is obvious, therefore, that legislation directed toward the control of clinical trials of drugs in man must be considered most carefully if the brilliant progress that has been made in pharmacotherapy over the past several decades and which has contributed so much to the health and welfare of the Nation is not to be jeopardized. The new regulations relating to the clinical trial of new drugs proposed by the Secretary of Health, Education, and Welfare are well conceived

and offer protection to the public. Sixty days are provided to consider opinions expressed by academicians, physicians, pharmaceutical industry and other interested persons. Surely if regulations are so carefully considered, legislation should be no less hasty and should result from recommendations of a carefully selected scientific study committee reporting to a congressional committee. There is no crisis in the offing that could result in any more serious consequences than legislation that is designed to promote public health but would have the opposite effect because of hasty judgment.

Finally, I am concerned that for many years in the future the objectivity of the dedicated personnel of the Food and Drug Administration is bound to be influenced by the thalidomide tragedy. I have recently addressed a letter to Secretary Celebrezze expressing my thoughts on this matter. I am enclosing excerpts from this communication in order to avoid some duplication of my above remarks and respectfully, request that they be incorporated in the records of your committee.

Very truly yours,

ALFRED GILMAN, Ph. D.,
Professor and Chairman.

EXCERPTS FROM A LETTER ADDRESSED TO THE HONORABLE ANTHONY J. CELEBREZZE, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AUGUST 3, 1962

You have assumed your responsible office at a time when decisions relating to the control of new drugs are apt to be made on an emotional rather than an objective basis. The glaring publicity focused on the drug industry as a result of the hearings conducted by Senator Kefauver coupled with the unfortunate outbreak of phocomelia from thalidomide has created an atmosphere that borders on hysteria. Therefore, decisions made at this time are very apt to be ultraconservative.

There is an aspect of the approval and release of new drugs that is being little considered in the present climate. The decision not to release a candidate drug which later proves to have unexpected toxicity leads to deserved praise for those responsible for the judgment. However, the decision not to release a potential therapeutic agent may also have devastating effects on public health. In fact, "the drug that wasn't there" may be a greater tragedy than one which causes unexpected toxicity. It is my concern that the pendulum may swing to such an overcautious attitude that the number of "drugs that weren't there" may grow so large as seriously to impede the important contributions that pharmacology can make to medicine.

Please do not infer from the above remark that I am recommending a laissez faire attitude on the part of responsible governmental agencies. Careful toxicity studies should be demanded before any drug is given to man. More stringent toxicity studies are needed when a drug goes from initial clinical trial involving small numbers of patients under the care of trained and experienced investigators to a more extended clinical trial involving a large number of patients under the care of practicing physicians. But eventually the final decision to release a drug must be made. It is my opinion that the decision could best be made by a group of qualified experts.

Before the Department of Health, Education, and Welfare supports a research project costing a few thousand dollars, it is reviewed by a study section and council. But the decision to release a new drug is largely the responsibility of one individual. How simple it would be to set up review boards of highly qualified individuals to act in an advisory capacity to the Food and Drug Administration. Ten such boards could cover the important areas of pharmacotherapy. Represented on such review boards would be pharmacologists and clinicians who are expert and experienced in the particular area for which a drug is designed. On the basis of this background of experience, a judgment could reasonably be made as to whether the therapeutic efficacy of a drug was sufficient to warrant the risk of some degree of toxicity. I know of at least one important drug which is being withheld from release because of the difficulty involved in such a decision.

I am sure that a program of this nature would receive the full support of basic scientists and clinicians. The number of new drugs submitted to these panels would not represent a great burden, especially if summaries of the material submitted were prepared by the present personnel of the Food and Drug

Administration. The advisory opinion of a panel of experts would do much to ease the burden of decision and help distribute the responsibility.

I trust the above remarks will merit your consideration.

Very truly yours,

ALFRED GILMAN, Ph. D.,
Professor and Chairman.

DRUG, CHEMICAL & ALLIED TRADES ASSOCIATION, INC.,
New York, N.Y., August 20, 1962.

Re H.R. 11581.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: The Drug, Chemical & Allied Trades Association, Inc., is a New York nonprofit corporation. It represents almost 800 firms located throughout the United States. These member firms are engaged in the manufacture, distribution, and sale of drugs, cosmetics, and chemicals, and in the supply of essential materials and services to those industries.

Our association believes that the existing provisions of the Federal Food, Drug, and Cosmetic Act have worked well in practice. We are not opposed, however, to changes in this act which are desirable from the public health standpoint, and which do not impose unwarranted governmental control over the industries which are subject to that act. In this letter, we should like to set forth our views on H.R. 11581, and we request that this letter be made a part of the record of the hearings on that bill.

TITLE I

PART A

Requirement of adequate controls in manufacture, section 101

Our association has no objection to an amendment of section 501(*a*) of the Food, Drug, and Cosmetic Act (hereinafter called the "act") so as to cause a drug to be adulterated if the methods, facilities, and controls used for its manufacture, processing, packing, and holding do not conform to current good manufacturing practice so as to assure that the drug will have the identity, strength, quality, and purity that it purports to have.

We submit, however, that the test of what constitutes such "current good manufacturing practice" in any given situation should be an objective one, and should be left to the courts for determination. The test should not be left to administrative determination by the Secretary. This would create the very real possibility that improvements in manufacturing and packaging methods and techniques would be seriously retarded by a regulatory straitjacket.

We would urge that "personnel" be deleted from section 101 of the bill since individual competence can only be judged by a long and close observation. It is our belief that any attempt, through regulations, to standardize the qualifications of the various personnel engaged in the manufacture and control of drugs would produce unwarranted burdens for industry and produce serious injury to the careers of individuals.

We would recommend that subsections (ii) and (iii) of section 101(a) of the bill be deleted since their precise meaning is unclear. Furthermore, the apparent subject matter of these two subdivisions is already adequately covered by other sections of the act, particularly section 502(j) and the full provisions of section 501 and 502.

Premarket showing of new drug efficacy, section 102(a)

Many drugs are no longer "new drugs" under the definition presently contained in section 201(p) of the act because they are generally recognized as safe for use as recommended. The proposal that a drug must be generally recognized as "efficacious," as well as safe, would create great confusion as to whether the above mentioned drugs continue to be of new drug status. Furthermore, this proposal would seem to require clearance through the new drug procedures for every new use claimed for old drugs, even though the safety of the drug for such uses is unquestioned.

Our association believes that the existing definition of "new drug" is adequate, and that the proposed amendment thereto should not be adopted.

Section 102(b)

We submit that it is basically unsound to put FDA in a position to deprive the medical profession of newly developed drugs on the basis of that agency's views as to the effectiveness of such drugs. This is particularly so in view of the fact that physicians will often differ as to the effectiveness of a particular drug. If a drug is safe, and there is substantial evidence of its efficacy, the medical profession should not be deprived of the availability of the drug. Accordingly, we would have no objection to a revision of section 505 (a) and (d) of the act, which would allow FDA to refuse to make a new drug application effective if the applicant has failed to submit "substantial," though not necessarily preponderant, evidence that the drug has the effects which he claims for it.

Records and reports as to experience on new drugs, section 103 and 106

Our association is not opposed to an amendment to section 505(j) and 507(g) of the act which would provide FDA with clinical information, respecting drugs covered by effective new drug applications or antibiotic certificates or releases, of a kind reasonably needed by it. Any amendment to accomplish this, however, should require that the providing of such clinical information should be with due regard for professional ethics and should limit its review to licensed physicians. To complement such a provision, FDA should be obliged to provide to the manufacturer clinical information obtained by it.

As to the proposed amendment to sections 505(i) and 507(d), however, our association feels that such amendments are unnecessary. The existing provisions of those two sections are entirely adequate to deal with the subject of clinical investigations. As you know, on August 9, FDA proposed extensive new regulations covering such investigations. Those proposals are based on the authority contained in section 505(i) and 507(d) of the act. Industry is currently studying those proposals.

Procedural changes as to new drugs, section 104(a)

We submit that it would be a mistake to require FDA to approve or disapprove new drug applications rather than to permit or refuse to permit them to become "effective" as is presently the case. Such a change in FDA's function could very well result in undue caution on their part resulting in extensive delays in the availability of newly developed drugs.

The proposed revision to section 505(a) of the act in practical effect, relieves FDA of any obligation to decide, within a given period of time, whether or not to permit a new drug application to become effective. As a matter of fact, FDA could let 180 days pass without even looking at the application, and could then give applicant notice of a hearing on the vague ground of whether his application is "approvable." Moreover, FDA would be under no obligation to even commence such a hearing within any particular period of time. In our view, the existing provisions of 505(c) have worked well in practice and should not be changed other than to increase the initial period for action by FDA from 60 to 90 days. Comparable mandatory time periods for review are already contained in the pesticide amendment (sec. 408(d)) and the food additives amendment (sec. 409(c)) of the act and these provisions serve as a worthwhile precedent for continuing the existing time provisions in section 505(c).

Additional grounds for withdrawal or suspension of approval of new drug applications, section 104(b)

Our association agrees that the standards for suspending effective new drug applications should be liberalized somewhat. We submit that a mere finding of "substantial doubt" of safety or efficacy is too vague a ground on which to permit suspension. Rather, the applicable standard should be failure of the available evidence to meet the same tests that had to be met in order for the new drug application to become effective, i.e., whether the drug is shown to be safe, and whether there is substantial evidence of effectiveness. Furthermore, the evidence justifying a decision by FDA to suspend a new drug application should be "new." FDA should not be allowed to change its mind on the basis of the evidence considered when it made the new drug application effective.

We urge that suspension of new drug applications not be authorized for failure to keep records, or make reports, or maintain manufacturing standards, since such failures can adequately be dealt with under other remedies already provided for in the act.

The provision of the bill which would authorize emergency suspension, prior to hearing, in some situations should also not be enacted since we are not aware of any situation wherein other remedies have not been adequate to terminate any immediate public health threat.

Certification of all antibiotics, section 105

Our association is opposed to the proposed extension of the certification requirement to all antibiotics for the following reasons:

1. Certification of antibiotics was conceived as a temporary measure at a time when production and control procedures had not advanced to a point where results were uniform. Currently antibiotics can be produced and controlled with as much uniformity as other drugs and hence the original need for certification no longer exists.

As an illustration of the advances that have been made in production of antibiotics, during fiscal year 1960 only 22 batches of the certifiable antibiotic drugs were rejected by FDA out of 16,601 batches tested.[1]

Even without the certification procedure, no reputable manufacturer would willfully market a batch of an antibiotic or other drug which was subpotent, unsafe or otherwise unfit for use, and if any company did there is ample authority in the act for proceeding against such substandard drug and its manufacturers. With or without certification, a manufacturer which distributes a substandard drug commits a criminal act by so doing.

2. Annual fees recently paid by industry for certification of the five currently certifiable antibiotics, and their derivatives exceeded $900,000. Proposals are pending to increase certification fees by 30 percent, to require FDA testing of nonantibiotic active components of certifiable antibiotics which will further increase fees and to substantially increase the testing and sampling performed on each batch. In 1959 approximately 150 man-years of FDA scientific, technical and administrative effort were devoted to certification.[1]

If the 30 antibiotics not presently certified, become subject to certification, it is conservatively estimated that industry's fees (disregarding the aforementioned proposed increases in fees) will increase to over $1,300,000.

3. Antibiotic certification is an extreme form of licensing power, giving FDA life and death control over the ability of a manufacturer to market certifiable antibiotic products. In view of the advanced state of the art of producing antibiotics, such burdensome control is not justified.

4. Extension of certification to the 30 noncertified antibiotics (several of which have been marketed for almost 12 years) would produce serious difficulty and confusion and undoubtedly would result in many unwarranted competitive advantages to manufacturers of the currently certified antibiotics.

Requests would presumably have to be submitted to FDA for regulations permitting certification of the hundreds of dosage forms containing the currently uncertified antibiotics, even though virtually all of these have previously been cleared by FDA under the new drug procedures and they are widely accepted by the medical profession. FDA would presumably have to re-review the data previously submitted with the hundreds of new drug applications covering these products. Furthermore, since most of these drugs are now off new drug status there have been some changes in formulation, manufacturing and testing procedures, etc. since the last new drug clearance was obtained, so that additional data may be required to be submitted and reviewed with respect to those changes. This reclearance will be unnecessary, wasteful of man-hours for Government and industry, and productive of great delay.

Biological drug, section 107 (a)

Section 351(b) of the Public Health Service Act requires a showing of "safety, purity and potency" before a license can be issued for a biological drug. This bill would add a requirement of showing "efficacy."

Our association opposes this proposed new requirement. The current requirement of demonstrating "potency" is adequate and realistic. Earlier we mentioned the differences that exist among physicians as to efficacy of particular drugs. This is particularly true in the case of biologicals. It is generally possible to demonstrate that antibodies are formed after administration of a vac-

[1] Report to Congress by the Comptroller General entitled "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education, and Welfare," dated September 1961.

cine, but proving that a particular disease is thereby prevented is far more difficult.

Biological drugs, and the proper degree of Government regulation thereof, are most complex subjects. Our association feels that there is a need for an overall review of the provisions of both the Public Health Service Act and the Food, Drug, and Cosmetic Act pertaining to such drugs. We submit that such a review should be made in due course, and that it is unwise to deal with this subject in piecemeal fashion as this section of the bill proposes to do.

PART B. STANDARDIZATION OF DRUG NAMES

Authority to standardize names, section 111

Our association has no objection to giving the Secretary standby authority to designate a "single standard name" for a drug. However, he should not be authorized to exercise such authority until a reasonable opportunity has been afforded for the persons in charge of the compendia in which the drug is listed to select such a name. We would urge that the Secretary be precluded from selecting any name which would infringe trademark rights, and we would urge that procedures for selection of such names by the Secretary be subject to the hearing and review procedures of section 701 of the act.

Name to be used on label, section 112

Our association has no objection to a listing on the label of the "established name" of a drug and, if fabricated from two or more ingredients the "established name" of each active ingredient.

In the case of over-the-counter drugs, however, we do oppose the requirement of listing the quantity of each active ingredient since the quantitative formulas of many over-the-counter drugs are highly valuable trade secrets.

As to the requirement that the "established name" should be given precedence over and be in type at least as large and prominent as any trademark, we are most strongly opposed to such a requirement. It would seriously weaken the value of trademarks, and reduce the incentive to produce superior products. We submit that section 502(c) of the existing act deals very adequately with the subject of conspicuousness of required labeling statements.

PART C

Special control for barbiturates and stimulant drugs, section 121 and 122

Our association supports increased FDA control of amphetamines and barbiturates. We feel, however, that the provisions of the Dodd-Wiley bill (S. 1939) are better than this bill in a number of respects.

We do not however, favor the provision of this bill (subsection (c)) which would make "possession" an offense unless such possession is with intent to sell or otherwise distribute such drug. We also do not favor the grant of authority to bring other drugs under the controls which would apply to barbiturates and amphetamines.

Furthermore, in our view, the term "barbiturate" should not include drugs containing, in addition to any such barbiturate, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate to cause a hypnotic or somnifacient effect; and the term "amphetamine" should not include drugs containing, in addition to any such amphetamine, a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of amphetamine to cause a stimulating effect on the central nervous system.

The record-keeping provisions should not require a set form or forms for keeping the required records so long as the commercial or other records kept in the usual course of business contain the required information Also it should not be required that the address of the patient be recorded in cases where the name and the address of the prescribing physician is shown on the prescription.

PART D

Amendments as to advertising, section 131

Our association fully supports the principle that full and complete information necessary for the use of drugs should be readily available to physicians. We submit, however, that "advertising" is not the manner in which such information should be made available. It is not, and it should not be the purpose

of advertising to give physicians full information on how to use the drugs. Moreover, in the case of many drugs, such information is so voluminous that it would be impractical to include it in advertising. Our association, therefore, opposes the provisions of section 131 of the bill. However, hearings in mind that the purpose of advertising is merely to remind physicians of the availability of a drug, we would have no objection to a provision which would require medical journal advertising to contain a statement to the effect that physicians should consult the manufacturer's literature for information concerning possible contra-indications and side effects.

TITLE II

Factory inspection, section 201

In the case of drugs, our association supports an extension of FDA factory inspection authority. We submit, however, that any new law should provide adequate safeguards against disclosure of confidential information and undue interference with the right of management to operate its own enterprise. Accordingly, the articles subject to inspection should be limited to those having a material bearing on the specific violations of the law. Furthermore, it should be specifically provided that the authority to inspect shall not extend to (*a*) financial records, (*b*) sales records, (*c*) pricing records, (*d*) personnel records, (*e*) records of research activity, and (*f*) complaint files.

In the case of complaint files, the limitation need not apply to communications from licensed practitioners and institutions, provided that inspection of such data be conducted with due regard for and consistently with the professional ethics of the medical profession, that access thereto be available only to licensed medical personnel of the Department, and that corresponding information held by the Secretary be made available to medical personnel of the drug manufacturer.

We are opposed to the extension of factory inspection authority proposed by section 201 of the bill. That section would increase the scope of such authority to such an extent as to raise questions of constitutionality, especially considering the fact that this act contains criminal penalties. Apart from those questions, however, we submit that it is wrong in principle to authorize virtually unlimited inspection authority. Such broad powers would seriously jeopardize the many valuable trade secrets possessed by members of all industries subject to the act.

Confidentiality of information obtained by inspection, section 202

We favor the proposed amendment of section 201(j) of the act, which would prohibit disclosure of any information obtained by inspection. We submit, however, that the proposed insertion of the words "as authorized by law" should be changed to read "as required by law."

It is our understanding that the Pharmaceutical Manufacturers Association intends to propose that the act be amended so as (*a*) to prohibit counterfeiting and (*b*) to require registration of drug manufacturing establishments and to require inspection of such establishments at least every 2 years. We support those proposals.

We are most appreciative of the opportunity to express our views on the provisions of this bill which are of such vital concern to the members of our association.

Respectfully submitted.

WILLIAM J. SCHIEFFELIN III, *President.*

THE REUBEN H. DONNELLEY CORP.,
New York, N.Y., August 22, 1962.

Re. H.R. 11581.

Hon. OREN HARRIS,
Chairman of the Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

MY DEAR MR. HARRIS: Once again, as we did in our letter to you of November 15, 1961, we would like to protest that part of H.R. 11581 which would require full disclosure in medical journal advertisements.

As publisher of six medical journals, and particularly as publisher of "Modern Drugs," which has for the past 25 years presented product brochures and complete descriptions of drugs, it seems to us to be entirely unnecessary for advertisements in this publication to repeat what is already presented in the text pages of the publication.

Last year we published over 7,500 pages of scientific literature for the information of physicians. This literature constantly gives the physicians the very latest in cautions and contraindications. Advertising carried in our pages is largely in the form of "reminder" copy.

We believe that if manufacturers are forced to pay for full disclosure advertising this will, in turn, have a decidely adverse effect on allocation of money for the research so necessary to the saving of lives.

We believe, for the good of all, that the requirement for full disclosure in advertising should be stricken from the bill.

May we request that this letter be made a part of the record.

Sincerely yours,

THE YORKE MEDICAL GROUP,
PLINY A. PORTER, *Publisher.*

AEROSPACE MEDICAL ASSOCIATION,
Washington D.C., August 31, 1962.

Hon. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
The House of Representatives, Washington, D.C.

DEAR MR. HARRIS: In view of our committed responsibility of guarding the safety, health, and welfare of our men in aviation and astronautics both in the air and on the ground, we take this opportunity to call to your attention the possible hazards of the advertising provisions of H.R. 11581. Such requirements as set forth in the measure could have serious effect on the initiative of investigation so necessary on the part of all of us who practice medicine.

I refer to the intuitive desire by the physician for complete information on any particular medical procedure or the prescribing of any specific drug. Before a physician prescribes either old or new pharmaceuticals, he is expected to first inform himself fully on all aspects of efficacy, side effects, and contraindications. We are reluctant to either assume or believe this information can be presented in advertising space of a size available in medical journals. Thus, you can see that the details necessary in the professional literature could not possibly be included in today's pharmaceutical advertising. We do not want to encourage the substitution of advertising for studying the scientific literature. Basically journal advertising of drugs for prescribing is a means of alerting the physician to their availability and basic therapeutic qualities. Such advertising has never been intended to say, "This drug will do so and so. Go ahead and prescribe it."

