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DRUG LISTING ACT, 1971

GOVERNMENT

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HEARING

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BEFORE THE

COMMITTEE ON

LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

NINETY-SECOND CONGRESS

FIRST SESSION

ON

S. 2167

TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROVIDE FOR A CURRENT LISTING OF EACH DRUG MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED BY A REGISTRANT UNDER THAT ACT, AND FOR OTHER PURPOSES

H. R. 9936

TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO PROVIDE FOR A CURRENT LISTING OF EACH DRUG MANUFACTURED, PREPARED, PROPAGATED, COMPOUNDED, OR PROCESSED BY A REGISTRANT UNDER THAT ACT, AND FOR OTHER PURPOSES

DECEMBER 8, 1971



Printed for the use of the Committee on Labor and Public Welfare

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DRUG LISTING ACT, 1971

WEDNESDAY, DECEMBER 8, 1971

U.S. SENATE,
COMMITTEE ON LABOR AND PUBLIC WELFARE,
Washington, D.C.

The committee met, pursuant to notice, at 10 a.m., in room 4232, New Senate Office Building, Senator Harrison A. Williams (chairman of the committee) presiding.

Present: Senators Williams, Nelson, Hughes, and Taft.

Committee staff members present: Robert E. Nagle, general counsel; Nik Edes, associate counsel; Jay B. Cutler, minority counsel.

The CHAIRMAN. The subcommittee will come to order.

Today we are undertaking consideration of legislation which is designed to amend the Federal Food, Drug, and Cosmetic Act to provide for a current listing of every drug manufactured, prepared, and distributed in the United States.

Perhaps the most important tool any regulatory agency can have is complete information about the subject which it has the duty to regulate.

At present, the Federal Food and Drug Administration, which is responsible for regulating drugs, has no authority to develop the ready means to determine what drugs are actually being manufactured and distributed by the companies registered under the law.

This is a surprising and most unfortunate situation. For without the existence of this authority, and more importantly, without the availability of an up-to-date inventory of drugs, it is all the more difficult for the Food and Drug Administration to properly carry out its mission. This is a situation which cannot be permitted to continue.

We have before us today two bills which would provide the Secretary of Health, Education, and Welfare with the necessary power to compile a list of currently manufactured drugs such as the marketing authority of each drug, the text of the labelling of each drug, and the advertising used to promote the sale of each drug.

The bill introduced by Senator Pearson, S. 2167, and the bill which passed the House of Representatives, H.R. 9936, differ in some respects and it is my hope that we can today learn something about these differences.

In addition, I would like to explore the reasons why no such list has been compiled in the past and to find out more about the voluntary program initiated by the FDA to secure an inventory of drugs subject to its regulation.

And, finally, I would like to examine the extent to which information collected pursuant to this proposed legislation can be made available to the public at large without violation of any legitimate trade secrets.

At this point we will enter a copy of S. 2167 and H.R. 9936.

(A copy of S. 2167 and H.R. 9936 follows:)

92D CONGRESS
1ST SESSION

S. 2167

IN THE SENATE OF THE UNITED STATES

JUNE 29 (legislative day, JUNE 28), 1971

MR. PEARSON introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for a current listing of each drug manufactured, prepared, propagated, compounded, or processed by a registrant under that Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. This Act may be cited as the "Drug Infor-
4 mation Act of 1971".

5 SEC. 2. Section 510 of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 360) is amended by adding at the
7 end the following new subsection:

8 " (j) (1) Every person who registers with the Secre-
9 tary under subsection (b), (c), or (d) shall, at the time of

1 registration under any such subsection, file with the Secre-
2 tary a list of all drugs (by established name (as defined in
3 section 502 (e)) and by any proprietary name) which are
4 being (or, in the case of a person who registers under sub-
5 section (c) or (d), proposed to be) manufactured, pre-
6 pared, propagated, compounded, or processed in each estab-
7 lishment included in such registration. Such list shall be
8 prepared in such form and manner as the Secretary may
9 prescribe and shall be accompanied by—

10 “(A) the formula showing quantitatively each in-
11 gredient of each drug listed,

12 “(B) a copy of all labeling used for each drug
13 listed,

14 “(C) in the case of each prescription drug listed,
15 a copy of all advertising used for such drug;

16 “(D) in the case of a new drug or antibiotic drug
17 (subject to section 507) listed, a reference to the au-
18 thority for the marketing of such drug and, in the case
19 of any other drug listed, the data from which it is deter-
20 mined that it is not a new drug or antibiotic drug sub-
21 ject to section 507, and

22 “(E) any production data the Secretary may re-
23 quire.