Much information on drugs becomes a part of medical society meetings, hospital staff meetings, and seminars. Here knowledge on new drugs is disseminated by lecture, discussion, and experience reporting. Under the proposed requirement it is possible that in many instances much of the information bearing on all aspects of the drug could not be printed because of limitation of space and it would most certainly, in some instances, result in the prescribing of the drug without all the pertinent data needed to insure the safety of the patient.

Much has been accomplished in many other features of the measure. However, we sincerely believe that to allow the section regarding the advertising provisions to remain would detract from and weaken the beneficial provisions.

Sincerely,

WILLIAM J. KENNARD, M.D.,
Executive Vice President.

FELTON CHEMICAL CO., INC.,
Brooklyn, N.Y., August 28, 1962.

Re H.R. 11581, proposed factory inspection provisions.

Congressman OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

Congressman VICTOR L. ANFUSO,
House Office Building,
Washington, D.C.

DEAR SIRS: The writer is an attorney at law, house counsel for Felton Chemical Co., Inc., assistant secretary of that company, and has been actively engaged in the essential oil and basic perfumery business for upward of 30 years. Our company is a member of the Essential Oil Association of the U.S.A. and the writer is a member of its legislative committee. As such, the writer is thoroughly familiar with the statement prepared by the Essential Oil Association of the U.S.A. and presented to this committee by Mr. Dittrich, its president, on August 23, 1962, as well as the statement presented by Mr. Eugene P. Grisanti, on behalf of International Flavors and Fragrances, Inc., a firm similarly situated.

On behalf of Felton Chemical Co., Inc. we wish to enter upon the record of the proceedings of the House Interstate and Foreign Commerce Committee our objections to and protest against the inclusion of the proposed "factory inspection" amendments contained in H.R. 11581, upon the facts and for the reasons given in the aforesaid statements of Mr. Dittrich and Mr. Grisanti.

Your attention to and consideration of the foregoing is most sincerely urged.

Respectfully yours,

FRANK BRUMBURGH,
Assistant Secretary.

BRAND NAMES FOUNDATION, INC.,
New York, N.Y., August 17, 1962.

Subject: H.R. 11581.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
New House Office Building, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The undersigned, a membership organization incorporated in New York State, respectfully wishes to present to you and your committee the view that certain provisions of H.R. 11581, being considered by your committee, are contrary to the public interest.

The foundation was incorporated December 11, 1943, as the Brand Names Research Foundation, Inc. Its name was changed with the approval of the State of New York, Division of Corporations, September 4, 1946.

The membership of this cooperation is listed in a printed roster, a copy of which accompanies this letter. You will note that it is comprised of commercial organizations manufacturing products sold in general distribution with advertised trademark identifications, professional advertising agencies, and the several media of communication.

Your attention further is called to the fact that although some of the companies making and distributing pharmaceutical products participate in our endeavors, they are a very small portion of our membership and account for less than 1 percent of our total revenue. Members of our board of directors speaking for the drug industry, including advisory, nonvoting directors, are only 4 in a total of 53.

PURPOSE OF BRAND NAMES FOUNDATION

The purposes of this corporation, as stated in our certificate of incorporation, are as follows:

(*a*) To advocate and advance the principle and philosophy of freedom of choice, inherent to free enterprise, and freedom to develop better products and receive due reward for results achieved.

(*b*) To defend the proven, typically American system of merchandising, using advertising of trademarked and branded products and to use any proper steps deemed necessary or desirable to advance the system to even greater usefulness.

(c) To create greater understanding on the part of the general public of the significance of trademarks and brand names in the exercise of freedom of choice.

(d) To demonstrate to an increasingly larger proportion of the public and to Government officials the jealous care shown by ethical manufacturers to maintain the highest standards of quality and value of their trademarked or branded products and the desirability of such care in each individual instance with consumers acting as their own judges.

(e) To carry out by every lawful means a campaign with respect to the desirability and value of trademarks and brand names, and to do any and all things lawfully permitted in furtherance of the foregoing purposes and objects.

CONVICTIONS

The members of Brand Names Foundation, Inc. believe that the manufacture and distribution of brand-named products result in a continued concern for public approval and patronage of trademarked items. Thus, there is a constant concern for consistency of quality and, through research, a constant aspiration for product improvement.

ACTIVITIES OF THE FOUNDATION

During the more than 19 years of its existence, in behalf of its diversified members, this corporation has engaged in continuous educational and promotional activities. The purpose of these has been to heighten the public's awareness that, no less than they are a means of facilitating the distribution and selling of products, manufacturers' brand names are a service and guarantee of responsibility and satisfaction to their ultimate purchasers.

OBJECTIONS TO THE PROPOSED LEGISLATION

We respectfully bring to your attention our opinion that certain aspects of H.R. 11581 ultimately will be hurtful to consumer interests. Although no comment is offered herein on the other provisions of the bill, this should not be interpreted as either approving or disapproving such other provisions:

Section 111

This would grant to the Secretary of Health, Education, and Welfare the right to designate a "standard name" for a drug which would be the "established name" for such drug.

The foundation has no objections to the standardization of names as such for any category of products. However, we believe that there should be a specific prohibition against the adoption of any valid trademark as the standardized name of any product. Section 111, as written, does not contain any limitation upon the name that may be selected by the Secretary and thus placed in the public domain. Potentially the affected name nevertheless could be a valued trademark.

A dangerous precedent would be set if a manufacturer were faced with the possible loss of exclusivity in his trademark by governmental fiat. Accordingly, it is our suggestion that section 111 should contain an express provision prohibiting the Secretary from designating as the standard name for a drug any valid trademark.

Section 112(a)

Brand Names Foundation also objects to section 112(a) which, as written, would require a drug manufacturer to give the "established name" of his drug precedence in position over the trademark or brand name, and use it in type at least as large as such trademark or brand name. This provision's admitted purpose is to encourage the prescribing and sale of drug products by their generic designations rather than by their trademarks.

This concept and precedent, once established, could at another time be applied to any other category of products that consumers purchase and use.

Thus, "drip-dry" shirts could be made an identification equal to or dominant over the trademarks or brand names now identifying the distinctive craftmanship, style standards, and qualities of several preferred brands.

"Pressed wallboard" could be an indication equal or dominant to the brand names of the wide variety of manufactured products that serve structural purposes.

"Vegetable soup" could, by the precedent of section 112(a), identify a substantial variety of products that today are represented by names like Campbell, Heinz and others, each representing distinctive flavors and ingredients. The housewife would be unable to serve her family according to its palate preferances if she followed only commonly established descriptive names.

Your committee readily will recognize innumerable other potential analogies.

The proposed radical departure from the present reliance on reputation could only result in the reduction or elimination of incentive to attract consistent patronage, and thus the deterioration of quality and of aspiration for progressively greater excellence now dominating the manufacturers of consumers' goods.

This provision, if enacted, would set a precedent for product mediocrity and encourage and protect the counterfeiter and substituter.

The community of industries and service organizations represented in Brand Names Foundation respectfully calls the committee's attention to the fact that of all the kinds of consumer products, those consumed internally could be the most dangerous among which to encourage mediocrity or to discourage the prevailing aspiration for excellence. In the manufacture of drug preparations, the trademark symbolizes not only the active ingredients, but also the quality, purity, and efficacy of the end products.

In the light of the foregoing conclusions, we again respectfully urge the committee to reconsider these provisions of H.R. 11581 with respect to their ultimate effect on consumer interests and the precedents they could set affecting the service of the traditional competitive trademark system.

Very truly yours,

HENRY E. ABT, *President.*

NEW YORK UNIVERSITY,
SCHOOL OF LAW,
New York, N.Y., June 26, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: On Friday, June 22, 1962, I attended the hearings of your Committee on Interstate and Foreign Commerce, in hopes of testifying before you on House bill H.R. 11581–87th Congress, 2d session. Unfortunately, the short time available to the committtee made it impossible for me to be called as a witness. Following your suggestion at the close of that hearing, I am, therefore, taking the liberty of submitting to you a number of comments on the bill which I otherwise would have made orally. In thus commenting on the bill, I am stating my views as a professor or criminal law (at New York University), and not as a representative of any organization or association. My interest in the bill is that of a citizen who dislikes adulterated food, because I may have to eat it, and as a law professor who dislikes adulterated laws, because I may have to teach them.

First of all, permit me to commend the committtee for the thorough way by which it investigates the need for further legislation in this field.

Next, permit me to note that everybody's concern centers on four points which seem beyond dispute. These I propose to discuss:

(1) Everyone agrees that the existing act and the proposed bill are full of "Weasel" words, vague standards, and uncommon meanings. Simply by way of example, what does the word "unsafe" mean in connection with section 402.2(*c*)? Through a maze of cross references, we learn ultimately that "unsafe" means failure to comply with the Secretary's view as to what is consistent with the public health, as expressed in a regulation issued for the promotion of honesty and fair dealing in the interest of consumers.

I could go on ad infinitum to point to a multitude of vague concepts and standards in the act. As a theoretician of the law, I cannot understand why a Nation as intelligent as ours cannot produce a legal draftsman capable of drafting bills which tell those regulated thereby what is expected of them. But let us assume that we cannot avoid the vague standards. Then I would think that we should go to pains to prevent possible abuses arising from such vague standards, namely by limiting bureaucratic discretions. Does the act do that?

No, and that leads to the second point.

(2) Broad discretions are joined so tightly with the vague standards that no man can put them asunder. The Secretary himself has enormous discretions. Thus, he might promulgate regulations whenever, in his judgment, such action

will promote honesty and fair dealing in the interest of consumers, etc., etc. The proposed bill is intended to enlarge these discretions. Is is necessary that the administration be granted such vast discretions? I personally seriously doubt that. But let us assume that the broad discretions are as necessary as the vague standards. This leads us to the third issue.

(3) Should the Secretary be invested with police powers greater than our armed law officers possess in preventing rape and murder? No police officer is vested with the power "at all reasonable times" to inspect the bedrooms of American citizens, although, according to Dr. Kinsey, most of such bedroom violations of the law constantly take place. Or does the police have the power to make inspection of houses and rooms therein even if they suspect that a dead body or a machinegun might be hidden there? No, they will have to obtain a warrant upon evidence sworn to, establishing probable cause that a crime has been committed therein. But H.R. 11581, in section 201(a), is the first example in American history in which our constitutional standards, developed on the basis of the fourth amendment, are completely set aside. This section, in effect, legislatively creates an irrebuttable presumption of facts and a presumption of an oath attesting to these facts, that all American food and drug manufacturers, etc., are probably continuously engaged in the commission of crimes in their establishment, for it creates the basis for entrance, search for evidence of crime, and seizure of such evidence without any formality. The committee is familiar with the cases in which the statutory right of health inspectors to inspect premises was upheld. In none of these cases were health inspectors empowered to search for the evidence of crime. There can be no doubt whatsoever that the authority which this act proposes to establish in the Food and Drug Administration is in violation of the fourth amendment to the Constitution. But apart from the fact that the provision is unconstitutional, there is inherent in this provision an incredible insult to an essentially law-abiding industry. No other industry has ever been deemed, impliedly or expressly, to be constantly engaged in the commission of crime, so that searches for evidence of crime may take place without warrant or warning. If the committee feels that the FDA needs particularly broad powers of search and seizure, for the protection of the public health, I think it is absolutely necessary that an incrimination-immunity proviso be added to the provision, to the effect that any evidence seized cannot be used in any criminal prosecution against any person or company from whom such evidence has been taken. I still maintain, however, that the effect of this provision is to antagonize an industry which otherwise would, in all probability, cooperate eagerly with the Food and Drug Administration.

(4) My last point pertains to the penalty section of the Federal Food, Drug and Cosmetic Act, especially section 333 (a) and (c), which the presently proposed amendments do not touch upon, but should.

On many occasions I have pointed out, in print and spoken word, that the absolute liability feature of this penalty section is repugnant to our American sense of injustice and flies in the face of every experience gathered in eight centuries of common-law history. Absolute liability means that the guilty and the innocent violator are punished alike, that the careful and the careless entrepreneur are both subject to punishment. Nothing can be plainer than that punishment of the careful will create frustrations. Obviously, if a man can be proven guilty, he should be severely dealt with, preferably by imprisonment rather than fine. But if a man is not guilty, he deserves an acquittal regardless of what happens to a tainted product which may have been innocently produced. It is no answer to say that the Food and Drug Administration will not pick the truly innocent violator for prosecution. In the first place, they have done so, as the long list of cases cited in the annotation of 21 U.S.C.A. section 333 indicates. In the second place, impunity of innocent persons should not be a matter of administrative graces but a matter of right. The law itself should make this clear. I urge your committee, therefore, to reconsider section 333 and to insert in line one, behind the words "any person who" the words "intentionally or recklessly." This, in turn, would make it possible to drop the entire subsection (c) with its currently wholly inadequate list of exceptions to the enormous sweep of otherwise absolute criminal liability.

I should be pleased if my few comments will be of help to you and the members of your committee, to whom I express my sincere respect.

Faithfully yours,

GERHARD O. W. MUELLER,
Professor of Law.

KINNEY & CO., INC.,
Columbus, Ind., June 18, 1962.

HON. ANCHER NELSEN,
House of Representatives,
Washington, D.C.

DEAR MR. NELSEN: Thank you for taking time from your busy day to visit with me last Thursday. I appreciate your attentive consideration to my point of view on certain provisions of the Harris bill, H.R. 11581.

You suggested that I write you on the subject and that you would make this letter a part of the record of the hearing on this bill.

Kinney & Co., Inc., is "one of the little fellows" in the industry. Our sales are less than a million dollars annually. We are, therefore, vitally interested in any provision of the proposed new drug law which would be particularly damaging to small companies.

As a small pharmaceutical company, we are deeply concerned about the proposed provision that the generic name of a product be given precedence in position over the trademark. The opinion has been expressed that drug products should be identified by generic names rather than trade names, the theory being that this would give the small drug manufacturer an opportunity to compete more effectively with the larger companies. The added competition anticipated is theoretically supposed to reduce the cost of drug products.

We are convinced that any legal provision that would tend to eliminate or downgrade the use of trademarks on drug products would also tend to eliminate the small drug manufacturer. The only chance for the small drug manufacturer to exist is through the development of worthwhile products which he can market under a trademark. Without a trademark, a small pharmaceutical manufacturer who develops a product of merit and markets it under the generic name would soon find that his business was gobbled up by larger manufacturers who would soon be selling the same product under the same name. The small manufacturer without any trademark protection could not maintain his business against the massive production distribution and promotional facilities of the large drug manufacturer.

The active competition of small pharmaceutical companies, each striving to carve a niche for itself, has resulted in many worthwhile contributions to medicine and to the public. We are convinced that the end result of generic drug products as against trademarked drug products would be the elimination of most small and medium size drug companies and the concentration of drug manufacturing and distribution in a few giant firms.

Such a concentration of drug manufacturing and distribution would not be a desirable objective from any standpoint. I hope your committee will take into consideration the destructive end result of this ill-conceived provision to hamstring the use of trademarks on pharmaceutical products.

Very truly yours,

H. S. KINNEY.

TRAPPE FROZEN FOODS CORP.,
Trappe, Md., June 25, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR SIR: We, as a frozen food packer, are vitally concerned with the provisions of proposed legislation in title II of H.R. 11581. The purpose of this letter is to go on record as opposing the amendment which would modify the Federal Food, Drug, and Cosmetic Act to expand factory inspection powers.

The statement submitted to your committee by the National Canners Association has our full support. There is very little we, as an individual packer, could add to this excellent statement, which would not be a repetition of what has already been expertly presented.

The general trend of most Government bureaus, departments, and agencies to gain more and more powers and control over the individual citizen as well as business is evidenced by the unwarranted powers provided by H.R. 11581.

We sincerely hope that, for the benefit of the country as a whole, this bill will never get out of committee.

Very truly yours,

G. K. CALVERT.

NATIONAL BAKERY SUPPLIERS ASSOCIATION,
June 21, 1962.

MR. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House Office Building, Washington, D.C.

DEAR MR. CHAIRMAN: The National Bakery Suppliers Association in behalf of its members who are the largest and most economically important in their industry, respectfully suggest that the proposed extension of the factory inspection power under the Federal Food, Drug, and Cosmetic Act, as proposed in H.R. 11581, is not warranted.

Our industry is not averse to factory inspection which is reasonably required for an effective administration and enforcement of the law to insure shipment of safe and clean foods properly labeled. However, we respectfully submit that experience under the existing law abundantly demonstrates that the present powers are fully adequate, at least insofar as the production and distribution of foods is concerned, to insure this objective.

We believe that granting of the sweeping administrative power as proposed in the bill will not contribute anything not now available and reasonably required for effective administration and enforcement of the act. For example, all foods and food ingredients which are not generally recognized as safe have to be approved for distribution in interstate commerce by formal regulation. The powers implicit in the pesticide chemicals amendment, the food additives amendment and the color additive amendments of the law, coupled with the present factory inspection power, completely cover all facts reasonably required to determine food safety.

In addition to the specific powers included in these amendments to insure food safety, the present law authorizes the entry and inspection of "any factory, warehouse, or establishment" in which commodities subject to the act are manufactured, and to inspect all of such premises and "all pertinent equipment, finished or unfinished materials, containers and labeling therein."

Under these provisions a duly authorized inspector is entitled to, and history of experience shows that he has always been getting, all information which can have any possible bearing on likely safety, cleanliness, and proper branding of foods. Samples of the raw materials or of the foods at various stages at its preparation, as well as samples of every item of printed matter which is on the container of a food or accompanies a food is available. Indeed it is impossible to conceive of any additional information needed to insure the indicated objective in the production and distribution of foods.

However, while the sweeping open-end provisions proposed in section 201 of H.R. 11581 will contribute very little, if anything, additional to information needed to achieve these statutory objectives, they would grant authority to demand delivery to an inspector of "all things" located in the establishment, including outside consulting laboratories engaged in highly confidential research "including records, files, papers, processes, controls and facilities" bearing on whether commodities which are not eligible for shipment in interstate commerce are being manufactured in such plant "or otherwise bearing on violations or potential violations of this act." This, it is submitted, would grant complete open-end authority to require submission of all sorts of highly confidential information, such as details regarding confidential formulate, processes, new products research, complaint files, personnel files, and the like, none of which would provide any real assistance in determining facts required to come to a conclusion as to whether a food is or is likely to be unsafe, unclean or misbranded.

It is understood, we are certain, that Federal inspectors are human beings, not some form of machine or tape that can be locked away in a Government vault. They are human beings, with all the freedoms this great country of ours insures its citizens. One of which is the freedom to change his job—to move from Government employment to private industry.

As stated, our industry is not averse to any inspection, or to providing any information, reasonably required to assure this objective. However, at least insofar as the food industry is concerned, no need whatever has been shown for the suggested extension of the inspection power. If the Department has been denied certain information which it can demonstrate to the satisfaction of this committee as being reasonably required in the effective enforcement of the act, then that area of need should be spelled out precisely by indicating the specific additional information required, so that this committee may then judge the merits on specifically claimed needs.

The problem, if one exists, should not be approached by adopting sweeping open-end legislation which will prove a burden to the reputable members of the industry but will be unenforcible against any member choosing to disregard it.

Respectfully submitted.

JOHN W. ALLEN, *President.*

NATIONAL FEED INGREDIENTS ASSOCIATION,
Des Moines, Iowa, August 16, 1962.

To: Mr. W. E. Williamson, Clerk, House Committee on Interstate and Foreign Commerce, the House of Representatives, Congress of the United States, Washington, D.C.

From: National Feed Ingredients Association, Des Moines, Iowa.

Subject: H.R. 11581 (title II), that portion of the bill to amend the Federal Food, Drug, and Cosmetic Act with respect to strengthening of factory inspection authority.

DEAR SIR: The National Feed Ingredients Association and all its members urgently recommend to the members of the House Committee on Interstate and Foreign Commerce of the Congress of the United States to reject the provisions of titel II of H.R. 11581 introduced by Congressman Oren Harris, of Arkansas, on May 3, 1962.

The association and its members have come to this conclusion because the authority given the administrative authority is so broad as to be an invasion of the liberties guaranteed by the Construction of the United States and because the administrative authority can achieve the same end results by due process of law.

Since the same results can be achieved by the administrative authority by due process of law, we urge that the House Committee on Interstate and Foreign Commerce of the Congress of the United States reject the provisions of title II of H.R. 11581.