24 If any such person proposes to use labeling or advertising a
25 copy of which has not been submitted to the Secretary in
26 accordance with clause (B) or (C), as the case may be, such

1 person shall, before using such labeling or advertising, submit
2 (in such form and manner as the Secretary may prescribe)
3 a copy of it to the Secretary.

4 “(2) Every person registered under this section shall,
5 upon first engaging in the manufacture, preparation, propa-
6 gation, compounding, or processing of a drug not contained
7 in any list filed by such person under paragraph (1) of this
8 subsection, immediately notify the Secretary of such fact
9 and shall include with such notification the information re-
10 quired under such paragraph.

11 “(3) Every person registered under this section shall
12 immediately notify the Secretary whenever such person
13 ceases or discontinues (in excess of such period of time as
14 the Secretary may prescribe) the production or availability
15 of any drug being manufactured, prepared, propagated, com-
16 pounded, or processed by him in any establishment and shall
17 include in such notice the reasons for such cessation or dis-
18 continuance. Upon resumption of the manufacture, prepara-
19 tion, propagation, compounding, or processing of such drug
20 after such cessation or discontinuance, such person shall
21 notify the Secretary of such resumption and shall include
22 with such notice the information required under paragraph
23 (1) of this subsection.”

24 SEC. 3. (a) Section 510 (e) of such Act is amended by
25 adding at the end thereof the following: “The Secretary may

1 also assign a registration number to each drug or class of
2 drugs listed under subsection (j).”.

3 (b) Section 510(f) of such Act is amended by inserting
4 before the period the following: “; except that the Secre-
5 tary shall exempt from inspection any list filed under sub-
6 section (j) and any information accompanying such list
7 unless the Secretary finds that such an exemption would be
8 inconsistent with protection of the public health”.

9 (c) The second sentence of section 510(i) is amended
10 by inserting “shall require such establishment to provide the
11 information required by subsection (j) and” immediately
12 before “shall include”.

13 (d) Clause (1) of the second sentence of section 505(e)
14 is amended by inserting “or failed to comply with the notice
15 requirements of the first sentence of section 510(j) (3)”
16 immediately after “subsection (j)”.

17 (e) Section 301(p) of such Act (21 U.S.C. 331) is
18 amended to read as follows:

19 “(p) The failure to register in accordance with section
20 510, the failure to provide any information required by sec-
21 tion 510(j), or the failure to provide a notice required by
22 section 510(j) (2) or section 510(j) (3).”

23 SEC. 4. The amendments made by this Act shall take
24 effect on the first day of the sixth month beginning after the
25 date of enactment of this Act.

92^D CONGRESS
1ST SESSION

H. R. 9936

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 17, 1971

Read twice and referred to the Committee on Labor and Public Welfare

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide for a current listing of each drug manufactured, prepared, propagated, compounded, or processed by a registrant under that Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 SECTION 1. This Act may be cited as the "Drug Listing
4 Act of 1971".

5 SEC. 2. The Federal Government which is responsible
6 for regulating drugs has no ready means of determining what
7 drugs are actually being manufactured or packed by estab-
8 lishments registered under the Federal Food, Drug, and
9 Cosmetic Act except by periodic inspection of such regis-

1 tered establishments. Knowledge of which particular drugs
2 are being manufactured or packed by each registered estab-
3 lishment would substantially assist in the enforcement of
4 Federal laws requiring that such drugs be pure, safe, effec-
5 tive, and properly labeled. Information on the discontinu-
6 ance of a particular drug could serve to alleviate the burden
7 of reviewing and implementing enforcement actions against
8 drugs which, although commercially discontinued, remain
9 active for regulatory purposes. Information on the type
10 and number of different drugs being manufactured or packed
11 by drug establishments could permit more effective and
12 timely regulation by the agencies of the Federal Govern-
13 ment responsible for regulating drugs, including identifica-
14 tion of which drugs in interstate commerce are subject to
15 section 505 or 507, or to other provisions of the Federal
16 Food, Drug, and Cosmetic Act.