Sincerely yours,

I. LEVIN, *Executive Secretary.*

AMERICAN NURSES' ASSOCIATION, INC.,
New York, N.Y., August 20, 1962.

Representative OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
U.S. House of Representatives, Washington, D.C.

DEAR MR. HARRIS: The American Nurses' Association has an interest in current hearings on drug legislation and supports Federal legislative proposals that seek to make readily available to all concerned professional practitioners current and accurate information on drugs.

Nurses do not prescribe drugs since this constitutes the practice of medicine, but under the licensing laws of the various States, nurses are permitted to administer medications under a physician's order. In carrying out this function, a nurse is legally required to understand the cause and effect of the order she executes.

The American Nurses' Association endorses the "Statement of Principles Involved in the Use of Investigational Drugs in Hospitals" which was developed by the American Hospital Association and the American Society of Hospital Pharmacists. The third principle of this statement is: "When nurses are called upon to administer investigational drugs, they should have available to them basic information concerning such drugs, including dosage forms, strengths available, actions and uses, side effects, and symptoms of toxicity."

We will not comment on other proposals in the bill you are considering since these are outside our area of competence.

We would appreciate having this letter included in the record of hearings on H.R. 11581.

Sincerely yours,

JUDITH G. WHITAKER, *Executive Director.*

WASHINGTON, D.C., *August 20, 1962.*

Re H.R. 11581.

HON. OREN HARRIS,
Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: As you may be aware, the Society of the Plastics Industry has previously requested time to appear before your committee to express its views with respect to the factory inspection provisions in H.R. 11581. On the strength of the indications in your announcement that the committee's interest is now in legislation relating to drugs, and with cognizance of your request that "organizations * * * be mindful of the time limitation under which the committee will operate," the society is not presently planning to appear.

We realize that the Senate committee which has been working on similar legislation has already amended its proposals to limit the factory inspections provisions to drugs. We are also aware of the President's suggestions that H.R. 11581 should be similarly amended.

We would like it clearly understood that we are still interested in any factory inspection proposal which might relate to food additives or other areas in which the society might have an interest, so we should appreciate being given an opportunity to present our views at a more appropriate time when and if these matters are to be further considered.

Respectfully submitted.

JEROME H. HECKMAN,
Counsel for the Society of the Plastics Industry, Inc.

PET FOOD INSTITUTE,
Chicago, Ill., May 31, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: The Pet Food Institute, a trade association comprised of over 50 manufacturers of pet foods and their suppliers, respectfully wishes to express its opinion with respect to the proposed broadening of factory inspection powers in the Federal Food, Drug, and Cosmetic Act. A review of our membership indicates that the pet-food industry has real misgivings concerning the true need for the expanded powers proposed by H.R. 11581.

These misgivings do not refer to the general regulatory principles of the FDA nor to the manner in which these principles are applied. As a matter of fact, the Pet Food Institute, representing one of the more important segments of the food industry, has felt that such principles generally have been fairly and reasonably administered to the distinct well-being of the general public. Our association has consistently approved and applauded the objectives of the Federal and State food, drug, and cosmetic laws. However, the current proposal to provide FDA inspectors with power to examine financial and personnel records and files seems to have scant reference to the intention and spirit of such legislation; surely no excuse can be set forth for an examination of records on research and development of product.

To be more specific, the past record of the food industry in general, and the pet-food industry in particular, indicates that the present provisions of the Food, Drug, and Cosmetic Act are more than adequate. Increased factory inspection powers would merely create additional and unnecessary requirements that would be needlessly time consuming and expensive to the pet-food industry, and therefore to the consumer.

It has been regular practice among pet-food manufacturers to make available all information needed by the FDA on a cooperative and willing basis wherever there has been any question regarding the wholesomeness or sanitation of product. Extended authority will very likely result in the need for the pet-food manufacturers to incur additional cost to operate in order to provide information asked for but of very questionable value insofar as the consumer is concerned, either from the point of view of health, sanitation, or deception.

There is no question that H.R. 11581 would open up for review confidential financial and product information having no bearing on product quality, safety, or possible deceptive practices. There has been no demonstrated need for additional authority by which a more effective enforcement of the Federal Food, Drug, and Cosmetic Act would be obtained and which is not available to it

under the present authority. If any such need can be demonstrated for extension of the authority in specific areas pertinent to the purpose of the act, legislation restricted to such specific areas of inquiry can be proposed for study.

The Pet Food Institute feels that experience, not only in its own industry, but in the food industry in general, has not been such as would justify the sweeping factory inspection powers now sought which include within its scope power to demand information regarding products and personnel rightfully considered confidential.

The board of directors of Pet Food Institute, after careful study, has adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers. We, therefore, wish to place ourselves on record with your committee urging that sections 201 and 202 be deleted from H.R. 11581 prior to submission of this bill to the House of Representatives for a vote.

Thank you for your attention to this matter. We shall be happy to provide additional information in support of the above points if you so desire.

Sincerely,

HENRY A. BUCKLIN, *President.*

AMERICAN SYRUP & PRESERVING CO.,
Nashville, Tenn., May 31, 1962.

Representative OREN HARRIS,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: With reference to H.R. 11581, I note that the National Preservers Association, of which our company is a member, and of which I am an officer and a member of the board, has taken a position opposing certain sections of this bill, mainly sections 201 and 202.

This company, and I, would like to go on record as supporting wholeheartedly H.R. 11581, as written, and urge that your committee, after full consideration of it, give it speedy approval.

May I add that the only way I think that this bill could be improved would possibly be to emphasize the adjective, "reasonable," that is used in part 2 of section 201. This should protect individuals from any undue exercise of powers by administrative agents of the Federal Food and Drug Agency.

I would like further to add that we feel that the highly sophisticated new foods, drugs, and cosmetics make it imperative that H.R. 11581, in its substantial form, be hurriedly enacted.

Respectfully yours,

WILLIAM MARTIN.

SEEMAN BROS., INC.,
New York, N.Y., May 29, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: I wish to express my opposition to the enactment in its present form of H.R. 11581, now before the House Committee on Interstate and Foreign Commerce. I would find the bill more acceptable if certain reasonable changes were made in it.

The bill is obviously a response to unique facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food and drug industries are different and have different problems and characteristics. Therefore, legislation intended for the drug industry should not include the food industry automatically and except for the most compelling reasons.

Accordingly, I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. This can best be accomplished at this time by suporting a severance of the factory inspection provisions

of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Sincerely,

PAUL E. ZEGER,
Vice President, Finance and Treasurer.

JUNE 1, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: The Popcorn Institute is a national trade association made up of the processors and distributors of popcorn. The membership comprises more than 40 companies doing business throughout the United States. Members of the Popcorn Institute are vitally concerned with a measure pending before your committee designated as H.R. 11581. The members of the institute, after careful study, have adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers. We wish to outline their objections to the proposed expansion of factory inspection powers, and respectfully request your consideration thereof.

Under the provisions of H.R. 11581, FDA inspectors whose previous duties have been limited to seeing that the public is protected as to food and drug products, would be given the additional right to probe into financial and personal records as well as to delve without reservation into confidential records concerning research and development of products. Our industry does not believe these powers are remotely connected with the statutory objective and with the preservation of the public interest. We do not believe that they can be classified as being essential for the protection of the public interest.

Questions of fact as to wholesomeness, preservation of health, and the prevention of deception are sound purposes for which the Food and Drug Administration should be given every necessary tool, but we respectfully submit that the review of confidential financial and research information have no bearing on quality of product, safety, or marketing practices.

We do not believe that the subject bill is needed to permit the effective operation of the FDA; we do not believe it is either necessary or in the public interest. We therefore respectfully request that the proposed sections 201 and 202 be deleted and that the agency powers and authority not be expanded into matters wholely apart from the statutory objectives.

If we may provide you or your committee with any additional information which would be helpful, we would be happy to do so.

Respectfully yours,

WILLIAM E. SMITH.

FROZEN PEA COUNCIL,
Chicago, Ill., June 12, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Frozen Pea Council is a national trade association comprised of frozen pea processors. Twenty-one companies throughout the country are active members. Recently, member companies have become vitally concerned about the measure now before your committee, which is known as H.R. 11581. The board of directors of the council wish to go on record with this letter as opposing the amendment which would modify the Federal Food, Drug and Cosmetic Act to expand factory inspection powers.

Presently, inspectors are empowered to protect the public concerning wholesomeness, accurate labeling, and deceiving practices relative to the marketing of food and drug products. All possible aid should be rendered to insure enforcement of these regulations.

H.R. 11581 empowers FDA inspectors to investigate financial and personnel records, and to go into confidential files concerned with company research and product development. The proposed powers are not related to statutory objectives and protection of the public interest.

The Frozen Pea Council respectfully submits the following points for your consideration:

(1) The review of confidential financial and research information has no bearing on quality, safety or marketing practices.

(2) The proposed bill is not needed.

(3) The proposed bill is not to be desired because it grants unwarranted powers.

(4) Proposed sections 201 and 202 should be deleted because the agency should not be given power over matters apart from statutory objectives.

The council and individual members will provide you and your committee with all possible assistance on this subject.

Sincerely,

FRANCIS C. KERR, *Executive Director.*

NATIONAL PECAN SHELLERS & PROCESSORS ASSOCIATION,
Chicago, Ill., May 31, 1962.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

SIR: The National Pecan Shellers & Processors Association is a trade association comprised of the shellers and processors of pecans. It is made up of more than 65 firms doing business throughout the United States. Its members are vitally concerned with a measure pending before your committee and designated as H.R. 11581. The board of directors of the association, after careful study, has adopted a resolution opposing the proposed amendment to the Federal Food, Drug, and Cosmetic Act expanding factory inspection powers and pursuant to their authority, we wish to set forth for your earnest consideration their objections to the proposed expansion of factory inspection powers.

Under the provisions of H.R. 11581, FDA inspectors, whose responsibilities and duties have heretofore been limited to seeing that the public is protected as to food and drug products, would be given the right to probe into financial and personnel records and to delve without reservation into confidential records relative to research and development of product. These powers are so remotely connected with the statutory objective and with the preservation of public interest that they cannot be defended as essential—or even reasonable—to the protection of the public interest.

Questions of wholesomeness, honest labeling, and preservation of health and prevention of deception are sound purposes for which the Agency should be given every necessary tool, but we respectfully submit that the review of confidential financial and research information has no bearing on quality of product, safety, or marketing practices.

The Congress of the United States must ever be vigilant lest is readily accede to unnecessary requests for administrative power expansion. The subject bill is not needed. It is not desirable. This enactment would not be in the public interest. We urge that the unwarranted powers sought by proposed sections 201 and 202 be deleted and that the agency not be given powers and authority to concern itself with matters wholely apart from the statutory objectives.

Our association and its members will be happy for the opportunity of providing you or your committee with any additional information if this would be helpful.

Yours very truly,

HENRY A. BUCKLIN, *Executive Secretary.*

MAYONNAISE & SALAD DRESSING MANUFACTURERS' ASSOCIATION, INC.,
Chicago, Ill., May 29, 1962.

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Mayonnaise & Salad Dressing Manufacturers' Association is a trade association of independent manufacturers of dressing products. Its members are vitally concerned because of a measure now before your committee—namely, H.R. 11581. After careful study, the board of directors of this association have adopted a resolution opposing the proposed amendment

to the Federal Food, Drug and Cosmetic Act, expanding factory inspection powers. We wish to set forth for your consideration our objections to the proposed expansion of factory inspection powers.

Under the newly proposed provisions of H.R. 11581, Food and Drug Administration inspectors, whose responsibilities and duties have heretofore been limited to protecting the public as to food and drug products, would be given the right to probe into financial and personnel records, and in addition, have access without reservation into confidential records relating to research and product development. These powers are so remotely connected with the statutory objectives and with the preservation of public interest that they cannot be defended as essential, or even reasonable to the protection of the public interest.

We believe that questions concerning the wholesomeness, honest labelling, preservation of health and the prevention of deception are sound purposes, for which this agency should be given every necessary tool. But we submit that the review of confidential financial and research information has no bearing on protection of quality, safety or marketing practices.

We believe the Congress of the United States must be vigilant lest it readily accede to unnecessary requests for administrative expansion of power. The subject bill, in our opinion, is definitely not needed. Moreover, it is not even desirable. The results would not be in the public interest. We urge that the unwarranted powers set forth under proposed sections 201 and 202 be deleted, and that the agency not be given powers or authority over matters completely apart from the statutory objectives.

If it would be helpful, our association and its members will be glad to provide you and your committee with additional information.

Sincerely,

WENDELL W. BISHOP,
President.

SEEMAN BROS., INC.,
New York, N.Y., May 31, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE HARRIS: I wish to express my opposition to the enactment in its present form of H.R. 11581, now before the House Committee on Interstate and Foreign Commerce. I would find the bill more acceptable if certain reasonable changes were made in it.

The bill is obviously a response to unique facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug, and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food drug industries are different and have different problems and characteristics. Therefore, legislation intended for the drug industry should not include the food industry automatically and except for the most compelling reasons.

Accordingly, I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. This can best be accomplished at this time by supporting a severance of the factory inspection provisions of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Sincerely,

WALKER R. GOODRICH,
Vice President, Personnel.

NATIONAL PRESERVERS ASSOCIATION,
Chicago, Ill., May 31, 1962.

Hon. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The National Preservers Association, a trade association comprised of the manufacturers of jams, jellies, preserves, and

fruit spreads, respectfully wishes to express its opinion with respect to the proposed broadening of factory inspection powers in the Federal Food, Drug and Cosmetic Act. A review of our membership indicates that the preserve industry has real misgivings concerning the true need for the expanded powers proposed by H.R. 11581.

These misgivings do not refer to the general regulatory principles of the FDA, nor to the manner in which these principles are applied. As a matter of fact, NPA, representing one of the more important segments of the food industry, has felt that such principles generally have been fairly and reasonably administered to the distinct well-being of the general public. Our association has consistently approved and applauded the objectives of the Federal and State food, drug and cosmetic laws. However, the current proposal to provide FDA inspectors with power to examine financial and personnel records and files seems to have scant reference to the intention and spirit of such legislation; surely no excuse can be set forth for an examination of records on research and development of product.

To be more specific, the past record of the food industry in general, and the preserve industry, in particular, indicates that the present provisions of the Food, Drug and Cosmetic Act are more than adequate. Increased factory inspection powers would merely create additional and unnecessary requirements that would needlessly consume time and would be expensive to the preserve industry, and therefore to the consumer.

It has been regular practice among preservers to make available all information needed by the FDA on a cooperative and willing basis wherever there has been any question regarding the wholesomeness or sanitation of product. Extended authority will very likely result in the need for the preserve manufacturers to incur additional costs to operate in order to provide information asked for, but of very questionable value insofar as the consumer is concerned either from the point of view of health, sanitation or deception. There is no question that H.R. 11581 would open up for review confidential financial and product information having no bearing on product quality, safety or possible deceptive practices.

There has been no demonstrated need for additional authority by which a more effective enforcement of the Federal Food, Drug and Cosmetic Act would be obtained, and which is not available to it under the present authority. If any such need can be demonstrated for extension of the authority in specific areas pertinent to the purpose of the act, legislation restricted to such specific areas of inquiry can be proposed for study. The National Preservers Association feels that experience, not only in its own industry but in the food industry in general, has not been such as would justify the sweeping factory inspection powers now sought which include within its scope power to demand information regarding products and personnel rightfully considered confidential.

In view of the above policy, the NPA board of directors has recently passed the following resolution:

"*Resolved*, That the National Preservers Association oppose any proposed amendment to the Federal Food, Drug and Cosmetic Act which would extend the factory inspection powers under the act beyond the powers as presently provided in the factory inspection provisions and the food additives amendment, of the Federal Food, Drug and Cosmetic Act; and that the officers and staff are authorized to do everything deemed reasonably necessary, in their judgment, to oppose any legislation which would expand this power and, to this end, cooperate and coordinate its actions with other affected industry groups."

We, therefore, wish to place ourselves on record with your committee, urging that sections 201 and 202 be deleted from H.R. 11581 prior to submission of this bill to the House of Representatives for a vote.

Thank you for your kind attention to this matter. We shall be happy to provide additional information in support of the above points if you so desire.

Sincerely,

J. M. MAJOR, Jr., *President.*

VINELAND, N.J., *May 31, 1962.*

HON. OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

MY DEAR CONGRESSMAN HARRIS: May I express my opposition to the enactment of H.R. 11581 in its present form, now before the House Committee on Inter

state and Foreign Commerce. The bill would be more acceptable if certain reasonable changes were made in it.

The bill appears to derive from certain facts disclosed during investigation of the drug industry by Senator Kefauver's Antitrust Subcommittee. The food industry was not involved in that investigation. The bill gives inspectors under the Federal Food, Drug, and Cosmetic Act unreasonable and excessively broad powers to inspect factories. These powers are clearly unrelated to, and go far beyond, those purposes of the act aimed at preventing adulteration and misbranding in the manufacture of food.

The food and drug industries differ. They have different problems and characteristics. Legislation intended for the drug industry cannot be applied automatically to the food industry.

May I strongly urge you to oppose the application of the factory inspection provisions of H.R. 11581 to the food industry. I suggest that this can best be accomplished at this time by supporting a severance of the factory inspection provisions of the act so that the food and drug industries will be treated separately and in accordance with their own distinctive problems.

Very truly yours,

FRANCIS V. ANDERSON.

STATEMENT OF HELENE CURTIS INDUSTRIES, INC., REGARDING H.R. 11582, THE COSMETIC CONTROL ACT

This statement is submitted by Helene Curtis Industries, Inc., in opposition to H.R. 11582.

Helene Curtis Industries, Inc., is one of the largest toiletries manufacturers in the United States and the leading U.S. company in the hair care field. The provisions of H.R. 11582 will vitally affect the operations of Helene Curtis and for this reason this statement of opposition is respectfully submitted to the Committee on Interstate and Foreign Commerce.

Helene Curtis objects to the proposed bill on two general grounds. The proposed changes are unnecessary for the welfare of the country and the proposed changes are unnecessarily economically burdensome to the companies concerned.

The great majority of toiletries and cosmetics sold within the United States are marketed by companies of the size, stability, and responsibility of Helene Curtis. These are companies that have shown over a period of many years that their products are tested carefully for safety and efficacy. The control procedures of these companies have been carefully and systematically set up to insure the safety of the public in its use of these products. Millions of dollars are spent each year by these companies that assume a moral responsibility that far transcends the legal responsibilities imposed on them.

The record of safety and care in this industry is one of which the industry can be proud. This is all the more impressive when it is considered that millions, perhaps billions, of these products have been sold and are in use at the present time. The sporadic instance of a product reaching the market that is not safe is a rare exception to this statement. It is certainly not normal or customary. Unfortunately the bad product will receive all of the publicity and the millions of safe uses are forgoten.

We respectfully submit that the occasional bad product that may reach the public can, first, be adequately controlled under the present law and, second, does not justify the greatly increased expense of operation that the new bill would place upon manufacturers.

Since so much will depend upon the regulations and rulings that will be issued under the proposed bill, we cannot know for sure exactly how the proposed procedures will operate. We can only assume that the procedures will be roughly comparable to those adopted for the introduction of a drug under the present law. Experience has shown that the obtaining of a new drug approval constitutes a major expense and a major undertaking of the company seeking such approval. We can assume that substantially the same will be true with respect to obtaining approval of a new cosmetic. As previously indicated, we believe that present testing by the companies in the toiletries field is careful and complete. To add to the problems inherent in the introduction of a new product those requirements that a Government agency would consider to be required is unnecessary. The law as it now stands gives adequate remedies and power to protect the public whenever and wherever this is required.

In addition to what has been stated above, the proposed amendment revoking the exemption of coal tar colors deserves a statement to itself. This one aspect of the bill will probably ruin an entire segment of the beauty industry. Almost the entire hair-coloring field utilizes coal tar colors which have had special dispensation under the present law, which dispensation has been amply justified over the years. If this is revoked, all of this business will be done away with, at a loss of millions of dollars to the manufacturers and at the cost of depriving those women of the world who desire to color their hair of the opportunity to do so. Again, this proposed revocation is being set forth in the face of a record showing successful and safe use of these coal tar colors over millions of applications and over many years. The revocation of the exemption for coal tar colors is unnecessary and uncalled for at this time.