17 SEC. 3. Section 510 of the Federal Food, Drug, and
18 Cosmetic Act (21 U.S.C. 360) is amended by adding at
19 the end of the following new subsection:

20 “(j) (1) Every person who registers with the Secretary
21 under subsection (b), (c), or (d) shall, at the time of regis-
22 tration under any such subsection, file with the Secretary
23 a list of all drugs (by established name (as defined in section
24 502(e)) and by any proprietary name) which are being
25 manufactured, prepared, propagated, compounded, or proc-

1 essed by him for commercial distribution and which he has
2 not included in any list of drugs filed by him with the Sec-
3 retary under this paragraph or paragraph (2) before such
4 time of registration. Such list shall be prepared in such
5 form and manner as the Secretary may prescribe and shall
6 be accompanied by—

7 “(A) in the case of a drug contained in such list
8 and subject to section 505, 506, 507, or 512, a refer-
9 ence to the authority for the marketing of such drug
10 and a copy of all labeling for such drug;

11 “(B) in the case of any other drug contained in
12 such list—

13 “(i) which is subject to section 503 (b) (1), a
14 copy of all labeling for such drug, a representative
15 sampling of advertisements for such drug, and,
16 upon request made by the Secretary for good cause,
17 a copy of all advertisements for a particular drug
18 product, or

19 “(ii) which is not subject to section 503 (b)
20 (1), the label and package insert for such drug and
21 a representative sampling of any other labeling for
22 such drug;

23 “(C) in the case of any drug contained in such list
24 which is described in subparagraph (B), a quantita-
25 tive listing of its active ingredient or ingredients,

1 except that with respect to a particular drug product
2 the Secretary may require the submission of a quantita-
3 tive listing of all ingredients if he finds that such sub-
4 mission is necessary to carry out the purposes of this
5 Act; and

6 “(D) if the registrant filing the list has deter-
7 mined that a particular drug product contained in such
8 list is not subject to section 505, 506, 507, or 512,
9 a brief statement of the basis upon which the regis-
10 trant made such determination if the Secretary requests
11 such a statement with respect to that particular drug
12 product.

13 “(2) Each person who registers with the Secretary
14 under this section shall report to the Secretary once during
15 the month of June of each year and once during the month
16 of December of each year the following information:

17 “(A) A list of each drug introduced by the reg-
18 istrant for commercial distribution which has not been
19 included in any list previously filed by him with the
20 Secretary under this subparagraph or paragraph (1) of
21 this subsection. A list under this subparagraph shall
22 list a drug by its established name (as defined in sec-
23 tion 502(e)) and by any proprietary name it may
24 have and shall be accompanied by the other informa-
25 tion required by paragraph (1).

1 “(B) If since the date the registrant last made a
2 report under this paragraph (or if he has not made a
3 report under this paragraph, since the effective date of
4 this subsection) he has discontinued the manufacture,
5 preparation, propagation, compounding, or processing
6 for commercial distribution of a drug included in a list
7 filed by him under subparagraph (A) or paragraph
8 (1); notice of such discontinuance, the date of such
9 discontinuance, and the identity (by established name
10 (as defined in section 502 (e)) and by any proprietary
11 name) of such drug.

12 “(C) If since the date the registrant reported pur-
13 suant to subparagraph (B) a notice of discontinuance
14 he has resumed the manufacture, preparation, propaga-
15 tion, compounding, or processing for commercial dis-
16 tribution of the drug with respect to which such notice of
17 discontinuance was reported; notice of such resumption,
18 the date of such resumption, the identity of such drug
19 (by established name (as defined in section 502 (e))
20 and by any proprietary name), and the other informa-
21 tion required by paragraph (1), unless the registrant
22 has previously reported such resumption to the Sec-
23 retary pursuant to this subparagraph.

24 “(D) Any material change in any information

1 previously submitted pursuant to this paragraph or
2 paragraph (1).

3 “(3) The Secretary may also require each registrant
4 under this section to submit a list of each drug product
5 which (A) the registrant is manufacturing, preparing, prop-
6 agating, compounding, or processing for commercial dis-
7 tribution, and (B) contains a particular ingredient. The
8 Secretary may not require the submission of such a list
9 unless he has made a finding that the submission of such
10 a list is necessary to carry out the purposes of this Act.”

11 SEC. 4. (a) Section 510(e) of such Act is amended
12 by adding at the end thereof the following: “The Secre-
13 tary may also assign a listing number to each drug or
14 class of drugs listed under subsection (j). Any number
15 assigned pursuant to the preceding sentence shall be the
16 same as that assigned pursuant to the National Drug
17 Code.”.

18 (b) Section 510(f) of such Act is amended by in-
19 serting before the period the following: “; except that any
20 list submitted pursuant to paragraph (3) of subsection (j)
21 and the information accompanying any list or notice filed
22 under paragraph (1) or (2) of that subsection shall be
23 exempt from such inspection unless the Secretary finds
24 that such an exemption would be inconsistent with pro-
25 tection of the public health”.