For the reasons set forth in this statement, we respectfully submit that H.R. 11582 should not be favorably reported out of this committee.

STATEMENT OF EDWARD J. MASTERS ON BEHALF OF HELENA RUBINSTEIN, INC., RE H.R. 11582

I am Edward J. Masters, director of product research and development of Helena Rubinstein, Inc. I have been employed in that capacity since 1948. This company, or its predecessor in interest, has been engaged in the manufacture, distribution, and sale of cosmetics and related products in the United States for almost 50 years. I hold a B.S. degree and a M. Ch. E. (chemical engineering) degree from the City College of the City of New York and a Ph. D. degree from Columbia University in the field of organic chemistry. Prior to joining the Rubinstein organization I was a research chemist and factory manager with Evans Associates, cosmetic manufacturers and consultants.

As director of product research and development of Helena Rubinstein, Inc., I am responsible for the technical development of each and every product.

This statement is limited to proposed title I of H.R. 11582 concerning the premarketing clearance of cosmetics for safety. Since I am not a lawyer, I am not in a position to suggest specific modifications to the sections proposed under this title. We understand that the Toilet Goods Association will appear and recommend specific modifications to clarify and improve certain provisions of H.R. 11582. My submission involves its provisions from a technical and scenitific point of view, with specific background data covering the practices and procedures of the company with respect to the premarketing testing of its products and the safety record over the past 8 years of products distributed by Helena Rubinstein, Inc. I trust that these background data will be of some value to the committee.

At the outset, I should like to make it clear that Helena Rubinstein, Inc., is in favor of appropriate pretesting of cosmetics prior to their release to the consumer. We consider such pretesting not only our moral responsibility, but also a practical business necessity. At the present time the provisions of the Food, Drug, and Cosmetic Act define cosmetics as articles which are intended to be applied to the human body for cleasing, beautifying, promoting attractiveness, or altering the appearance. Any cosmetic product which is intended to affect the structure or function of the skin is considered a drug. Thus some preparations, having a duality of function, may be both drugs and cosmetics. Deodorants and bleach creams, for example, have been and are classified both as drugs and cosmetics, or in our terminology, "cosmetic drugs." These cosmetic drugs, designed for a physiological effect upon the skin of the person using them, are subject to all the drug provisions of the present law, including the provisions relative to new drugs. Helena Rubinstein, Inc., distributes both cosmetics and cosmetic drugs.

We, at Helena Rubinstein, Inc., have no objection to premarketing testing of new cosmetics provided that a new cosmetic can be defined in understandable language and provided, further, that said testing does not impose a completely unnecessary an unwarranted burden upon the cosmetic manufacturer. However, in reviewing the definition of a new cosmetic under proposed section 605(a), I have found it to be so vague and indefinite that I cannot interpret practically what is and what is not "new." In fact I cannot determine whether our old products would be in the category of products used for "a material extent or for

a material time." Section 605(a)(2) would appear to require the filing of a new cosmetic application (the equivalent of that required for a new drug) if a manufacturer wished to incorporate any supplemental ingredient, even though such ingredient is fully recognized as safe but is merely new to the existing time-tested formula. And even a minor improvement of an existing formula would subject the product to the new cosmetic sections of the act. Last year, for example, our product line alone was subjected to 140 minor or major changes—any or all of which might subject these products to the proposed new cosmetic provisions. Every modification of such nature might entail the filing of a complete new cosmetic application involving not only a substantial expenditure of time and money, but also the compounded administrative work of those who must process these applications. We have found that the processing of a new drug application covering our cosmetic drug products costs a minimum of $25,000 and 3 years in time.

I should also like to comment concerning section 605(d)(2), the section dealing with the presumptive carcinogenic potential of cosmetics. For instance, the use of the phrase "any reasonably forseeable use" is vague and capable of varied interpretation. The phrase in section 605(d)(2)(B) "or after other relevant exposure of man or animal to such cosmetic" opens the door to the imposition of requirements which are utterly unrelated to the prospective use of the cosmetic. It is known that persistent and chronic irritation from any source can produce cancer after a long period of insult. Pure water itself has been reported to have produced cancer after repeated injection into the skins of susceptible animals. And one cannot consider water a carcinogenic agent. Therefore the protocol for testing a cosmetic intended for topical application for potential carcinogenicity should be limited to topical application in a dosage range appropriate to the intended use of the product.

Apart from these comments, this committee may be interested in the procedures employed by Helena Rubinstein, Inc., in the testing of its products. A typical evaluation of a new product may involve testing for basic toxicity, primary irritation and sensitivity. In the normal order of testing, the basic toxicity and the primary irritation characteristics are first established. Allergic sensitivity tests on human beings then follow along with use tests. The company maintains animal facilities and a histological and histochemical laboratory to perform both safety and other studies. Basis toxicity and primary irritation tests are run on animals of different species (mice, rats, guinea pigs, rabbits). If the product is to be used in the vicinity of the eye (shampoos, eye cosmetics), then a test is run on rabbits (Draize rabbit eye test) to establish whether any injury occurs on instillation into the eye. If all the above tests indicate the product is satisfactory, then patch tests are run on a panel of human beings by our consultant dermatologist to establish whether the product is a sensitizer. Physicians then run clinical use tests to establish further its safety and acceptability.

If the new ingredient or product falls in the category of a new drug, all the safety test data along with formula, labeling, control, and manufacturing procedures are submitted in the form of a new drug application to the Federal Food and Drug Administration. A number of products in our line fall into this category.

In December 1959, at a symposium on cosmetic allergy presented before the Section on Allergy of the Medical Society of the County of Kings and the Academy of Medicine of Brooklyn, subsequently published in the New York State Journal of Medicine, volume 60, No. 12, June 15, 1960, a copy of which is annexed hereto,[1] I discussed allergies to cosmetic products. In this paper, I incorporated a summary covering "a major cosmetic company's experience on complaints of reactions to its products" during the period from July 1, 1954, to August 31, 1959. The major cosmetic company to which I referred was Helena Rubinstein, Inc.

The following tabulation sets forth our cumulative experience for the period July 1, 1954, through April 30, 1962. Here, too, the number of reactions given include all complaints of alleged adverse reactions to the use of a specific product.

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[1] The symposium may be found in the files of the committee.

Reactions compared with unit sales for period July 1, 1954–Apr. 30, 1962

Categories	Reactions	Units sold	Reactions per 1,000,000
1. Depilatories	164	4,659,338	34.9
2. Special cleaners	81	4,743,262	17.2
3. Permanent wave lotions	18	1,132,075	16.4
4. Permanent hair rinses	75	7,932,423	9.5
5. Hormone creams and lotions	45	5,059,983	8.8
6. Medicated creams and lotions	40	5,016,722	8.0
7. Lotions	84	16,502,396	5.1
8. Eye products	91	18,133,573	5.0
9. Creams	28	6,015,718	4.7
10. Sun tan lotions and oils	3	732,102	4.3
11. Deodorants	17	5,550,995	3.0
12. Hair dyes	10	3,554,047	2.8
13. Hair rinses	13	4,898,957	2.7
14. Miscellaneous hair treatment products	19	7,470,068	2.5
15. Shampoos	35	17,454,740	2.0
16. Makeup	21	14,419,401	1.5
17. Face and body powder	6	11,555,393	.5
18. Colognes and perfumes	8	21,890,882	.4
19. Lipsticks	5	19,654,145	.3
20. Nail polish	0	681,177	0
Total	763	177,057,397	4.3

NOTE.—A total of 763 reactions in 177,057,397 units sold is good testimony to the general safety of cosmetic products.

STATEMENT OF MISS BETTE JACKSON ON BEHALF OF COSMETIC CAREER WOMEN, INC., ON H.R. 11582

My name is Bette Jackson. I am product publicity manager of Shulton, Inc., manufacturers of cosmetics, a large part of whose business is in products for men. I am here representing Cosmetic Career Women, Inc., an organization of executive women engaged in the cosmetic and toilet preparations industry, with a membership of approximately 200.

We requested an appearance before your honorable committee because we believe that H.R. 11582 is poorly calculated to accomplish its ostensible purpose; namely, to protect the men and women of this country from harmful products. The fact of the matter is, we are by no means convinced that the perfumes, cosmetics, and other toilet preparations sold by the manufacturers in this country have any capacity for harm to anyone other than to perhaps some person who is allergic. Even for the allergic person, the possibility of harm from strawberries, shellfish, and many other common and familiar products, is far greater than it is from cosmetics.

Our organization believes in safe products and it has no objection to the principle of this bill which is ostensibly designed to require really new products to be tested before they are sold, but we are convinced that the methods attempted by the drafters of this proposed legislation show less sign of consumer protection than an effort to place unduly restrictive controls, far stronger than those in effect on foods and drugs, on an entire industry, which contributes greatly to the American economy, which employs many thousands of people and which pays retail excise taxes to the Government annually of nearly $150 million, in addition to the other taxes which any prosperous American industry pays.

We are particularly interested in this measure because women are the principal users of the products of the industry and the principal buyers, even of those products which are used by the male population. We know from personal experience that the use of cosmetics and other toilet preparations contributes not only to health, to cleanliness, to our appearance but also greatly to our morale. The morale factor is very important. We would point out, for example, that during World War II, the British Government believed it could abolish the manufacture of cosmetics in England and took steps to do so. The result was an immediate and sharp decline in the morale of the many patriotic and brave women working in the war plants. They felt they did not look right and accordingly, did not feel right about their jobs, about their positions in society or about their Government. Further than that, during the very short time before the British Government found its mistake, a black market in cosmetics made in garages, stables, apartments, and other places, menaced the

welfare of the women of that country. Also, among our own members, there are women who are sent out by their companies to lecture to inmates of prisons and patients in mental hospitals on the morale-boosting effects of cosmetics, and Cosmetic Career Women annually contributes money to assist in good-grooming classes for blind women in New York City.

Insofar as the proposed legislation which we are discussing is concerned, undoubtedly it would deprive women of certain products which they are accustomed to use and which we believe they have every right to use. For example, hair-coloring materials which now account for about $100 million at retail annually and for some $10 million in excise taxes to the Treasury, would no longer be available to those who desire them. We know, of course, that some people do not like women to color their hair but we also know that a large and growing percentage of American women desire to do so and we can see nothing wrong with the custom if women want to indulge in it. Incidentally, many women undoubtedly need to indulge in hair coloring to save their jobs and perhaps even to hold their husbands.

In addition, we resent any legislation in the United States which places the control of any industry, and particularly our industry, at the whim of a governmental department which could act under this proposed legislation in a completely arbitrary manner, and deprive us of products which we desire, and prevent a manufacturer from manufacturing the products which he desires to make. This, gentlemen, we feel to be an open end bill, giving to the Secretary of Health, Education, and Welfare and accordingly, to the Food and Drug Administration complete authority over every product we make. The sections of the bill designed to bring about the testing of what the bill calls new cosmetics, and the definition of "new cosmetic" in the measure are so imperfect, that if the Secretary desired, and we can foresee that at some time he could so desire, he could stop the sale of cold cream, invented by Galen, the Greek physician, about 200 A.D., nearly 1,800 years ago, if he should find in his wisdom that the product had not been found to be safe and he could require that manufacturers using the Galen formula (and many manufacturers are using somewhat the same formula today), spend many thousands of dollars proving something to be safe that had been in use for 1,800 years by millions of women without any history of damage. This, we respectfully submit, is far too much authority to give to any bureaucrat.

One of the leaders in our industry some years ago, in a magazine interview, stated "This industry is one of ideas and ingenuity and what we are really selling is hope." This may seem at first glance to be a slur against the industry, but we submit that if the women of this country should lose the opportunity of continuing to look young and beautiful to their menfolk, we would be in a sad state indeed. Further than that, the industry has over the years realized that hope to which I previously referred. The products of the industry have brought beauty, health, and a sense of well-being to practically every woman in the country and to a great many men as well, who have found that the use of such things as deodorants, aftershave lotion, and similar products have made it easier for them to face the world when they go out to their places of business each morning. Not only has the hope been realized, but the completely indefensible claims of damage to the public from the use of these so-called untested products do not agree with the facts which every careful competitive manufacturer develops from day to day. The number of claims of harm caused by cosmetics are so trifling as to be negligible. In fact, we are advised that in the nearly 25 years since the enactment of the Food, Drug, and Cosmetic Act, slightly over 200 cases have been brought by the Food and Drug Administration against cosmetic products were other industries covered by the same law have been cited far more often.

We realize that it is the tendency of Government bureaus to seek more and more authority—that is history. This measure, if it should unfortunately be passed, would place a tremendous burden upon the industry. It would do nothing but increase materially the price of safe cosmetics to every American woman. It would do nothing but discourage those ideas and that ingenuity to which I have already referred because the small fellow with a bright idea for a new cosmetic could never get into business under this measure but would have to do, hat in hand, to a big manufacturer, hoping to sell the idea for a few dollars and a job. We do not believe that this committee nor the Congress itself desires to jeopardize the small businessman or the ingenuity and ideas which have made the industrial picture of America so great.

Others are more competent than we to discuss the technical aspects of this bill and we shall leave that to them, but we urge that this committee send the measure back to its drafters in the Food and Drug Administration and in the Department of Health, Education, and Welfare with the suggestion that they draft a more perfect measure to accomplish a laudable principle and that, since this is such a tremendous job, every phase of it be discussed with industry before another bill is brought before your committee next year.

Thank you for allowing me to appear.

STATEMENT FOR CONSUMERS' RESEARCH, INC., BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11582, SECTION 302

This amendment, which would relax present anticancer clauses with respect to feed for animals, is objectionable, and dangerous in many respects.

The feeding to food animals of substances which are known to be cancer-causing is so obviously a risky business that it should not be tolerated at all except perhaps for the most compelling reasons, such as imminent famine or the emergency of nuclear warfare. The proposed legislation, however, opens the floodgates without any regard to the needs for the proposed additives.

Subsection 302(b) goes to the absurd length of permitting potentially dangerous food components to be used for no other purpose than to impart color to feeds for animals. Are we to increase our possible exposure to cancer, by any unknown amount, even if small, in order that cattle and swine feeds can be made in attractive hues, for appearance, or to distinguish one type of feed from another, for farmers' and feed dealers convenience?

If the section were adopted, animals raised for food production would be given less protection against carcinogenic materials than would all other animals fed by man, such as beasts of burden, domestic pets, and the denizens of zoos.

A "finding" by the Secretary that certain conditions of use and feeding are "reasonably certain to be followed in practice" will be no protection to the thousands, ultimately millions, of consumers who will eat the flesh and drink the milk of those animals which represent the unavoidable deviations from the "reasonably certain" feeding procedures.

Under this section's provisions, the health of every consumer will depend on the willingness and ability of countless farmers and farmhands to read, understand, and carry out complicated, precise directions for mixing feeds and distributing them to animals. There are no literacy tests for farmworkers, and it is traditional that directions are not read and followed even by people who read well.

The language of the bill calls for the Secretary to find "(ii) that no residue of the additive will be found * * * in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal." However, no provision is made for dealing with the situation if such residues are found despite the Secretary's "finding" that they will not be. A variation is conditions of feeding, climate, or animal health could readily invalidate findings made under the necessarily used laboratory conditions.

Furthermore, the conditions under which the Secretary's findings as to absence of residues are to be made are not clearly stated. Perhaps unintentionally, the proposed amendment is worded so that the phrase, "under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice" (p. 26, lines 20–22) does not apply to clause (ii) beginning on line 24. [There is analogous wording in subsection (b).] The net result of this wording is that the Secretary must determine in advance that no residue will be found, without any statement of the conditions of use or feeding under which such finding is to be made. This is not a valid requirement, since no finding could ever be reached that the edible animal products will never contain a residue of a carcinogenic substance.

However, the most important objections to section 302 are (*a*) that it does not provide for a showing of compelling need before use of an additive which has been shown to be carcinogenic, (*b*) that it permits use of carcinogenic color additives for which surely there has not been and never is a compelling need in animal feed, and (*c*) that it makes no provision for dealing with the situation in which a residue is detected in human food despite a prior finding that it would not be.

We believe that section 302 in its entirety should be deleted from H.R. 11582.

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STATEMENT FOR CONSUMERS' RESEARCH, INC., BY F. J. SCHLINK, PRESIDENT AND TECHNICAL DIRECTOR, CONCERNING H.R. 11582, SECTION 303

We are in agreement with the general intent beginning of this section, up to line 16, page 28. We are concerned, however, about the implications of the phrase, "if such prior sanction or approval had been made public" (lines 16–17) and we are disturbed that the amendment appears to provide a special method of treatment for prior sanctions or approvals which were not made public.

We believe that all sanctions or approvals should be publicly granted or not granted at all, that all such actions as have been taken secretly in the past should be required to be made public now, or else should be rescinded and have no further force and effect, and that any future actions with respect to prior sanctions or approvals (for example, as provided in the proposed amendment under discussion) should be taken only with full public notice and opportunity for interested persons to be heard, regardless of whether any earlier related action was public or secret.

TESTIMONY OF MR. JOHN F. MALO ON H.R. 11582

My name is John F. Malo. I reside at 2455 South Jackson Street, Denver, Colo. I am vice president and one of the owners of Intermountain Elevator Co. at Denver, Longmont, and Hudson, Colo., which company manufactures cattle feed supplements for sale in large bulk quantities to cattle feeders. The cattle feeding business is a major industry in this country, and cattle feeding is a highly developed science, being particularly important to the economy of the State of Colorado.

One of the developments has been the increasing use of antibiotics, vitamins, minerals, diethylstilbestrol and other ingredients designed to promote growth and increase feed efficiency.

I am appearing here in support of the proposed section 302 of the Harris bill. The reason is that under the present law as interpreted by the Food and Drug Administration I cannot manufacture my feed supplements in an efficient way and I do not receive equal treatment to that of some of my competitors. The proposed section 302, which is sponsored by the Food and Drug Administration, and supported by the President, will give to the FDA the authority needed to bring about fair and equal treatment and to permit greater efficiency.

Let me explain why. We use a substance called diethylstilbestrol (DES) in our feed supplements to promote growth of the cattle. Prior to 1958 the FDA had issued hundreds of new drug applications or supplements permitting the use of DES in a variety of formulas and in varying combinations with other ingredients. We, in fact, have several authorizations to use DES in our formulas.

In 1958, after the passage of the food additives amendment which included the "Delaney clause," the FDA refused to issue any new supplements for the use of DES or to permit any amendments or supplements to existing authorizations such as ours. They took this position, I understand, because apparently DES was a carcinogen.

However, based on all available data we have, and here the Food and Drug Administration agrees, DES will not cause cancer in beef cattle, nor will any harmful residues remain in the edible portion of the treated animal.

Indeed, since the drug was not harmful to cattle, the FDA permitted the existing authorizations to remain in effect after 1958.

A basic unfairness has resulted. A newcomer cannot obtain an authorization to use DES. Existing holders of authorizations, such as our company, are not permitted to amend or supplement their authorization. We recently desired, at the request of one of our large customers, to combine DES and aureomycin into one cattle supplement, a combination which involved no dangers to health. The FDA would not approve this change in our authorization. The sole net result of the Administrator's action is simply to drive our customers to our competitors who by sheer chance happened to hold a prior issued authorization for the right combination. The cattle feeder desires, for reasons of economy of time and money, to have both ingredients in the feed pellet. He doesn't care which supplier he uses if he is able to obtain the desired combination. Thus all—and I wish to repeat—all the present law does is to discriminate as between manufacturers of these feed supplements. There is absolutely no element of public health involved whatsoever. Cattle are still being fed DES in

combination with other ingredients, and people are still eating the beef. But some manufacturers are favored over others. This, I am sure, was not the intended congressional purpose.

To point up the ridiculousness of the present situation, let me give you two further illustrations. Though we are not permitted to mix DES with new ingredients, the feeder himself can. Thus, I can furnish him a feed pellet with DES in it; he can obtain some other component and mix it together in his mixers. It is more expensive for him; it is less efficient; it may even be less safe. But he can do it and we can't. I have attached to this testimony a letter I received from one of my good customers, Mr. David C. Wilhelm, of Rocky Ford, Colo., pointing out how silly this seems to the cattle feeders and how they will simply have to switch their purchases to another manufacturer. I am also attaching a letter from Kenneth Monfort, a large cattle feeder in Greeley, Colo., attesting to the need to combine DES and other ingredients for maximum efficiency. I have already lost business on this account and I expect to lose more unless this situation is remedied immediately.

Another illustration further highlights the need for change. We recently installed brandnew facilities at Longmont, Colo., brandnew equipment, subject to careful controls, and we certainly are able to manufacture these supplements as safely, if not more safely than many of our competitors. Yet we are forbidden to use these new, modern facilities, because some of our existing authorizations specify a different plant location, and we can't even change the location.

Obviously our company is vitally concerned with the health of our Nation; we don't desire to introduce into cattle feed any ingredient which may possibly jeopardize the health of man or animals. But DES used in the combinations we propose cannot, in any way, be harmful or dangerous.

As I said before, the proposed section 302, which is sponsored by the FDA, will give the FDA the express authority to issue new drug applications or supplements where it can be shown that the drug would do no harm to the animal, and where, under prescribed conditions of use, no residue of the carcinogen remains in the edible tissue of the treated animal. In short, where it can be shown that the beef would be absolutely safe for human consumption, then the Secretary could issue the authority. This would clearly cover our situation and is, we believe, a sound and fair position. The emphasis will be again on safety to the public, where it belongs, and not on favoritism as between competitors.

I appreciate this opportunity to come before you and briefly describe what has happened to us in Colorado, because I know our case is typical of other feed manufacturers. I am confident that as you hear these examples of how the present law is being applied, you will see the need for the proposed legislation.

WILHELM-MANCINI FEED LOTS,
Rocky Ford, Colo., June 19, 1962.

Mr. JOHN F. MALO,
Vice President, Intermountain Elevator Co.,
Denver, Colo.

DEAR MR. MALO: You have manufactured our feed for our cattle feeding operation now for 5 years, and we have always been satisfied with your treatment of our demands. We finish approximately 20,000 cattle per year, and I am sure the business is a benefit for you also.

However, we are now interested in having you incorporate both stilbestrol and either terramycin or aureomycin into our protein supplement. We are able to buy the stilbestrol in our protein now from you, but you have told us that we must buy our aureomycin in a product called Aurofac 40 and add that to our feed ourselves. We realize we can do this, but this is most cost consuming because of the costs of storage, mixing, and feeding. We would like you to incorporate this additive rather than us, and you say you are prohibited by law. We don't understand this nonsense. This seems unfair, unfounded, and without reason. Whatever the reasoning is, however, we may be forced to switch our protein purchases to another manufacturer, who has the license to mix the above ingredients, because, as I know you understand, we must feed as efficiently as possible.

Please see if there is any way to remedy this matter and inform us immediately.

Yours very truly,

DAVID C. WILHELM, *Managing Partner.*

JUNE 18, 1962.

MR. JACK MALO,
Intermountain Elevator Co.,
Denver, Colo.

DEAR JACK: This letter is in answer to our telephone discussion of today regarding your attempt to get set up to supply us with our formula food supplement. As you know, I believe it extremely silly that you cannot supply us with the formula of feed that we desire while your competitors in the area can and do. I believe that in order to assure our competitive position in the livestock production business, we must be able to take advantage of competitive bids on our supplementary feed mix. We can get these competitive bids only if it is possible for every competent feed supplier in the area to bid on our mix according to our specifications.

As you know, we feed and market about 70,000 heads of fed cattle per year. Our county is the largest single cattle feeding county in the country. A sizable percentage of the choice and prime beef consumed both on the east coast and the west coast comes from the feedlots in northern Colorado. We, at our feed lot, and other cattle feeders in the area have tested different rations for years. Colorado State University, along with other land-grant universities and colleges have conducted far reaching and extensive testing of feeding rations and additives in order to make cattle feeding a truly immense and economical part of the farming picture. I think it worth noting here that the cattle feeding industry is a part of agriculture that is wholly self-sufficient and extremely healthy. This has been accomplished only by the use of all available technology in the field. The cattle feeding industry not only is tremendously healthy, but, in fact, is growing so rapidly that it is today showing signs of eventually being able to devour our present burdensome supply of feed grains. These facts are only presented to you as background material for the request that follows.

As you know, our tests as well as university tests have proven to us that we should feed both stilbestrol and an antibiotic to our cattle on feed. I believe the majority of the other feeders in the area need and want to do the same thing. At the present time there is only one mill with significant capacity that is licensed to produce such a feed. To me, this is completely ridiculous and anything that you can do to alleviate this situation will not only be appreciated, but will be a service to our area and the cattle feeding industry throughout the country.

Sincerely,

KENNETH MONFORT, *Vice President.*

STATEMENT OF THE NATIONAL HAIRDRESSERS & COSMETOLOGISTS ASSOCIATION IN OPPOSITION TO SECTION 103 OF H.R. 11582 SUBMITTED BY ROBERT A. COLLIER

This statement is submitted by the National Hairdressers & Cosmetologists Association, Inc., in opposition to section 103 of H.R. 11582, the Cosmetics and Therapeutic Devices Amendments of 1962. The association represents more than 65,000 beauty salon owners and operators with a total employment of more than 150,000 trained and licensed cosmetologists.

Section 103 of H.R. 11582 would repeal the special exemptions of hair dyes contained in the Federal Food, Drug, and Cosmetics Act. The effect of this proposed repeal would be to subject the color additives used in hair dyes to the listing and certification requirements of section 706 of the act.

Under present law, coal-tar dyes are not subject to the statutory provision relating to cosmetics if the label bears the following legend conspicuously displayed thereon:

"Caution.—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness."

The present statute also requires that the label bear adequate directions for such preliminary testing.

Only coal-tar dyes have proven effective in the manufacturing of hair dye products. The many years of experience with the hair colorings currently in use, especially those of the oxidation type, have demonstrated the safety of using these colorings when applied by professional cosmetologists. Moreover, the

continued use of these products has increased our understanding of their effects and has in turn led to the use of purer ingredients compounded to more exacting standards.

Any individual who reacts adversely to these hair colorings does so solely because of an individual allergy to the product. The percentage of the total population who have an allergic reaction to coal-tar hair colorings is now so low that many other products currently marketed show a higher incidence of allergic response. The very small percentage of allergic reactions can easily be prevented by the method which is prescribed by the statute—the application by the cosmetologist of a simple preliminary test.

It is, therefore, indeed difficult to understand what useful purpose this proposed change in the law would serve. If this legislation were enacted, it would, of course, have no effect on the increasing demand for hair dye products. It is a well-known fact that the only effective hair colorings are made from coal tar.

Clearly, in view of the increasing public demand for hair dyes, and the lack of any appreciable incidence of allergic reaction, coal-tar dyes will in any case continue to be used by the public. In the event effective hair colorings were banned from legal distribution, then the great demand would, in all likelihood, create a "black market" to be filled by those who are unqualified to produce these colorings under anything resembling safe standards. If, as is more likely the case, the Secretary of Health, Education, and Welfare were to certify some coal-tar dyes under section 706, there would nevertheless remain a percentage of users who would have an allergic reaction to the dye. Some allergic reactions will inevitably remain even though the product meets certification requirements. It is highly doubtful whether this percentage will be any less than it is under present conditions and under the present state of the law. However, those who will remain allergic to the hair dye will not receive the benefits of the present law which requires that the label contain directions for preliminary testing. By eliminating this requirement, section 103 of this bill will serve to remove an existing safeguard to the public health without substituting any workable or effective alternative.

The public interest in effective and safe hair colorings is indeed great, and the evidence shows that this interest is being served by professional cosmetologists under the safeguards contained in the existing law. If a need exists for subjecting coal-tar hair dyes to the scrutiny of the Food and Drug Administration, such need is not based upon the experiences of patrons of professional cosmetologists.

Hair colorings serve a social, personal, and economic need. Individuals, especially females, seek to maintain their youth. Of course, youthfulness cannot be recaptured, but its appearance can be, and hair colorings help achieve and fulfill this desire. Women need to look young for social, as well as personal, reasons. To many, this appearance is mandatory if they are to compete successfully in the job market, particularly when the tendency is to cast in the "junk pile" anyone who is over 40. Gray hair is one of the first outward indications of advancing age; its concealment fulfills an economic need of many people.

The near-perfect safety record which cosmetologists have attained in the use of coal-tar hair dyes to serve these needs is the result of the proper application of these products by trained experts. It can be assumed that the relatively few adverse reactions occur in the self-application of coal-tar hair dyes by inexperienced home users of these products. To enact legislation which will include all coal-tar dyes within its scope, regardless of whether self-applied or used under an expert cosmetologist's supervision, is to penalize the professional cosmetologist for a situation which he has not created and which occurs because his services were not solicited. Thus, if the exemption is to be repealed, there is no justification for including the use of coal-tar hair dyes by professional cosmetologists within the scope of the repeal. Unfortunately, section 103 as presently written does not make this vital distinction between home use and professional application.

In view of the very doubtful benefits which this bill would provide, the economic losses to hairdressers and beauty salon operators would be appreciable. Hair coloring has become one of the most popular and most profitable aspects of the cosmetologist's business. Approximately 36 percent of the services rendered to beauty salon patrons consists of hair coloring. Of those utilizing these services, 70 percent are in the older and middle age classifications, and 58 percent are in the middle and lower income brackets. The disrupting effect of the bill upon this source of revenue can easily be imagined.

The 500,000 cosmetologists in the United States are dependent upon the use of coal-tar dyes for a significant part of their income, and they have used these products with a remarkable degree of safety in coloring hair. To enact legislation which may well prohibit their operations in this field on its present basis is to injure an important segment of the American economy without any assurance of corresponding benefits to the populace as a whole.

As recently as 1960, in the color additives amendment, Congress explicitly exempted coal-tar hair dyes from the scope of that legislation. That amendment to the Food, Drug, and Cosmetic Act made extensive changes in authorizing the use of suitable color additives in accordance with regulations to be issued to the Secretary of Health, Education, and Welfare. After an exhaustive study specifically directed to color additives the exemption for coal-tar hair dyes was permitted to remain in the act. To now amend the law, through a bill designed primarily to require a premarketing showing of the safety of cosmetics and the safety of therapeutic devices, would be contrary to the interests of the public and to the interests of the cosmetology industry.

In conclusion, the association contends that the present law is more than adequately protecting the public health in the use of hair dyes. Not only would section 103 of H.R. 11582 cause unjustified substantial economic loss and hardship to hairdressers and beauty salon operators, but it would also result in unnecessary added expense in the operations of the Food and Drug Administration. Most significantly, it would provide no assurance that the interests of the public would be more effectively protected than under present law.

STATEMENT OF THE AMERICAN PAPER & PULP ASSOCIATION, BY ROBERT E. O'CONNOR, EXECUTIVE SECRETARY, WITH RESPECT TO H.R. 11582, THE COSMETICS AND THERAPEUTIC DEVICES AMENDMENTS OF 1962

This statement is submitted to the House Committee on Interstate and Foreign Commerce by the American Paper & Pulp Association, the overall national association of the pulp and paper industry, in lieu of making a personal appearance with respect to H.R. 11582, the Cosmetics and Therapeutic Devices Amendments of 1962.

Section 303 of the Cosmetics and Therapeutic Devices Amendments of 1962, H.R. 11582, which is now before the Committee on Interstate and Foreign Commerce, would amend the prior sanction clause of the food additives amendment.

The section provides that the exemption afforded in clause (4) of section 201(s) of the Federal Food, Drug, and Cosmetic Act shall be inapplicable if the Secretary finds that there is substantial doubt as to the safety of such substances. Except in cases of imminent hazard to public health, the Secretary may take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public.

There was published in the Federal Register of March 1, 1960, a list of substances used in the manufacture of paper and paperboard for food packaging which are exempt from the law in accordance with prior sanctions or approvals granted prior to enactment of the food additives amendment.

All of these substances are of vital importance to the pulp and paper industry, and the status of any of them should not be changed without a public hearing to determine whether substantial doubt as to safety exists.

Under section 303 of H.R. 11582, the Secretary's action, even though in conformity with section 4 of the Administrative Procedure Act, would not afford an adversely affected person an opportunity for a public hearing on the issue of whether substantial doubt as to safety exists. Therefore, we request and urge that section 303 of the bill be amended to provide that in all cases within 30 days after the Secretary's notice of proposed action, any person adversely affected may file objections thereto and request and receive a public hearing thereon. In the event that the Secretary finds that there is an imminent hazard to public health, a public hearing shall be held within 30 days after such determination.

Our recommendation may be accomplished by inserting at line 21, page 28 (sec. 303), of H.R. 11582, before the period, a comma and the following: "*Provided further*, That, within thirty days after notice of such proposed action, or, when the Secretary finds that there is an imminent hazard to public health, within thirty days after such determination, any person adversely affected by such proposed action or actions may file objections thereto and request and receive a public hearing on such objections as provided in subsection (f) of section 409

of the Act with respect to food additive regulations and the right of judicial review as provided by subsection (g) of section 409 of this Act with respect to food additive regulations."

AFFIDAVIT SUBMITTED BY NORMAN M. FROIKIN, ASSISTANT SECRETARY OF GLO-RNZ, INC.

STATE OF OHIO,
County of Montgomery, ss:

Norman M. Froikin, being first duly sworn according to law deposes and states—

That he is an assistant secretary of Glo-Rnz, Inc., an Ohio corporation; and

That said corporation is engaged in the manufacture and distribution of hair coloring products; and

That Glo-Rnz hair coloring products have been manufactured, marketed, and distributed nationally in the United States of America for more than 30 years; and

That during said period, many hundreds of millions of applications of Glo-Rnz hair coloring products have been sold and applied to human hair in both professional beauty shops and directly by the consumer in home applications; and

That to the knowledge of this affiant, there is not a single known instance of serious damage or injury claimed or proved, attributable to the use of hair coloring products manufactured and distributed by this firm; and

That in 1943, the Glo-Rnz Distributing Co. caused its products to be tested and studied by Smyth Laboratories, of Philadelphia, Pa., for the purpose of determining the safety of its products for use and consumption on human hair; and

That the method of testing employed in that study was that proposed by Dr. Louis Schwartz, Director of the Division of Industrial Dermatoses of the U.S. Public Health Service, and a copy of the Smyth Laboratories report is marked "Exhibit A" attached hereto and made part hereof; and

That following said testing and study, said Smyth Laboratories, by Dr. Herman A. Shelanski and Henry Field Smyth, M.D., D.P.H., reported:

"In all of the subjects studied, not a single reaction was obtained on this initial application with any of the test substances in either series. Therefore, we may safely say that the substance is not a primary irritant."

"The patches on second application were allowed to remain in contact with the skin for a period of 48 hours, at the end of which time they were removed and the skin reactions noted. Forty-eight hours is deemed sufficient to bring out a sensitization reaction if one has become sensitized. No reactions were obtained on any of the subjects on the second application with any of the test substances. Thus the substances do not appear to be sensitizing agents.

"Since no reactions were obtained on the first application of any of these substances, we say that these substances are not primary irritants, and since no reactions were obtained on second application, it appears that the substances are not sensitizers. From the above evidence, it is our belief that these preparations are neither sensitizing agents nor primary irritants."

That this company has maintained products bodily injury and property damage insurance coverage for its products for many years, and that to the knowledge of this affiant, not a single substantial claim has ever been paid in behalf of this company, to any individual as a result of a claim for serious bodily injury; and

That for the period approximating 3 years from April 7, 1959, to May 22, 1962, a total of $10 was paid for losses by the insurance carrier for bodily injury losses as a result of claims submitted, which obviously was a nuisance claim, and reference is herewith made to the statement of Wallace E. Stauffer, agent for Insurance Co. of North America, the products liability carrier, in statement marked "Exhibit B" attached hereto and made part hereof; and

That this company has taken reasonable preliminary precautionary steps to assure that its products are safe for their intended end use; and

That by virtue of the hundreds of millions of applications of hair coloring consumed by humans of its products with complete safety, and by virtue further of the studies and tests conducted by a responsible and recognized clinic and laboratory under the direction of medical and pharmaceutical doctors, according to methods proposed by outstanding authorities and, in particular, a former Director of the Division of Industrial Dermatoses of the U.S. Public Health Service, this affiant states and submits—

(*a*) That the hair coloring pigments and dyestuffs used in the manufacture and sale of this company's hair coloring products are reasonably safe for use on human hair.

(*b*) That this company has acted in a reasonably prudent manner to investigate and establish the safety of its products, and has continuously ever since conducted itself in a reasonable and prudent manner to maintain the safety and effectiveness of its products.

Further affiant sayeth not.

NORMAN M. FROIKIN,
Assistant Secretary of Glo-Rnz, Inc.

Sworn to and subscribed before be this 3d day of July 1962 by the aforesaid Norman M. Froikin.

[SEAL] ——— ———, *Notary Public.*

Lifetime notary commission.

STATEMENT OF M. PIER CO. BY C. P. PROSSER ON H.R. 11582

We would like to oppose, vehemently, H.R. 11582—the Cosmetics and Therapeutics Devices Amendments of 1962 with special emphasis on section 103 which repeals the special hair dyes exemptions. Our reasons follow:

AS REGARDS THE BEAUTY SALON INDUSTRY

1. The Federal Food, Drug, and Cosmetic Act passed in 1938 provided that hair dyes should be exempt provided such products were labeled in accordance with section 601(a) requiring an appropriate patch test be applied before use of the product.

Once again, in 1955, the FDA confirmed the safety of hair dyes in a letter by Food and Drug Commissioner Larrick to Jacob Reck dated June 3, 1955.

Again, in 1960, Congress in the color additives amendments affirmed the exemptions for hair dye products due to the nature of their application, use, and labeling.

The entire hair dye industry, employing thousands of people and involving the investment of millions of dolars has been based on and has been operating under these exemptions in the law

2. Since 1938, due to the removal of impurities, hair dye products have improved immeasurably. It is estimated that over 15 million women currently and safely use and are pleased with today's hair dye products.

3. There are over 800,000 hairdressers currently employed in the Nation's beauty salons. It is estimated that between 33⅓ percent and 40 percent of their receipts is derived from the application of today's hair dyes. These hairdressers will face unemployment or vastly reduced income if the hair dyes exemptions are repealed. Needless to say, the 15 million women currently using hair dyes will also be highly displeased when deprived of hair coloring products.

4. Many companies such as ours would be forced out of business if the hair dyes exemptions are repealed with resulting unemployment and loss of invested capital. In addition, there would be greatly reduced income or failure for the hundreds of beauty supply dealers which supply beauty shops, and lost or appreciably reduced income for their employees.

5. There would obviously be loss of public purchasing power, and loss of taxes to the Government if the hair dyes exemptions are repealed. A bootleg hair dye business would in all likelihood develop promptly with resultant danger to users as a result of inferior products. This would be virtually impossible for the Government to control.

AS REGARDS OUR OWN COMPANY

1. Our major product is TIZ— creme and color rinse (approximately 85 percent of our business). TIZ— is a temporary hair dye which does not change the basic color of the hair but gives the hair color casts. TIZ— has never been made from certified colors. (Exhaustive tests have proved we cannot give results satisfactory to the consumer when certified colors are used.) We will, therefore, be out of business if the hair dyes exemptions are repealed.

2. In the interests of public safety and for our own reputation we have made it a practice to have Draize and allergenicity tests performed on our products by a highly reputable laboratory—the Laboratory of Vitamin Technology in

Chicago. Our products passed these tests or we would not have sold them. We are confident all other reputable companies in our industry run similar tests.

3. Since 1951 we estimate that over 250 million applications of our hair dye have been given in beauty salons or at home. The attached letter from our insurance carrier will testify to the safety of our products, the premium rate reductions our products have earned, and the minute number of complaints we have received compared with the number of applications given.

4. Our company has outgrown three plants. At present, over 200 people are directly dependent on the prosperity of our company for their support. As stated previously, repeal of the hair dyes exemptions will result in their immediate unemployment.

In conclusion, we started as the very smallest of small businesses. We are still small business, but small business or large, we can't believe it is the intention of the Government to penalize a company, its employees or in a larger sense, a major industry and 15 million satisfied users of today's hair dyes. This would certainly be the case if the hair dyes exemptions are repealed.

CHICAGO, ILL., *June 11, 1962.*

Mr. C. P. PROSSER,
M. Pier Co., Inc.,
Pompano Beach, Fla.

DEAR MR. PROSSER: In accordance with your request we wish to give you the following information.