1 (c) The second sentence of section 510 (i) of such Act
2 is amended by inserting "shall require such establishment to
3 provide the information required by subsection (j) and"
4 immediately before "shall include".

5 (d) Clause (1) of the second sentence of section 505
6 (e) of such Act (21 U.S.C. 355 (e)) is amended by in-
7 serting "or to comply with the notice requirements of
8 section 510 (j) (2)" immediately after "subsection (j)".

9 (e) Section 301 (p) of such Act (21 U.S.C. 331 (p))
10 is amended to read as follows:

11 "(p) The failure to register in accordance with section
12 510, the failure to provide any information required by
13 section 510 (j), or the failure to provide a notice required
14 by section 510 (j) (2)."

15 SEC. 5. Section 301 (j) of such Act (21 U.S.C. 331
16 (j)) is amended—

17 (1) by inserting "(1)" immediately after "any
18 information",

19 (2) by inserting "510," immediately after "507,"

20 (3) by striking out "any method or process" and
21 inserting in lieu thereof "any method, process, or in-
22 formation", and

23 (4) by inserting before the period at the end the
24 following: "or (2) which (A) was contained in a
25 list submitted pursuant to paragraph (3) of section 510

1 (j) or accompanied a list or notice submitted pursuant
2 to paragraph (1) or (2) of that section, and (B) was
3 acquired under the authority of section 510”.

4 SEC. 6. The amendments made by this Act shall take
5 effect on the first day of the sixth month beginning after
6 the date of enactment of this Act.

Passed the House of Representatives September 16,
1971.

Attest:

W. PAT JENNINGS,

Clerk.

The CHAIRMAN. This is the first time during this session of Congress that this committee is considering legislation in the complex and often controversial area of the FDA's regulatory powers relating to drugs.

I think that it is only fitting that we begin with the vital subject of authorizing a comprehensive inventory of drugs so that the FDA can better fulfill its role of assuring that these products are pure, safe, effective, and properly labeled.

This is indeed a threshold matter and one which we all hope will lead to a more thorough understanding of what further legislative initiatives may be necessary in the months and years to come.

It is my pleasure to welcome all of the witnesses scheduled to appear before us this morning, and I look forward to a most productive session. We certainly welcome our witnesses here this morning.

Senator Nelson, do you have a statement?

Senator NELSON. No, Mr. Chairman. Thank you very much.

The CHAIRMAN. Our first witness is the Honorable James B. Pearson, U.S. Senator from Kansas.

STATEMENT OF HON. JAMES B. PEARSON, A U.S. SENATOR FROM THE STATE OF KANSAS

Senator PEARSON. Thank you very much, Mr. Chairman.

Mr. Chairman, I sincerely appreciate the opportunity to appear before this eminent committee whose members have distinguished themselves over the years by their commitment to the health of this Nation.

I particularly want to express my gratitude to you, Mr. Chairman, for finding the time in a crowded schedule, to hold these hearings. This is the kind of work and dedication which you have shown again and again and which expresses, in my judgment, a personal determination to come to grips with the abuse of drugs in our society.

S. 2167, which I introduced, and H.R. 9936, an improved version of the companion to my bill which was guided through the House of Representatives by Congressman Rogers of Florida, provide for a current listing with the Food and Drug Administration of all drugs on the market today.

This legislation is urgently needed. In fact, it is as the chairman indicated in his statement somewhat amazing that this authority was not granted long ago.

I wish to direct my remarks to H.R. 9936, the bill which has passed the House, and offer my support to it. I believe that the refinements and improvements made by the House Subcommittee on Public Health and Environment and the full Committee on Interstate and Foreign Commerce are sound and properly clarify the intent of my original proposal.

Further, I am advised that all interested persons, including consumer groups, the FDA, and affected segments of the drug industry support the House passed measure.

I, therefore, urge this committee to approve my bill with the House modifications. Mr. Chairman, the FDA knows there are a great many drugs on the market which have not been submitted to it for approval. Indeed, the FDA has no idea how many drugs there are on the market.

To expect this agency—charged with protecting us from impure, unsafe, and ineffective drugs—to accomplish that task without a registration or a master list of all drugs, as this bill proposes, is much like, to quote Congressman Rogers, “Expecting the SEC to regulate the traffic of securities without a listing of all stocks and bonds.” At present, only the producers and certain wholesalers of drugs are required to register annually with the FDA.