The Continental Casualty Co. has handled the insurance of M. Pier Inc. and its subsidiaries since 1951. We do not have audit figures of sales dating back that far, but we do have a list of the total premiums that you have paid to date which aggregate $30,890.96. Therefore, if your sales since 1956 aggregate $6,837,957 all you need to do is to take from your own records your sales down to 1951 and add it to this figure. I imagine that they would be well in excess of $9 million.

Since 1951 you have reported a total of 39 complaints or claims. Thirty-four of these cases have been settled for total payments of $2,947.95. The majority of the complaints were without foundation, they aggregate, if anything, only nominal injuries and most of the payments made were in an effort to preserve the business relationship between you, our assured, and your customer. None of these claims, in our opinion, could have been substantiated and certainly they would not have occurred had your products been used in accordance with your printed directions.

Since 1951 your premium rate has been reduced periodically to the point that the present rate is $2.25 per $1,000 of your sales. In addition, we have greatly increased the limits of liability under your policy. Under your current policy which expires July 26, 1962, there have been a total of five claims presented. Two cases have been settled for a total payment of $550 and there are three pending of doubtful value. We would classify practically all of those paid as of the nuisance variety.

I have no way of knowing how many millions of applications of your products have been made, but perhaps you can determine this from your own sales records. However, from the information given above we can state that as far as we are concerned, you have an excellent record and this has been reflected in the steady lowering of your rates.

If there is any additional information that I can give you, please advise.

Sincerely,

W. H. ALGER.

NATIONAL AMERICAN COSMETOLOGY SCHOOLS, INC.,
Newark, N. J., July 5, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CHAIRMAN: This statement of protest against H.R. 11582—and particularly section 103 thereof—is filed on behalf of the membership of this national association, embracing more than 750 private beauty culture schools located throughout the United States.

Individually owned, these private training schools represent an overall investment of many millions of dollars. They employ thousands of instructors,

plus general office help and maintenance workers. They teach upward of 125,000 students annually.

All of these schools and their owners, every instructor, every clerical worker, every maintenance employee, and every student can be adversely affected by passage of this unnecessary and unwarranted measure.

This association stands solidly in favor of legislation that benefits the entire beauty culture industry and is in the interest of the countless millions of women who patronize the Nation's estimated 150,000 beauty salons.

But this legislation is neither in the interest of this industry nor in the interest of women generally.

Instead, its immediate effect would be economic disaster for the entire beauty profession, since it would immediately deprive every salon of a service that now constitutes a major portion of its billion-dollar income.

Likewise manufacturers would be adversely affected, and their employees discharged.

Approximately 500,000 beauty salon operators would suffer loss of income with loss of employment by many. Owners of these salons would be faced with the loss of millions of dollars of life's savings now tied up in beauty shop investments.

Aside from the indicated effect upon school owners and instructors, the 125,000 students now in training in beauty schools would suddenly find that their future in the beauty industry is in jeopardy and the huge sums invested in tuition would have greatly lessened value.

The ostensible purpose of this stanchly opposed measure supposedly is protection of the public. With due respect, we ask: "Protection against what?"

The Government already provides protection against possibly ensuing allergies in its present requirements for patch tests, and the record of haircoloring to date show that such unfavorable reactions as may occur are infinitesimal against the total services rendered and are due to occasional allergies.

Surely, the great efforts and the millions and millions of dollars spent in research by the laboratories of our hair-coloring manufacturers have not been devoted to building products whose qualities are inherently toxic. They have been—and are—devoted to creating beauty with safety.

Removal of the special exemptions now accorded hair dyes not only can create economic chaos in this billion-dollar industry, but unemployment figures and relief roles will be swelled to record highs—all without need.

We respectfully urge your committee to reject this measure, particularly section 103.

Very truly yours,

BENEDICT V. GRIPALDI, *President.*

GODEFROY MANUFACTURING CO.,
St. Louis, Mo., June 18, 1962.

Re. H.R. 11582.

Hon. OREN S. HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: We respectfully submit our objection to H.R. 11582, which is now before you and your committee. We address ourselves particularly to section 103, which removes the exemption for coal tar hair dyes.

This company has been manufacturing cosmetics since 1882, and coal tar derivative hair dyes since 1894. Over this span of years many millions of applications of our hair dyes have been made, and only an infinitesimally small number of persons have experienced allergic reactions, the result of the failure of the user to follow the directions for patch testing. Hair dyes have a favorable ratio with thousands of other products consumed by the American public.

Constant research is being made by this firm, and many others, but to date only the coal tar derivatives produce a satisfactory hair coloring which meets the needs of the consuming public. These products have become an economic necessity for hundreds of thousands, as it is estimated that 15 to 30 million men and women regularly color their hair.

Banning hair dyes from the legitimate market would have far-reaching dire effect. The consuming public would be deprived of a satisfactory product; thousands of beauty salons whose revenue from these services are vital to their existence would suffer; and likewise, many thousands of persons engaged in the manufacture and sale of these products would be without employment. Elimi-

nating business amounting to $600 million or more can only further help to damage our already jittery economy.

This firm, which has been established since 1882, would be forced to close its doors as over 95 percent of our business is, and has been the manufacture of coal tar derivative hair dyes. Surely, this is not the time to enact extreme hardship measures which experience proves are not warranted. We urge your favorable consideration of continuing to protect the consumer by the retention of the present hair dye exemption, and thereby retaining the buying power of hundreds of thousands now employed in the manufacture, sale and distribution of these products.

Respectfully submitted.

E. L. EMME, *General Manager.*

D. E. WINEBRENNER CO., INC.,
Hanover, Pa., May 31, 1962.

Hon. GEORGE A. GOODLING,
House Office Building,
Washington, D.C.

DEAR MR. GOODLING: It has come to our attention that public hearings will begin June 19, 1962, on H.R. 11581 (drug and factory inspection amendments) and on H.R. 11582 (pretesting of cosmetics).

We as food manufacturers are definitely opposed to these two amendments because such unlimited power is not only unnecessary but subject to possible misuse by inexperienced Food and Drug Administration field inspectors. Mandatory inspection should not extend to the food field, to a manufacturer's processes and formulas, to his complaint and personnel files, or to his private consulting laboratory. Exercise of such broad power endangers property rights and valuable formulas and trade secrets, and may well operate to discourage industry from keeping important research and quality control records. Therefore the enactment of H.R. 11581 should be opposed by food manufacturers unless the bill is amended by striking all of "Title II—Clarification and Strengthening of Factory Inspection Authority."

H.R. 11581 proposes new factory inspection power which goes beyond anything reasonably required for enforcement of the Federal Food, Drug and Cosmetic Act. Section 704 of the act is first amended to cover a manufacturer's consu'ting laboratory as well as his own establishments. Next, the bill amends section 704(a)(2) of the act to bring under factory inspection "all things therein * * * bearing on violations or potential violations of this Act." Finally, section 302(a) is amended to strike (f) thus enabling the FDA to force an entry by court order if a factory manager refuses to permit inspection.

Considering the new language proposed for section 704(a)(2) there would appear to be no limits that a food manufacturer can place upon the demands of an inspector, even where the records and things called for seem irrelevant to the statutory objective of preventing adulteration or misbranding. Apparently an inspector could cite this broad authority to require a manufacturer's disclosure of consumer complaints, secret formulas and patents, personnel qualifications, quality control and laboratory records, and office documents dealing with production, packaging, labeling, advertising, marketing, pricing and financing. Any doubt that the FDA would have an interest in financial and economic records tends to disappear in the light of recent enforcement actions dealing with such matters as "cents off" promotional labeling and "economy size" package designations.

Less than 10 years ago the food industry cooperated with the FDA in enacting the compulsory factory inspection amendment of 1953. At that time Congress was quite firm about limiting inspection powers to matters reasonably related to the prevention of violations. It specifically declared against "fishing expeditions" designed to obtain evidence for legal prosecution and it confined inspections to matters of sanitation.

The food manufacturer must oppose excessive factory inspection, not because he has something to hide, but because he has a right and duty to protect his private property in valuable formulas, trade secrets, etc., and also because consequences detrimental to consumers may result from a policy of unrestricted inspection. As regards secret formulas, etc., a manufacturer observes that inspections may be made not only by Federal agents but by commissioned State

and municipal agents as well. He notes that these inspectors may leave government service to become employees of a competitor, and that it would be difficult in any case to prove an unlawful breach of confidence, whether deliberate or inadvertent, with respect to trade secrets. As regards consumers, the manufacturer sees a prospect of harm in the fact that unrestricted inspection discourages the keeping of many records important for quality control and research. Above all, the food manufacturer sees in this amendment a shift from traditional FDA inspection practices to a system of search and seizure. And he remembers that violation of the Federal Food, Drug and Cosmetc Act can mean a personal criminal conviction even in the absence of guilty knowledge or intent.

H.R. 11581 was drafted by the FDA as a result of the drug industry investigation conducted by Senator Kefauver's antitrust subcommittee. The bill principally affects drug products, and it probably would never have involved food at all had there been separate food and drug provisions for inspection as in the case of the adulteration and misbranding sections. Drug manufacture differs from food manufacture in many respects, and what is necessary for one may be unwarranted in the case of the other. The desirable solution of this problem is to revise H.R. 11581 so as to eliminate drug references from existing section 704(a) of the Federal Food, Drug and Cosmetic Act, and to enact a new section 704(b) which will specifically govern drug factory inspection. The food industry would have no reason to oppose enactment of a separate drug inspection provision, especially if its form were sound and it invited the support of that industry.

Please excuse the length of this letter; however, we are very seriously concerned about the outcome of this proposed amendment, and we ask that you oppose it in behalf of all food manufacturers in your district as well as ourselves.

With kindest regards, we are,

Most sincerely,

WIRT S. WINEBRENNER,
Vice President.

STATEMENT OF NATIONAL COUNCIL OF FARMER COOPERATIVES ON H.R. 11581 AND H.R. 11582

The National Council of Farmer Cooperatives is a national federation of 127 farmer-owned and farmer-controlled cooperative marketing and purchasing associations, which are local, State, regional, and national in scope. Our affiliates include 5,700 farmer cooperatives throughout the Nation serving 3 million farmer memberships.

We wish to express our views on three particular subject areas contained in H.R. 11581 and H.R. 11582. They are:

(1) Permitting an exemption for feed and color additives causing no harm to animals and leaving no residue in food produced for human consumption as provided for in H.R. 1582, title III, sections 302 and 303.

(2) Broadening the Secretary's powers of factory inspection as provided for in H.R. 11581, title II, section 201.

(3) Using H.R. 11581 and H.R. 11582 for the establishment of uniform standards of quality and sanitation applicable to domestic and imported products.

FEED ADDITIVES LEAVING NO RESIDUE IN FOOD FOR HUMANS

Approximately one-fourth of the national council members own and operate feed manufacturing facilities producing animal feeds for the livestock, dairy, and poultry industries. According to the USDA Farmer Cooperative Service, farmer cooperatives produce 24 percent of the total animal feed manufactured in the United States.

With this broad membership interest in mind, the national council wishes to express its views on the use of feed and color additives in animal feed as stated in H.R. 11582, title III, sections 302 and 303. Section 302, as it is written, will give authority to the Food and Drug Administration to grant an exemption for the inclusion of food and color additives in animal feed which are harmless to the animals and leave no residue in the product processed or prepared for human use. New permits for the inclusion of diethylstilbesterol in animal feeds have not been granted since the passage of the Delaney amendment in 1958, nor have intracompany transfer of permits from an outmoded plant to a new

facility been granted. Enactment of this section will establish a sound procedure whereby the FDA will permit animal feed manufacturers again to use additives which have been helpful in improving growth, lowering feed conversion rates, and enriching the appearance and value of their products produced for the livestock, dairy, and poultry industries. Improvements in feed efficiency and growth with the corresponding decreases in costs of production have been mostly passed on to the American consumer in the form of lower costs of animal products.

We are opposed, however, to the unlimited discretionary power given to the Secretary in determining the "zero residue" requirement. We urge that section 302 be further improved by amendment to take into account the best scientific judgment available.

At the 1960 annual meeting of the National Council of Farmer Cooperatives, the delegates approved the following:

"* * * The council proposes that there be established an impartial commission to review applicable legislation now in effect with a report of its findings to the President or the Congress. Such commission should also report and recommend such administrative procedures as will give adequate protection to consumers, but at the same time protect producers from intemperate, unreasonable, and precipitate action by Government agencies which would result in serious loss to them * * *."

In 1960, the President's Science Advisory Committee made several significant recommendations, the standards and operating procedures of which, in our judgment, should be incorporated in section 302 and 303. The Science Advisory Committee, in 1960, stated:

"1. That the Secretary of Health, Education, and Welfare appoint a board advisory to him to assist in the evaluation of scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds.

"The advisory board should be composed of scientists from the National Cancer Institute, the Food and Drug Administration, the U.S. Department of Agriculture, and the scientists outside of Government from a panel nominated by the National Academy of Sciences.

"It would be the function of the board to weigh evidence and to make recommendations to the Secretary of the Department of Health, Education, and Welfare on the basis of available scientific data, both on applications for approval of new food additives and in all cases where the withdrawal of a prior approval or sanction is under consideration. The board would consider among other matters:

"(*a*) Whether or not the tests for carcinogenicity are appropriate and reasonable,

"(*b*) Whether the substance is or is not in reality carcinogenic as determined histopathologically or by other criteria,

"(*c*) Whether addition of the substance to agricultural products would result in a concentration of the substance above the natural background level of such substance.

"(*d*) What assay techniques are appropriate to determine whether a specific carcinogen is present in food.

"It would also be the function of this board to review from time to time its recommendations and to modify them in the light of new scientific knowledge. Further, the board would assume the responsibility of recommending to the Secretary of Health, Education, and Welfare specific research problems to be undertaken to provide necessary scientific data.

The national council supports the statement of the President's Science Advisory Committee and recommends that appropriate language be incorporated in sections 302 and 303 to take advantage of the competent efforts of the advisory committee to establish sound procedures and safeguards for the protection of consumers and manufacturers using feed and color additives.

Incorporating the recommendations of the Science Advisory Committee into sections 302 and 303 will broaden the scientific data available to the Secretary, while at the same time, assure the user of the feed and color additives fair and impartially imparted information for men and women of competent scientific achievement.

It is scientifically and politically unwise to seek tolerances for additives known to induce cancer, nor do we make such a request. However, it must be recognized that there is serious controversy among scientists on the methods and

techniques employed in determining residues in various products. It is from these methods and techniques that many of the past decisions of the Food and Drug Administration have been rendered, many of which, in our judgment, are based on inconclusive or disputed scientific evidence. The President's Science Advisory Committee in 1960 commented on this subject:

DEFINITION OF INDUCED CANCER IN ANIMALS

"The recommendation procedure for testing the possible carcinogenicity of a chemical additive calls for its incorporation into the diet of several animal species, at several dosage levels, and for the duration of the animal's life span where feasible. Like all biological assay methods, this procedure has more inherent variables than do procedures involving physical and chemical methods. Further, recognition of a carcinogen by the bioassay technique presents greater difficulties of interpretation than are usually encountered in assaying the effects of other pharmacologically active substances. These difficulties of interpretation are related to the identification of the tumor as a cancer, and to the way in which the experiment is designed.

"The criteria for defining whether or not a 'cancer' has been induced in the experimental animal are varied. They include the microscopic appearance of the tumor (histopathology), its ability to metastasize, its transplantability to other animals of the same species or inbred strain and its local invasiveness. The most commonly employed criterion is the histopathological diagnosis. However, this depends on the judgment of pathologists and diversity of opinion among them is not uncommon. A further difficulty emerges from the fact that not all tumors are cancers and that there is a difference of opinion regarding the possible, subsequent malignancy of at least certain benign tumors."

Further, techniques that are currently available and in use may not be able to find residues in food prepared for human use. Yet, in a short time, improvement of current techniques may enable scientists to find traces of residue. With the constant advancement in scientific techniques, this is far more than a remote possibility. If this occurs, the law would require the immediate cancellation of all permits even though no change occurred in the product. The helpful aspects of sections 302 and 303 to the animal feed manufacturing industry would then be negated.

AUTHORITY TO BROADEN HEALTH, EDUCATION AND WELFARE'S POWERS OF FACTORY INSPECTION

The national council believes H.R. 11581, title II, section 201 will give the Secretary of Health, Education, and Welfare unnecessary and undesirable powers to search the premises and records of the manufacturers, processors and packers of food products for human use. The broad and sweeping language in section 201 would grant inquisitorial powers since no need for the search and inspection action has to be shown. It would authorize "fishing expeditions" for violations.

The Secretary currently has the right to inspect premises to determine sanitation practices and the adequacy of processing equipment, when it is known that a manufacturer or processor has placed an adulterated food product in the marketing channels. However, the amendments offered in section 201 will permit a "search" of records, including formulation procedures and data, personnel files, processing procedures and other private papers. Such "searches" create grave danger of a "leak" of confidential information if employees of FDA leave for private industry assignments. The passing on of vital information to competitors might well cause irreparable harm to the business income of the manufacturer or processor of food products involved in such inspections.

We can readily understand, for the protection of the public, that when adulterated food products are found in the channels of distribution, the FDA should have the authority to investigate sanitation practices, raw materials and the adequacy of processing equipment of the suspected offenders. FDA has much authority in this field now. Modest expansion of this authority to remove adulterated food from marketing channels may be desirable to protect public health.

However, section 201, in our judgment, would grant authority far in excess of that necessary to protect the consuming public. We are strongly opposed to this section and recommend it be deleted from H.R. 11581 or FDA be re-

quired to show good and sufficient cause before search warrants for specific items relevant to protection of public health would be granted.

USE OF H.R. 11581 AND H.R. 11582 FOR ESTABLISHING UNIFORM STANDARDS OF QUALITY AND SANITATION APPLICABLE TO DOMESTIC AND IMPORTED PRODUCTS

These bills and the authority they would grant the Department of Health, Education, and Welfare should be directed toward the maintenance of comparable standards of quality and purity for imported as well as for domestic food products. At the 1959 annual meeting of this organization delegates approved the following policy statement:

"*Inspection of food imports.*—Food coming into the United States is not subject to a Federal Food and Drug Administration inspection of their producing premises and is subject only to inspection of the finished product itself. * * *

"We urge that Congress take action to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land."

These bills strengthen the inspection authority of the FDA regulations for domestic production of foods, drugs, and cosmetics. This organization has many members in the field of processing and marketing of food and fiber products. They and other food manufacturers have voluntarily established high standards of quality and sanitation—at increased cost—to protect consumers and to raise demand for their products. This action might incidentally place our manufacturers at a competitive disadvantage if foreign plants should resort to the shipment of substandard products, and inspection in consumer channels does not disclose the use of comparable plant standards and raw material standards. We recognize that the canning and processing facilities and premises of foreign food manufacturers are not available for inspection on the same basis as are U.S. food processing plants. Even though comparable U.S. inspection is not available, uniform standards applicable to the final product may encourage the governments of foreign countries to establish high sanitary standards for raw materials and plant facilities in order to protect consumers as well as to develop more equitable competitive standards in foreign and domestic commerce.

We believe the establishment of uniform sanitary standards is desirable, not only from the standpoint of establishing a fair and equitable competitive climate in the retail markets for food and fiber products, but to protect the consumer against wide variations in quality and value of the products they purchase from whatever source.

SUMMARY

We recommend the passage of sections 302 and 303 of title III of H.R. 11582 provided the Secretary of Health, Education, and Welfare be required to have available and to take into account broad, scientific information and procedures as recommended in the report of the President's Science Advisory Committee. Action taken contrary to the recommendation of such an advisory committee should be reported to Congress with justification therefor.

Further, H.R. 11581 and H.R. 11582 will strengthen the inspection authority of the FDA regulations for domestic production of foods, drugs and cosmetics. This organization has many members in the field of processing and marketing of food and fiber products. They and other manufacturers have voluntarily established high standards of quality and sanitation—at increased cost—to protect consumers and to raise demand for their products. We believe the establishment of uniform sanitary standards desirable not only from the standpoint of establishing a fair and equitable climate in the retail markets for food and fiber products, but to protect the consumer against wide variations in quality and value of the products they purchase from whatever source.

Section 201, title II, H.R. 11581 will give the Secretary of Health, Education, and Welfare unnecessary and undesirable powers to search the premises and records of the manufacturers, processors and packers of food products for human use. The Secretary currently has the right to inspect the premises to determine sanitation practices and the adequacy of processing equipment, when it is known that a manufacturer or processor has placed an adulterated food product in the marketing channels. We believe this is ample authority. Section 201, in our judgment, would grant authority far in excess of the necessary to protect the consuming public. We are strongly opposed to this section and recommend that it be deleted from H.R. 11581 or the FDA be required to show good and

sufficient cause before search warrants for specific items relevant to protection of public health would be granted.

NATIONAL COUNCIL OF FARMER COOPERATIVE POLICIES

Opportunity for trade.—Various devices, such as quotas, licenses, seasonal embargoes, bonus dollars, and many other restrictions, have become of even greater significance in regulating and restricting international trade than tariffs. As a consequence, in the presence of such highly restrictive measures, tariffs assume subordinate importance as a bargaining instrument.

The expansion of exports and international trade will come from increased economic strength in foreign countries, currency convertibility, the development of the proper climate for capital investments, particularly in the newly developing areas, and the elimination of the many practices which hamper rather than encourage the exchange of commodities. We recommend these principles.

Inspection of food imports.—Food coming into the United States are not subject to a Federal Food and Drug Administration inspection of their producing premises and are subject only to inspection of the finished product itself.

American-produced food products are subject to an inspection of producing premises and foods emanating from such premises can be seized if they are produced "* * * under insanitary conditions where it may have become contaminated * * *."

We urge that Congress take action to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land.

In addition, the National Council of Farmer Cooperatives seeks specific congressional action, during the 1959 session of Congress to require the Food and Drug Administration to apply comparable sanitary standards to all food products whether produced in the United States or in a foreign land.

Food and Drug Act administration of agricultural chemical regulation.—The administrative procedures followed by the Department of Health, Education, and Welfare with respect to laws governing the use of certain agricultural chemicals used in the production or preservation of foods or feedstuffs said to be harmful to consumers, have created deep concern among farmers of the Nation.

The health and well-being of consumers of farm products is of paramount interest and concern to producers of those products. Yet conflicts in findings of two Government agencies with responsibilities in this field give rise to serious question as to the value of legislative requirements of such rigid nature. Such requirements are held by distinguished scientists to be unreasonable.

The council proposes that there be established an impartial commission to review applicable legislation now in effect with a report of its findings to the President or the Congress. Such commission should also report and recommend such administrative procedures as will give adequate protection to consumers, but at the same time protect producers from intemperate, unreasonable, and precipitant action by Government agencies which would result in serious loss to them.

Such commission should also make recommendations with respect to adequate research on improved agricultural chemicals and methods of application and use which will safeguard consumers.

In the interim we insist that the administration of the pure food and drug laws governing use of agricultural chemicals used in the production or preservation of foods and feedstuffs be tempered with as much reason and concern for farmers as for consumers. This would entail proper information to farmers as to proper methods of application, prior warning before commodities are condemned with ample time and opportunity to be heard and to take corrective action before condemnation.

EVANS RESEARCH & DEVELOPMENT CORP.,
New York, N.Y., July 5, 1962.

Re H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: In accordance with your permission dated June 15, 1962, we would like to make the following statement for the record.

The proposals contained in the H.R. 11581 and H.R. 11582 which would allow unlimited inspection of consulting laboratories seems to us entirely unnecessary and constitutes a definite hazard to the rights of consulting laboratories, their clients, and the Federal Government.

There are several different types of laboratories called consulting laboratories; many of them do basic research for industrial clients and often Government agencies as well. They also do product development in many different areas for both industrial clients and the Government. In many cases the Government contracts involve confidential and secret research. Only qualified and U.S.-cleared personnel are allowed access to these records. It is obvious that such agreements with the Government to maintain proper safeguards against the disclosure of records involved in such work would have to be maintained and would be in direct conflict with the proposed legislation.

The very lifeblood of our American economy has been the development of new products and the patent system which offers them protection. In many cases a small variation in formulation or process is the difference between a superior product, from a customer's standpoint, and a less desirable one, even though both would pass any inspection of raw materials, processing, etc.

In our opinion it would also be an unnecessary burden of expense to the laboratories being inspected to have to furnish the personnel to observe and explain activities and furnish the necessary cooperation to make the information required available.

If any inspection of consulting laboratories is granted to the Food and Drug Administration, it should be strictly limited to such control work as may be carried on by the laboratory directly in connection with the actual manufacturing process of products to be used by the public and should not relate in any way to research and development of new and different products and methods.

We respectfully submit that the destruction of private rights, which would be occasioned by this legislation, plus the burden of carrying out the activities, far outweigh any possible minor value to the common good which might be derived.

Respectfully,

WILLIAM E. HOLLAND, Ph. D.,
Vice President.

SALES AFFILIATES, INC.,
New York, N.Y., July 11, 1962.

Re H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR SIR: This organization is a New York corporation with its principal office located at 801 Second Avenue, New York, N.Y. We distribute our own brands of professional permanent waves, hair colorings, cosmetics, and similar items through wholesalers to the beauty trade for use by licensed operators in beauty salons. The factory is located in Waterloo, Seneca County, N.Y., and has been for 20 years the principal business in that community. While we are far from the largest organization in our industry, we are also not the smallest.

In accordance with permission granted on June 13, 1962, we hereby file the following statement of our views of the above bills pending before the Committee on Interstate and Foreign Commerce.

H.R. 11581, TITLE II

We object to sections 201, 202, and 203 of title II of this proposed bill, which sections relate to the inspection of factories and consulting laboratories.

We believe that the authority for factory inspection granted by section 201 is so far reaching as to be plainly violative of the fourth amendment of the Constitution of the United States. Authority is here sought to be given to Government agents to enter any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction, and to inspect such factory, warehouse, establishment, consulting laboratory, and all pertinent equipment, finished and unfinished materials, containers, and all records, files, papers, processes, controls and facilities therein.

All of this search and inspection may be done without the prior showing of any necessity whatsoever for doing them. Correlative with these acts will be the disclosure of secret formulas, processes of manufacture, and other valuable trade secrets which are the very lifeblood of the business of the person whose business premises (or home) are the subject of the search. It is well within the realm of possibility that these secrets may soon find themselves in the possession of a competitor after their disclosure.

Consulting laboratories are universally researching and developing new ideas, many of which have no present commercial application. As proposed, this bill would require flagrant violations of trust and lay bare to the inspecting Government agents all of the most secret records, files, papers, processes, controls and facilities which show the results, as well as the work in progress, of such a laboratory, causing irreparable and unnecessary damage to the laboratory and its clients, without one iota of benefit inuring to the public interest. Should such a right exist in the Government, it is easy to visualize a great curtailment in research, with the inevitable result that private consulting laboratories would soon find themselves without clients and in the process of liquidation, thus completely depriving the public of the great benefits which accrue from such research.

Furthermore, research in the field of cosmetics is generally a small part of such laboratories' work. Most of these laboratories are engaged in a multitude of research problems, many of which have nothing or little to do with foods, drugs, or cosmetics. To compel disclosure of the innermost secrets of such work would be absolutely irrelevant to the protection of the public from harmful foods, drugs and cosmetics, grossly unfair to the laboratory and its clients, and cause untold harm to the public interest.

Should the Government be granted any right of inspection of consulting laboratories that right should be limited strictly to the inspection of control tests conducted in connection with the actual manufacture of products for sale to the public and should specifically be denied as to research and development activities.

H.R. 11582, TITLE I, SECTION 101

Section 101 provides for the approval prior to marketing of all new cosmetics.

While we cannot fault the purpose of this section, we most respectfully direct your attention to the fact that under the provisions of the present food, drug, and cosmetic law the Food and Drug Administration is fully armed with authority to seize and prosecute speedily any harmful cosmetic which may find its way to the marketplace. Since the enactment of the present law, there have been very few dangerous cosmetics marketed. The proof of this statement is evidenced by the very small number of seizures of cosmetics made by the Food and Drug Administration during the past several years; and the fact that so few seizures have been necessary is also proof the manufacturers of cosmetics do make sure their products are safe before the products are marketed. In some instances, such as those of a fingernail adhesive and a home hair waving solution, the harmful propensities of the products were not discovered (and probably could not have been discovered) during premarket testing but were found only after millions of applications of each product had been used. In all likelihood the proposed law would not have uncovered the harmful propensities of these products; for like so many of the new miracle drugs which have been granted Food and Drug approval the full nature of all possible side reactions to such cosmetics could only be determined finally by their actual universal distribution and mass usage. When the harmful possibilities of these products were discovered they were promptly removed from the market.

This proposed legislation is plainly discriminatory against the small- and medium-sized business and in favor of the giant cosmetic manufacturer. Without question, and of necessity, the general test procedures which would be established under this law to cover a wide variety of products for many different uses, would go far beyond the test procedures now needed to determine the safety of any particular product and the dangers to be anticipated from its sale and use. Because of his size and wealth, the large manufacturer will be able to afford to spend the huge sums of money the required generalized testing will entail. The small firm, and even the fairly large firms, will not be able to afford to expend the large sums of money unnecessarily required for this generalized testing, and they will be forced out of business. Their business will be gobbled up by the big firms, and a few giants will then control the entire cosmetic industry.

H.R. 11582, TITLE I, SECTION 103

Section 103 seeks the repeal of special exemptions for hair dyes.

We have sold and distributed the permanent type of coal-tar hair dyes to the beauty trade for more than 30 years. Our records since January 1, 1959, show that we have sold many millions of applications of the permanent and temporary types of these products and that we have had few reports of alleged injuries resulting from their application during that time. These reports have been received at the phenomenal ratio of about 1 alleged injury per 2,800,000 applications sold. Furthermore, none of these alleged injuries was of a serious nature nor has any lawsuit been commenced by anyone of those reporting alleged injuries.

And not a single report of alleged injury was received during that period resulting from the application of the permanent type of coal-tar hair dye which we market.

Insurance companies issue product-liability insurance on an extremely realistic basis. The rates are based on actual experience. Our company carries a liability policy on all of its products with high limits of liability. The primary rate charged for our hair colorings is less than the rate which is charged for our face and hand creams and lotions, shampoos, etc., and only one-half the rate charged for permanent waving solutions.

All of the said reports of alleged injuries which we have received on hair colorings were based on claims of allergic reactions to some product contacted by the user. In several of the alleged instances, the offending allergen may well have been the shampoo, the wave set, or some other product contacted at or about the time of the application of the hair dye and not the hair dye itself. So far as allergy is concerned, there are hundreds of common foods and drugs in universal use which have a much higher incidence of allergic reactions to them by susceptible persons than do the coal-tar hair dyes. Shellfish, strawberries, milk, eggs, etc., are all offenders. Aspirin, iodine, adhesive tape, ad infinitum are all allergens to large groups of susceptible individuals.

At a hearing before the Food and Drug Administration held in Washington on January 6, 1956, Dr. Adolph Rostenberg, a consultant for the Food and Drug Administration, testified to the effect that the patch test was prescribed by the present Food, Drug and Cosmetic law was a highly accurate means of discovering whether or not a prospective user of coal-tar hair dyes was allergic to the product.

Dr. Louis Schwartz, former medical director of the U.S. Public Health Service, testified at the same hearing to the effect that the incidence of allergy to paraphenylenediamine hair colorings (paraphenylenediamine is a chemical commonly used in the permanent type of hair dyes) was low; that he had examined thousands for incidence of allergy to such dyes and it was nil. His testimony further showed that of millions of bottles of a well known permanent type of coal-tar hair dye sold, a ratio of less than 0.00001 percent complained of alleged allergic reactions.

No one has ever claimed that hair dyes were toxic or poisonous. The incidence of injury due to allergic reaction is much too small to justify the proscription of these widely used products.

There are over 150,000 beauty shops in the United States. Over 800,000 persons are employed in the beauty shop industry. Gross income received by beauty shops totals over $2,500 million a year. Hair coloring is estimated to constitute over 40 percent of the business of these beauty shops. Without hair-coloring business, few of the 150,000 beauty shops could survive, and hundreds of thousands of idled hairdressers and other employees would greatly expand the already large body of unemployed.

Drug and department stores sell millions of dollars worth of hair dyes yearly. Should section 103 be adopted, these stores would lose an important segment of their business.

Despite the economic disaster which would follow the outlawing of hair colorings, we would not urge it as an excuse for permitting the sale of coal-tar hair dyes if such sale were not amply justified. However, from all of the facts available it must be clear to any impartial observer that there is no justification whatsoever for prohibiting the sale and use of these materials.

Millions of women today color their own hair or have it colored in beauty shops. They will not willingly abandon the use of hair colorings for the enhancement of their personal appearance. Should legitimate hair colorings be removed

from the market by the passage of section 103, these women will surely resort to the use of the bootleg hair colorings which will most certainly flood the market. The positive harm to these women in such an event is incalculable. They will demand hair colorings. Their demand will be met by fly-by-night peddlers. A multitude of impure and potentially dangerous concoctions, produced under most unsanitary conditions, will fill the vacuum created by the forced withdrawal from the market by legitimate manufacturers of the present eminently safe and pure hair colorings with which the unscrupulous cannot now compete.

CONCLUSION

For all of the above reasons, we most urgently request that approval of tile II—Clarification and Strengthening of Factory Inspection Authority, of H.R. 11581, and title I—Premarketing Clearance of Cosmetics for Safety, of H.R. 11582, be withheld by your committee.

Respectfully submitted.

RALPH L. EVANS, Ph. D.
President.

NATIONAL COTTON COUNCIL OF AMERICA,
Washington, D.C., July 17, 1962.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, Washington, D.C.

DEAR MR. HARRIS: The purpose of this letter is to advise you of the views of the National Cotton Council on H.R. 11581 and H.R. 11582. The National Cotton Council is the overall organization of the raw cotton industry, representing cotton farmers, cotton ginners, cotton merchants, cotton warehousemen, cotton spinners, and cottonseed crushers.

Since cottonseed oil is a food product and cottonseed meal is used as an animal feed, we are interested in these bills and their possible effects on the consumption and use of these products.

Our concern about H.R. 11581 is with title II, section 201. This section confers upon the Secretary of Health, Education, and Welfare broad authority to enter the premises of manufacturers or processors of food products for the purpose of inspecting their production facilities and procedures. It further authorizes the examination of records maintained by such establishment.

We oppose this section as an unwarranted grant of power. While some type of inspection may be necessary to meet the requirements of the Federal Food, Drug and Cosmetic Act, it should at least be based upon good and probable cause as determined by a responsible officer of the Government and not upon the discretion of a Federal employee designated to perform such inspection.

With respect to H.R. 11582, we support section 302. This section would permit an exemption from the so-called Delaney cancer clause for feed and color additives in animal feed upon a finding by the Secretary that such additive will not adversely affect the animal and that it will leave no residue in any part of the animal prepared for human use.

This is desirable for several reasons. It can help to avoid some of the serious consequences of previous applications of the Delaney clause. It would also relieve the inflexibility of existing law and introduce reasonableness into its administration. The highly restrictive nature of present law could hamper the development of agricultural chemicals which are vital to maintaining efficiency in U.S. agricultural production. The narrow application of existing law has and can result in severe financial losses to farmers and others dealing with agricultural commodities without necessarily reducing the incidence of cancer in human beings.

We believe that section 302 is a desirable addition to existing law and urge its enactment.

We would appreciate having this letter included in the record of hearings on this legislation.

Sincerely,

J. BANKS YOUNG.

VERSIS FOODS, INC.,
Washington, D.C., June 21, 1962.

HON. OREN HARRIS,
House Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Constitution of the United States of America guarantees every citizen of this country of ours the right of "due process of law." This is the right (not the privilege) which lies at the heart of our respect for the individual and his privacy. This right protects every individual from the abuses which can occur when individual persons are given lead to use their prerogative.

Presently, I believe that any court of this land may subpena any record it wishes to look through. The process of subpena is involved and time-consuming especially when other legal processes are employed to slow it down. We realize this and we realize that these procedures make it possible for some persons to evade the law. Now the basic question you are challenging is whether it is better to let some extra legal operators escape while we give all men every opportunity to protect their privacy or whether we choose to leave no individual privacy in the hopes of catching a few dumb crooks.

To me the preferable choice is obvious, especially considering the logical fact that a smart crook won't put anything on paper. My individual rights and privacy and yours, and the privacy of all Americans is worth more than the opportunity to clamp now on a few operators who can be caught in other ways, although not as easily.

Operators who are found to be violating the law, whether through carelessness or intent, could be given probationary periods to prove their good faith. During these periods, these violators could be prohibited from any Federal, State, or other bid. This would be a definitely positive force in correcting any deviations from the law and feel that this system would honor the individual who obeys the law as it punishes the lawbreaker. The present system you propose would at least be troublesome, annoying, and even economically harmful to the law-abiding citizen as well as the violators whom it only might bring to light.

America, as the land of freedom, has grown more rapidly than any other country before or since. In order to remain the land of freedom, and to continue to grow, we must protect the individual and his rights as diligently as if our existence depends on it for in truth it does.

Sincerely,

A. S. VERSIS.

AMERICAN CONGRESS OF PHYSICAL MEDICINE AND REHABILITATION,
Chicago, Ill., May 31, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR MR. HARRIS: Enclosed is a copy of a resolution which was unanimously supported by our organization of more than 600 physicians at our last annual session, August 1961.

Our organization is composed of physicians who have a major interest in the field of physical medicine and rehabilitation. In our practice we use many of the devices which come under the purview of the Food and Drug Administration. Therefore, we are most anxious to support legislation which will provide better protection for our patients as well as the public at large.

Yours very truly,

DONALD J. ERICKSON, M.D., *President.*

RESOLUTION

Be it resolved, That the American Congress of Physical Medicine and Rehabilitation be on record as supporting the enactment of an amendment to the Federal Food, Drug and Cosmetic Act, as it pertains to medical devices, by making such devices subject to the provisions of a new device law; be it further

Resolved, That the American Congress of Physical Medicine and Rehabilitation recommended to the U.S. Congress the provision that the Food and Drug Administration be empowered to accept and adopt various physical standards which have been devised, accepted, and recognized as reflecting the expert quali-

fied opinion of representatives of such organizations as are generally accepted and recognized as reflecting the opinion of their respective specialities; be it further

Resolved, That the American Congress of Physical Medicine and Rehabilitation go on record as considering that the advertising of useless devices as acceptable for "adjunctive therapy" has been detrimental to the welfare of the patient. The sense of this resolution is, therefore, in the best interests of the American public, the present laws or regulations being inadequate for the protection of the public from such abuses.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, D.C., June 18, 1962.

Re statement of views of National Agricultural Chemicals Association on H.R. 11581 and H.R. 11582.

Hon. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The above bills, on which hearings have been scheduled to begin June 19, 1962, have been carefully studied by National Agricultural Chemicals Association. Agricultural chemicals manufacturers and formulators are not directly covered by this legislation. However, it has been decided to file this statement due to the fact that in many cases a procedure once established by the Food and Drug Administration is extended to other segments of industry.

We have no objection to H.R. 11582.

H.R. 11581, however, contains two provisions against which we, as an industry potentially subject to similar legislation, must strenuously object.

FACTORY INSPECTION PROVISIONS

Title II of H.R. 11581 would broaden the factory inspection authority of the Food and Drug Administration to empower FDA officials to inspect as a routine matter all books, records, files, papers, processes, controls, and facilities of companies and consulting laboratories subject to the act.

The power of government officials to examine private citizens' books and records is an extraordinary police power which normally may be exercised only upon the obtaining of a warrant or a subpena and under circumstances which indicate probability that a crime has been or is about to be committed. On the other hand, the factory inspection provisions of the Federal Food, Drug and Cosmetic Act are intended to enable the Food and Drug Administration to exercise routine and continual surveillance over the factory conditions under which foods, drugs, and cosmetics are manufactured or processed. We do not believe power to examine books and records as a routine matter has been demonstrated to be reasonably necessary to the adequate enforcement of the act.

Power to inspect company books and records as a routine matter would add little, if anything, to the effective enforcement of the adulteration and misbranding provisions of the act. However, by providing easy access to business records and trade secrets of regulated companies without any necessity of a showing of probable cause and without giving private enterprises any means of safeguarding their rights of privacy and of property in trade and business secrets, this legislation would open the door to all sorts of conniving, discrimination, and other abuses.