H.R. 9936 would include all over-the-counter, prescription, and antibiotic drugs in interstate as well as intrastate commerce. It would provide annual up-to-date information on drugs currently on the market. Importantly, it would require notification when production of any drug is discontinued. Mr. Chairman, in recent years certain drugs, because of their threat to public health, have been the subject of widespread concern and intense scrutiny by the FDA.

Perhaps the most widely publicized incidence of this sort, related to the so-called fat reducing pills. On that and other occasions, the FDA has been frustrated and embarrassed by the lack of information so crucial to its responsibilities. The FDA was not and is not now able to identify all the manufacturers of a given drug.

Indeed, in several instances when the FDA has determined to publish notice that a given drug was impure, unsafe, or ineffective, it has found that by the time it discovered the questionable drug and its manufacturer, the drug had disappeared from the market.

And information as to why the drug was withdrawn, when it was discontinued, or when its marketing was resumed again—facts critical to the public health—are all unknown to the FDA.

The FDA in fiscal year 1970, initiated 66 corrective actions with regard to improper labeling and deceptive advertising, to deal with “serious admissions, unsupported claims, and promotionally biased statements” which would seriously mislead the physicians and affect the safety of patients.

But, as Commissioner Edwards has said, they were not able to proceed against every deceptive promotion, because of the lack of information about the advertising or labelling of a drug.

Mr. Chairman, and Senator Nelson, I think these examples point to a fundamental gap in the grant of legislative authority to the FDA. I believe it goes to the very heart of the consumer protection role which we expect the FDA to play. I would make brief reference to the clarifications made by the House Committee. First, in response to a concern of industry about burdensome filing and paperwork requirements, the report of the House committee explains that the members agreed to require only that the name and amount of active ingredients be listed.

Further, only representative samples of advertising, rather than copies of all advertising—which could include movie clips and voluminous information unrelated to the thrust of this bill—shall be listed.

Finally, production data, as well as a data to substantiate classifications for drugs have been, due to concern about trade secrets, limited. Provision was made, however, to allow the Secretary to request a list of all ingredients with respect to a particular drug product. I believe these changes reflect reasonable thinking and improve the bill.

In summary, Mr. Chairman, I believe H.R. 9936 is an essential legislative proposal. It is a product of careful legislative analysis and is supported by all segments of the public. It will be a helpful tool to benefit the public health. Finally, Mr. Chairman, I would pause to admit that this bill tries to answer only a small part of the many problems connected with drugs in our society.

This committee, with its expertise and insight on such problems, knows the dimensions of this crisis far better than I. But a step forward, even though it be a small step, should be taken.

And, in that spirit, I hope the committee will lend its efforts toward the enactment of this legislation.

The CHAIRMAN. Thank you for your statement, Senator Pearson.

I gather you would suggest to this committee that it deal with the House bill, rather than your bill?

Senator PEARSON. I think so, Mr. Chairman. It does not make any difference what bill we deal with.

I indicated in my statement that I thought modifications made in the House bill, as to sampling of the advertising, as to the listing, and so-called paperwork problem, and as to—

The CHAIRMAN. Availability of the information?

Senator PEARSON. Yes; though I would, of course, like to see my bill passed as originally drawn, I think the modifications, with respect to trade secrets, listing, and the other provisions they made are reasonable ones and ought to be accepted.

The CHAIRMAN. I am sure Senator Nelson would want to deal with that one aspect, the change in the House bill, that makes a significant difference from the bill you introduced, dealing with the availability to the public of the information that accompanies the listing of these drugs. I am sure we consider it a significant change. I do not have any other questions, except I am glad we could receive your statement.

Senator PEARSON. Once again, these are in the closing hours, and I am very grateful you feel we ought to attend to these matters.

The CHAIRMAN. Senator Nelson?

Senator NELSON. I have no questions.

The CHAIRMAN. Senator Taft?

Senator TAFT. Thank you for your remarks. In reviewing the House bill, perhaps this ought to be directed as much to the staff as to the witness, but what are the new animal drugs, can you answer that?

Senator PEARSON. I do not think I can answer that. Perhaps my associate can.

Mr. WOODY. Senator, that is a classification made under section 512.

Senator TAFT. What type of drugs?

Mr. WOODY. It can include all types of drugs used in animal feeds, but the intent of this legislation is to include only animal drugs and not animal feeds which may contain drugs.

Senator TAFT. Perhaps the report ought to clarify that.

Senator PEARSON. I think it should.

Senator TAFT. Because drugs are put in animal feeds quite often. I have no further questions. Thank you very much.

The CHAIRMAN. Are there any further questions?

Well, thank you very much for your appearance, Senator Pearson.

Senator PEARSON. I thank you for the opportunity to appear.

The CHAIRMAN. Our next witness is Dr. Merlin K. DuVal, Assistant Secretary for Health and Scientific Affairs, U.S. Department of Health, Education, and Welfare, and he is accompanied by Mr. Henry Simmons, Director of the Bureau of Drugs, Food and Drug Administration, Dr. John Zapp, Deputy Assistant Secretary for Legislation, U.S. Department of Health, Education, and Welfare, and Mr. Peter Barton Hutt, Assistant General Counsel for Food, Drugs, and Environmental Health, U.S. Department of Health, Education, and Welfare.

STATEMENT OF MERLIN K. DUVAL, M.D., ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY HENRY SIMMONS, DIRECTOR OF THE BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION; DR. JOHN ZAPP, DEPUTY ASSISTANT SECRETARY FOR LEGISLATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; AND PETER BARTON HUTT, ASSISTANT GENERAL COUNSEL FOR FOOD, DRUGS, AND ENVIRONMENTAL HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. DuVal. Mr. Chairman, thank you for this opportunity to testify on H.R. 9936, a bill to require a current listing of all drugs on the market.

This legislation is essential to the effective administration of the Federal Food, Drug, and Cosmetic Act.

On various occasions the FDA has been asked how many drugs—both prescription and nonprescription—are on the market, who makes them, and what their ingredients are.

These questions have arisen in connection with the National Academy of Sciences drug efficacy study, with respect to the regulation of amphetamines and the fat-reducing rainbow pill business, before Congress and on a number of other occasions.

In order for the FDA to fully accomplish its mission, we believe it necessary to have a mechanism at hand which will provide for prompt data on all drugs that are commercially available.

We have begun to take an inventory of the Nation's drug supply by submitting a questionnaire to the industry and requesting voluntary cooperation in this effort.

This legislation will complement that survey, and will also provide a mechanism to keep such an inventory current.

In fairness to the industry as a whole, legislation will also insure that the inventory will not discriminate against those willing to assist us in this endeavor.

H.R. 9936 would, first of all, require the manufacturers and repackers of drugs to register their drug products with us and update this list semiannually.

Presently, establishments which manufacture, prepare, propagate, compound, process or repack drugs must register their names and places of business but do not have to identify the drugs they produce

Thus, although FDA can issue warnings about products, we may not be able to identify the manufacturers of all preparations subject to such warnings.

This is a paradoxical situation. Over the years we have issued many warnings or restricted certain uses.

Examples of such warnings or restrictions include drugs containing mineral oil, tannic acid, phenacetin, aminopyrine, calamus, and stramonium.

Did FDA reach all the manufacturers, processors, or repackers?

Were all firms properly notified?

These are questions we cannot answer. Yet they are fundamental questions, going to the very heart of our consumer protection program.

In addition, knowledge of which drugs are being produced, and where, will assist us in determining inspection principles.

The bill also provides that for each drug listed which is subject to the preclearance or certification provisions of the act, the registrant shall provide a reference to the authority for marketing such drug.

In the case of drugs which the manufacturer has determined are not subject to those provisions the Secretary may request a brief statement of the basis for this determination. I think it would be appropriate at this time to explain why we read this information on the statute of all drugs. There are a great many drugs on the market today that have not been submitted to this agency for approval.

These are known in the trade as "me too" preparations. This means they are similar to, or identical with, drugs that have the protection of the grandfather clause or drugs that were cleared through the new drug procedures between 1938 and 1962, and later achieved general recognition as to safety.

The complexity of the "me too" problem confronted us during the last year in connection with thyroid-amphetamine combination drugs.

We had to go through the catalog of available drugs to identify and notify producers of these combinations that such drugs could not be regarded as generally recognized as safe or effective for weight control.

The bill would also require persons registering under the act to provide FDA with additional information for drugs which have not been precleared.

This information would include a quantitative list of active ingredients, except that the Secretary may require the complete formula, including inactive ingredients, if necessary for carrying out the purpose of the act.

For prescription drugs which have not been precleared, a copy of all labeling and representative sample of the advertising would be required except that the Secretary may require copies of all advertising if necessary. With respect to nonapproved drugs which are not restricted to prescription sale, the registrant would have to submit a copy of the label and any package insert.

Presently it is mandatory that formula information and proposed labeling be submitted with applications for new drug approvals.

This bill would, however, extend our jurisdiction, by authorizing FDA to require the formula and labeling of drugs not subject to the premarket testing provisions of the act.