Accordingly, we believe Congress should not grant to the Food and Drug Administration power to inspect books and records as a routine part of its factory inspection authority. Such extraordinary power is now necessary or appropriate to the effective enforcement of the act and would constitute an unreasonable extension of the Government's police power.

Moreover, we do not believe the attempt, in section 202 of H.R. 11581, to relax the provisions of the act which safeguard the confidentiality of information obtained by FDA officials during the course of their inspections of factories, is justifiable. This attempted relaxation of confidentiality safeguards is especially onerous in view of the above-discussed proposal to broaden the factory inspection authority. We recommend that section 202 of H.R. 11581 be deleted from the bill.

STANDARDIZATION OF DRUG NAMES

We also wish to call to your attention the very serious situations which can result from the establishment of standard names for drug products as provided in title I, part B, of H.R. 11581. If such a provision were extended to our agricultural chemicals industry, it would seriously affect research and marketing.

This industry has had considerable experience in the use of common names since the passage of the Miller pesticide amendment to the Food, Drug, and Cosmetic Act. The problems involved in the arbitrary selection and establishment of common names are serious ones and have a direct effect on trademark registration and the obtaining of patents. The problem is also considerably involved at the present time with the adoption of common names in various European countries, many of which are pirating American trademarks.

Our industry now has a committee studying this entire problem, and for that reason we believe legislation on common names should be given very careful consideration and no immediate action taken at this time.

It is the position of our industry that manufacturers who spend several million dollars in research to develop a product which they expect to place on the market have a property right in such an investment and in the product, and should be able to choose whether a common name should be adopted and if so what the common name should be, or the privilege of merchandising their product under the technical name of a chemical without the use of a common name.

Many of our companies are adopting common names under a procedure now established through the American Standards Association, which is a nonindustry agency equipped to review such proposals. Giving authority to a Government agency to assign a common name to a manufacturer's product without his consent, we believe, is not in the interest of the public, will result in further confusion in world markets, and definitely infringes on the property rights of a developer.

We would appreciate it very much if you would give these comments your careful consideration and make this statement a part of the record.

Very truly yours,

L. S. HITCHNER, *President.*

UNIVERSITY OF OREGON MEDICAL SCHOOL,
Portland, Oreg., August 29, 1962.

HON. OREN HARRIS,
Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.

DEAR SIR: This is in support of the night letter sent to you Wednesday, August 29, a copy of which is enclosed. I have been informed that an objectionable proposal has been written into the bill on drug regulation to be considered on Thursday, August 30, and which bill is similar to S. 1552. This proposal would require those doctors who are looked upon as expert clinical investigators of drugs and who perform trials of new drugs on humans, of which I consider myself one of the group, will be required by law to register with the Secretary of Health, Education, and Welfare each and every time they undertake to test a new drug on patients.

In addition, this proposal requires that at the beck and call of the Secretary, all records, reports, case histories, and other information pertaining to the particular drug under trial shall be submitted to the Secretary. This proposal would limit the interests and activities, as well as be a considerable burden and, as well, be of little value to the Government if included in the new proposed FDA regulations.

The redtape involved in the way of preparation, duplication, secretarial work, and other labor and expenditure of time on the part of the investigator would discourage his interest in conducting such studies. Also, this proposal would be an invasion of the doctor-patient relationship; and would be the submission of privileged communications to a third party (member of the FDA staff) who may not be a physician or qualified "expert" or a pharmacologist knowledgeable in this field.

The proposed amendment as it now reads in the published regulations provided by George Larrick on August 9, and printed in the Federal Register, August 10, 1962, provides that communications from investigators and sponsoring pharmaceutical companies and, from them, be sent to the FDA authorities. Also, the regulations call for the investigator "making available to FDA inspectors all data on research studies." While this last provision may be objectionable to some, I look upon it as satisfactory providing the sponsoring company is informed immediately of such inspections and can cooperate with the investigator and the FDA to reveal and make available any or all information concerning a toxic or adverse effect of the drug.

I am enclosing some material which the Upjohn Pharmaceutical Co. has recently sent me and which I have answered according to the attached photostats.

Very truly yours,

NORMAN A. DAVID, M.D.,
Professor of Pharmacology.

[Night letter]

AUGUST 28, 1962.

Representative OREN HARRIS,
Chairman, Interstate and Foreign Trade Committee, Washington, D.C.:

Object to proposal in bill to be considered Thursday that "such regulations may also include provisions requiring said expert clinical drug investigator to register with Secretary HEW, and upon request of Secretary at other times to submit any or all records pertaining to drug investigations undertaken by expert." Such procedures should be through the sponsoring drug company. This proposal, not clearly published in 21 CFR 130 issued August 9, would stifle clinical investigation new drugs as qualified experts would consider this as more Harrison Narcotic Act redtape and an added administrative and secretarial chore. I approve of most of the other provisions of S. 1552, however. Letter follows.

NORMAN A. DAVID, M.D.,
Professor of Pharmacology, University of Oregon Medical School.

[From American Men of Science, 10th ed., 1960, Cattell Press]

David, Dr. Norman A(ustin), University of Oregon Medical School, Portland 1, Oregon. Pharmacology. San Francisco, Calif, Oct. 22, 02; m. 32; c. 2. A.B, California, 25, Eli Lilly fellow, 30–32, M.D. 31. Asst, California, 30–32, asst. prof. and head dept. Pharmacol, sch. med, West Virginia, 32–35; asst. prof, col. med, Cincinnati, 35–36, assoc. prof, 36–37; prof and head dept, med. sch, Oregon, 37–; Director, Public Health Venereal Clinic, City Health Dept, Portland, 46–54; Physician, outpatient dept, North. Permanente Hosp, Vancouver, Wash, 44–45. Summers, surgeon Civilian Conservation Camps, U.S. Army, 33–37. With Office Sci. Research & Develop, 42–45; Soc. Pharmacol; Am. Med. Asn; Pres., West. Soc. Clin. Research, 1950; Toxicologist, Multnomah County Coroner's Office, 50–; Chairman, Committee Drugs and Pharmacy, Oreg. St. Med. Soc., 1956–; Consultant, Oreg. St. Poison Control Center, 55–; Pres., Multnomah County Med. Soc., 61–62; Pres., West. Soc. Pharmacology, 1962; Secty, N.W. Acad. Occupat. Med. Chemotherapy of amebiasis; pharmacology of barbital drugs; chronic effects of opium drugs and synthetic analgesics. Member, Council on Drugs, American Med. Assoc., 1962–.

THE UPJOHN CO.,
Kalamazoo, Mich., August 17, 1962.

NORMAN A. DAVID,
Professor, Head, Department of Pharmacology,
University of Oregon Medical School, Portland, Oreg.

DEAR DR. DAVID: As you are undoubtedly aware, the Federal Food and Drug Administration has published a proposed new regulation controlling the clinical investigation of new drugs (in the Federal Register, Aug. 10, 1962). We feel that you, as an individual who has been interested in clinical drug evaluations, should have the opportunity of reviewing the proposed new regulations and are enclosing a copy for your study.

We of the medical group at the Upjohn Co. feel that the proposed regulations are of profound importance and are most anxious that all parties who will be concerned with their function give careful consideration to the proposal during the 60-day period allowed by the Food and Drug Administration for review. After you have had an opportunity to review the enclosed proposed regulations, we would very much appreciate your honest opinions either in the form of a letter or by completing a short questionnaire which we have included for your convenience. As time is short, we would ask that you return your opinions and comments to us by September 1 at the latest. We will compile the returns from all clinical investigators and make this information available to you and the Food and Drug Administration as soon after September 1 as is possible.

The proposed new regulations contain six amendments to section 130.3. The regulations affecting clinical research investigators in particular are included in paragraph (a), subparagraphs 8 and 9 (pp. 2–3), and subparagraph 12 (pp. 5–7).

Briefly, in the future investigators will be required to —

(1) Submit detailed information supoprting experience and training for research studies.
(2) Submit a detailed protocol to be followed and presumably amendments in advance to cover changes from original.
(3) Report in some detail results of clinical studies.
(4) Report immediately serious side effects or toxicity.
(5) To keep records of drug disposition and accurate case histories.
(6) Make available to FDA inspectors all data on research studies.
(7) Comply with regulations or the FDA is impowered to notify pharmaceutical manufacturers that experimental drugs may not be supplied without special approval of the Commissioner.

We sincerely hope that you will share our regard for the importance of this proposal and make your opinions known to us by September 1, 1962.

Sincerely yours,

HAROLD L. UPJOHN, M.D.

DEAR DOCTOR: After you have had an opportunity to review the Food and Drug Administration's notice of proposal to amend regulations of new drugs for investigational use, we would appreciate your thoughts and opinions, either in the form of a letter or by using this short questionnaire.

As time for review of this proposal is limited, we would urge that you return your comments to us by September 1, 1962. An addressed, stamped envelope is enclosed for your convenience.

Sincerely yours,

THE UPJOHN CO.

	Yes	No	No opinion
In your opinion will the proposed new FDA regulations enable you to perform clinical investigations of new drugs with greater safety to your patients?	☐	☒	☐
Will the regulation stimulate better controlled and designed clinical studies?	☒	☐	☐
Will the proposed "plan of investigation" which investigators will be required to submit in advance of a study seriously restrict your research studies? (see p. 6 of proposed regulations)	☐	☒	☐
Would you agree that pharmaceutical companies and the FDA can and should judge investigator's qualifications for drug research studies? (see pp. 2 and 3)	☒	☐	☐
Do you agree with the proposal that once an investigator has failed to comply with the regulations, he is no longer entitled to receive investigational drugs unless approved by the Commissioner? (see pp. 7 and 8)	☒	☐	☐
Do you agree in principle with making your files and case reports available for inspection by FDA inspectors?	☒	☐	☐
Do you generally approve of the proposed new regulations?	☒	☐	☐

When the proposed regulations become effective, will you modify your study of investigational drugs?

Stop altogether	☐
Curtail present number	☐
No change	☒
Increase testing	☐

Do you have any suggestions for revisions of the proposed regulations?

Name

Date

Institution or private practice

Percent of time devoted to clinical drug evaluation:

Less than 5 percent	☐
5 to 20 percent	☒
20 to 50 percent	☐
50 to 100 percent	☐

[Supplement to PMA Newsletter, vol. 4, No. 33, Aug. 9, 1962]

FDA Issues Proposed Regulations Governing Clinical Trials

FDA Commissioner George Larrick today (Aug. 9) issued proposed new regulations governing the testing of drugs in clinical trials. They are reproduced in full in the following pages. Industry has 60 days in which to comment, and final regulations will not be issued until such comments have been considered by HEW and the Food and Drug Administration. In announcing the proposals, HEW Secretary Celebrezze emphasized three points:

(1) The regulations require that FDA be notified and given complete details on distribution of drugs for investigational use.

(2) Manufactures required to satisfy FDA that the investigations will be based on preclinical (chemical and animal) studies of such a nature to assure safety for patients.

(3) The clinical studies would have to be properly planned, executed by qualified investigators and FDA kept fully informed of the progress of the investigations.

The secretary said the "clear purpose" in drawing up the regulations is to impose "no unneeded restrictions on the conduct of investigational research," yet provide assurance that the public will be fully protected against risks that may attend the development of new drugs.

Prior to issuance of these proposed regulations, the Pharmaceutical Manufacturers Association board had scheduled a special meeting for Tuesday, August 14, at PMA headquarters in Washington, D.C., to consider current legislative developments. At that time the board also will study the proposed clinical trial regulations made public today.

In the legislative area, the Senate Judiciary Committee continues its reconsideration of the Kefauver drug control bill, S. 1552, and has agreed to incorporate in it a number of the amendments proposed by President Kennedy. A vote on the Senate floor is likely next week. On the House side, Chairman Oren Harris, of the Interstate and Foreign Commerce Committee, has announced reopening of hearings August 20 on H.R. 11581, the administration's drug control bill. He said hearings will be completed by August 24. During this period PMA witnesses will testify. All of these developments will be reported in detail in the PMA newsletter to be published August 10.

SAN LEANDRO, CALIF., *June 7, 1962.*

Mr. ARTHUR J. YOUNGER,
Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR SIR: I have been a cosmetologist for 25 years, and from experience know that proposed H.R. 11582 will produce definitely measurable adverse effects. I therefore urge you to consider the following:

(1) Many heads of hair become dull and unattractive with age, by reason of chemical changes within the body.

(2) Many positions require certain standards of appearance which would be impossible to achieve without bleaching and coloring of hair.

(3) The national trend toward restricting upper age limits because of retirement benefit costs forces many women to avail themselves of every means of preserving the appearance of youth.

(4) It has been firmly established that morale, among women especially, is directly related to appearance and in these turbulent times attention should be directed to improving our Nation's strength rather than to creating a demoralizing influence.

(5) Part of the most effective argument is eloquently apparent in the fact that bleaching, tinting, and dying constitutes anywhere from 60 to 100 percent of the average salon's volume. Which leads to:

(6) The very livelihood of thousands of people would be directly affected. (There are over 8,000 registered cosmetologists in the State of California alone.) In turn this—

(7) Reduces national income, from which—

(8) Government revenues vary in direct proportion.

Therefore, as president of a local unit, fifth vice president of the California Cosmetologist Association, and a member of the California Hair Fashion Committee, I request that you oppose this bill with vigor and purpose.

Respectfully,

IRIS M. SIMMEAU.

THE PHYSICIANS FORUM, INC.,
New York, N.Y., September 6, 1962.

Congressman OREN HARRIS,
Chairman, House Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN HARRIS: The Physicians Forum, a national organization of physicians, is delighted that your committee is giving serious consideration to a bill to strengthen Federal control of the prescription drug industry.

The Physicians Forum testified in support of and fully endorsed S. 1552. The purpose of this bill was to promote fair prices and competition as well as to control generic names and descriptive information and assure quality and efficacy of prescription drugs. We still believe that Federal legislation, with all of these provisions, is necessary in addition to voluntary action by industry to correct abuses in the pricing and promotion of drugs as well as to eliminate weaknesses in the current Government regulation of the drug industry.

Enclosed is a statement of the board of directors of the Physicians Forum which fully states our position and which we would like to see included in the record.

Sincerely yours,

LEO MAYER, M.D., *Chairman.*

COSTS, QUALITY, AND PROMOTION OF ETHICAL DRUGS, A STATEMENT OF THE BOARD OF DIRECTORS OF THE PHYSICIANS FORUM, JUNE 1961

Expenditures for ethical prescription and proprietary (over the counter) drugs have increased from $300 million in 1929 to over $2½ billion in 1960. Of this total, close to $2 billion goes for ethical drugs. The average price of a prescription has increased from 90 cents in 1929 to $3.50 in 1960. The greatest part of ethical drug expenditure is attributed to the sale of the wonder drugs and price increase is likewise due to a switch from the low cost and standard pharmaceuticals to the new and more expensive trade-name drugs—to the antibiotics, tranquilizers, antidepression drugs, hormones, metabolic agents, antiobesity drugs, diuretics, anticoagulants, and others. Not only has there been an increase in the average price per prescription, but there has also been an increase in the number of ethical drugs prescribed, from 7.6 per family in 1950 to about 12 per family in 1959, a rise of some 55 percent in 10 years.

Despite this increasing expenditure for new and expensive drugs, the part of the medical-care dollar devoted to drug costs has not shown any increase. In other words, the drug share of the medical dollar, amounting to about 22 cents, has remained about the same in the past 30 years or so.

Drug costs vary a great deal according to age. In 1959, the Senate Subcommittee on Problems of the Aged and Aging showed that while all age groups spend on the average $19 per person per year on drugs, those 65 and over, spend about $42 per person, or about 2½ times as much. The prescription bill of a sick person is usually much higher, often as high as $200 for a chronic illness. In other words, the greatest burden of drug costs is borne by the older age groups, by the population with the most chronic illness and with the greatest need for drugs, and with the least ability to pay for them. While the cost of each prescription has increased in general, the income to pay for them has not.

Another factor contributing to the burden of drug costs is that for the most part they are not covered by medical care insurance.

Confronted with limited income or financial reverses, the average family can and does put off buying automobiles, household appliances, clothes, and even higher priced foods, but they cannot put off buying drugs or find cheap substitutes. Ethical drugs, as Senator Kefauver has expressed it, have an intermediary between the producer and the buyer—the physician who writes the prescription. "In this respect, the drug industry is unusual in that he who buys does not order, and he who orders does not buy." The consumer, in other words, is completely captive. When he is sick, he must buy the drug the doctor orders, and unlike automobile buying, he cannot or does not know how to shop around for a different model or a lower price.

Thus, the pricing policies of the largest pharmaceutical companies are almost completely removed from the corrective discipline of consumer sovereignty, and from the laws of supply and demand. In most instances, drug prices are set by administrative decision and are held constant over extended periods of time. The drug industry is, indeed, a highly competitive industry, but its competitive efforts seem expended mainly in capturing the prescription pads of the busy doctor who in most instances cannot judiciously weigh the real properties of drugs against the promotional claims for it. Competition in prices of drugs has been replaced largely by competition in promotion. Price competition tends to lower prices and increase efficiency. Promotional competition does the opposite—it increases both the use and the price of drugs.

Some critics have contended that the retail druggist's margin is excessive. But this is denied by spokesmen for the retail druggists who point to the high manufacturer's prices of drugs, and the inventory cost of stocking a single drug under a variety of trade names.

When a company has a patent monopoly on a drug or when it licenses one or more companies to package and sell the drug, an understanding is usually reached about the price of the drug, so that the primary company's interests are protected. In such circumstances, the price under the generic name, and the price under the trade name are the same.

Most doctors prescribe by trade name rather than by generic name, and they prefer to do this because trade names are forcefully brought to their attention by effective and sustained promotional methods, and because most trade names are easier to remember and write than the complex industry provided generic equivalents. Another important reason for the preference for trade names is fear that generic products of the smaller companies are not of as high a quality as the trade-name products of the big companies.

That the profits of the drug industry are high is indicated by the following statement in May 1960 issue of Fortune magazine: "There is no doubt that the drug business has been remarkably profitable by all the usual standards. Drug companies commonly earn 15 to 20 percent on invested capital after taxes, and their aftertax margins on sales run 10 to 15 percent, figures that few other manufacturing companies attain except in boom years. The drug company's advantage lies principally in the fact they deal in innovations which in any industry tends to be very profitable." According to the Kefauver committee, the drug industry has a rate of return of 21.4 percent, which is the highest of any manufacturing industry and approximately double that of the average of all manufacturing, which is 11 percent.

Research expenditures to develop new products have been cited by manufacturers as an important factor contributing to current drug prices. However, expenditure for research by the 20 largest drug companies is only 6.4 percent of sales. Much of this research has been termed "molecule manipulation," "me-too" research.

Selling expenditures, including promotion by detail men, brochures, pamphlets, newspapers, magazines, special conferences, cocktail parties, golf tournaments, phonograph records, and other methods account for 24 cents of the sales dollar or almost four times the amount spent on research.

The Physicians Forum fully endorses Senate bill S. 1552 introduced by Senator Estes Kefauver.

In general the legislation is designed to promote competition and protect the public interest in these principal ways:

1. By making it unlawful under the antitrust laws for large drug companies to agree upon which company will obtain a patent, to agree which companies shall be awarded licenses in the event that a patent is issued, and to make similar restrictive agreements.

2. By requiring compulsory licensing of qualified applicants (after 3 years) under the product patents for prescription drugs.

3. By providing that the Food and Drug Administration shall pass on the efficacy as well as the safety of drugs.

4. By seeing to it that physicians are provided with clearer, better, and additional information on the bad as well as the good features of drugs.

5. By requiring fuller and more comprehensive inspection of drug manufacturing plants, thereby giving to physicians greater confidence in prescribing on the basis of generic rather than trade names.

6. By providing for the licensing of drug manufacturing companies which should also give physicians greater confidence in prescribing by generic names since a company could lose its license to do business if it did not meet the requirements of the Food and Drug Administration.

7. By giving to the Food and Drug Administration authority to establish the official or generic names for drugs, thereby providing a means of simplifying generic names which, in contrast to the short and simple trade names, are often so long, complex and unpronounceable that they are not remembered or used by physicians.

Much is wrong with prices and promotion of ethical drugs; obviously Federal legislation is necessary in addition to voluntary action by industry to correct abuses and regain deficiencies in Government regulation of the drug industry.

Mr. ROBERTS. The hearings are now adjourned.

(Whereupon, at 12:30 p.m., the hearing was adjourned.)

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