It also provides that the Secretary may require each registrant to submit a list of drug products he produces which contain a particular

ingredient thus facilitating notification of the appropriate manufacturers when a particular ingredient presents a potential health hazard.

FDA is, as you know, responsible for regulating advertising for prescription drugs and reviews advertising copy as part of the new drug approval process.

However, our responsibility to regulate advertising extends to all prescription drugs whether approved or not.

The bill would provide greater access to advertisements for prescription drugs which have not been approved or certified and therefore assist in our effort to provide uniform regulation of all prescription drug advertising.

The bill also would solve another troublesome problem. Except for new drugs and antibiotics, under the present requirements a firm need not notify FDA when it discontinues the marketing of a prescription drug or over-the-counter drug.

Prompt notice of such discontinuance will aid us in determining the reasons for such withdrawals—reasons which might assist us in evaluating other products and otherwise assessing the safety of the drug supply. Moreover, we need this information to reduce our paperwork burden. Old files on discontinued drugs should be closed, and no such drugs should be remarketed until their registration is made current.

The bill would also authorize the Secretary to assign registration numbers to products provided they correspond with the numbers assigned in the National Drug Code Directory.

This directory, a voluntary effort of FDA in cooperation with industry, contains descriptions of more than 34,000 prescription and over-the-counter drugs marketed by more than 260 labelers.

The directory identifies the drug products listed by product or generic name, manufacture or labeler name, dosage form, strength, route of administration, and legal status and package forms and sizes.

The directory and its magnetic tape counterpart were established to meet the needs of present and potential users, in government, and the private sector, for a standard drug product data processing code.

Through the drug industry's voluntary efforts, the standard codes required for the automated processing of drug product information have been made available for use in inventory control, applications, drug utilization review studies, hospital billing activities and, in particular, for application to prescription drug reimbursement plans underwritten by third party insurance.

It would also have application in Government agencies for such diverse purposes as an adverse reaction reporting system, drug utilization review, poison control center operations, and drug product recalls.

In summary, the bill would require that all manufacturers, processors, or repackers of drugs, whether or not engaged in interstate commerce must supply FDA with a list of all drugs they produce. They must also notify us on a semiannual basis of drugs newly introduced or drugs which have been discontinued.

All drugs listed must refer to the authority for marketing or the Secretary may request a brief statement as to why clearance was not necessary.

In addition the following would be required for nonapproved drugs:

1. A quantitative listing of active ingredients (a complete formula if requested).

2. For prescription drugs all labeling and a sampling of advertising (or all advertising if requested).

3. For over-the-counter drugs a copy of the label, any package insert and a representative sample of other labeling.

The bill would also permit the Secretary to obtain information on which drugs contain a particular ingredient.

Additionally the bill would provide that information submitted pursuant to this act would be confidential.

Importers could also be covered by the provisions of the bill. This bill is in no way a licensing law. We could not refuse registration to deny marketing. Registration would merely notify us of facts we are entitled to acquire under our inspectional authority.

The bill would facilitate more expeditious enforcement, but would not otherwise restrict the marketing of drugs or change our basic legal framework. I would be pleased to answer any questions the committee may have. I want to thank you for the opportunity of presenting this statement.

The CHAIRMAN. Thank you very much, Dr. DuVal.

Where is it that the Food, Drug, and Cosmetic Act first defines drugs that fall within this legislation and your other legislation?

Dr. DuVAL. The term drug is defined in the section 201(g) (1) of the Federal Food, Drug, and Cosmetic Act.

The CHAIRMAN. Here you address yourself to the requirements under this bill that there would be a furnishing of all representative advertising, in connection with prescription drugs.

How does this reach the druggist who puts together the command from the medical profession that I always thought was the prescription drug?

This is not an advertised drug, where you take your order to the drug store, this is a prescription, and it is put together.

How is this, it is not a commercial product, how is this reached?

Dr. DuVAL. Of course, the commercial products that are the subject of a prescription are advertised very heavily in professional circulars.

The CHAIRMAN. The elements of the prescriptions are advertised?

Dr. DuVAL. Yes, in single drug prescriptions.

The CHAIRMAN. I had the layman's view, that this advertising was commercial advertising, and I was just thrown off.

That is not what you are talking about?

Dr. DuVAL. When generally speaking of advertising, it would be advertising directed at the professional market, not commercial advertising in the weekly news magazine sense.

The CHAIRMAN. Now, Senator Pearson mentioned something about representative advertising, and this would remove any doubt that it was not meant to include movie clips, and a lot of other things?

Do you know what he was talking about?

Dr. DuVAL. I think we heard him, but I am not entirely sure I understood his reference.

The CHAIRMAN. I think he was thinking, as I was thinking, as an absolute layman in this professional area of drugs and medicine.

Mr. HUTT. With respect to prescription drugs advertising, there are, I would say, two kinds: those where the manufacturer is a pharmaceutical company, and for which the package is sent to the phar-

macist who then dispenses them on prescription; and in your question, those which are dispensed after being compounded from the ingredients by the pharmacist. I think you are entirely correct that there would be no advertising as such, for the compounded version.

However, the vast majority of drugs are now made directly by pharmaceutical manufacturers, and they are heavily advertised in medical journals, and, if you would, movie clips used for promotion to the prescribing profession, namely the practitioner.

Now, I do not think it would be useful to try to break down today the difference between labeling and advertising. We do have regulations which set out in some detail the Food and Drug Administration viewpoint under the law as to which type of promotional material is labeling, and which type is advertising.

The CHAIRMAN. Now, in the normal commercial advertising, do you reach that?

This basically goes to the public on over-the-counter, am I right on that, over-the-counter drugs, and your advertising of them?

Mr. HUTT. On over-the-counter drugs, there is basically joint supervision between the Food and Drug Administration and the Federal Trade Commission. The FTC has the direct legal authority over it. We have taken the position in court cases, and have prevailed, that if there are any indications in advertising of an over-the-counter drug, there must be adequate directions for such uses on the label. Therefore, our regulatory actions do affect advertising.

The CHAIRMAN. Does this legislation close all gaps, and bring to you complete information on the drugs that are being sold, but you will hear as a result of this legislation, you will know all of the drugs that are manufactured for the market?

Mr. HUTT. Yes, sir.

The CHAIRMAN. I am a little confused of this period, 1938 through 1962. Evidently during that period, there was less demand on manufacturers, and yet drugs manufactured during that period became standard. In medical practice, and is that what you recalled, through the period of grandfather allowed drugs, later led the manufacture by others, as a "me too" we are doing it just as they are?

Dr. DuVAL. Yes, sir; I would interpret it this way. Let me repeat, using a different set of words, that before the drug clarification in the law in 1962, there were a number of drugs that were marketed.

Many of those are still being marketed today, but we also have new ones arriving today, which are in fact, the same formulation, or minor formulation variants from those earlier.

They would technically be grandfathered. Under the circumstances, they could enter the market, without going through the new drug application.

In that situation, this bill treats that, by authorizing the Secretary, to ask the manufacturer to indicate why, he indicates authority for putting that "me too," and bypassing the preclearance for new drug application procedure, and that is what is meant by that reference.

The CHAIRMAN. Prior to this the manufacturer made the determination he was grandfathered, even though he was new in this particular field, and it was just a matter of chance, he was discovered not to be indeed qualified?

Dr. DuVAL. That is correct.

The CHAIRMAN. What is this going to mean in terms of administrative matters, how much of a burden on the Department, and how much does it mean in the industry, is it very expensive as a listing procedure?

Dr. DuVAL. I do not think so. Everything is relative, Mr. Chairman.

It will probably cost us about \$460,000 in fiscal 1972, to accomplish this objective.

There will be an additional burden, of course, imposed on industry, but we have had appropriate conversations with them, and I think that they agree with us that there is not much of an additional burden here in exchange for the benefit that accrues to us for having taken the step.

The CHAIRMAN. I see in the House report, they say, it is anticipated about \$2 million budget for the Department.

Now, this would be a request for the Department, would it not, in the budgetary process for the additional money?

It would not be taken off necessarily other activities, such as investigations or inspections?

Dr. DuVAL. This would be new money.

The CHAIRMAN. This is a new money item then in the upcoming budget.

I do not want to monopolize all of the time. I mentioned in my opening statement the FDA voluntary program is designed to get a lot of this information out of that.

How does that work?

Dr. DuVAL. It is working now. We started this fall, so we are maybe 15 percent into it. About 1 out of 6 of the questionnaires have been returned to date.

The CHAIRMAN. This basically seeks the same kind of information under the bill that would be required in law?

Dr. DuVAL. Much of the information is the same, yes.

The CHAIRMAN. That was the warmup. Now I will turn it over to Senator Nelson.

Senator NELSON. Thank you, Mr. Chairman. I notice, Doctor, you keep referring to "this bill."

Would you identify what you mean by "this bill"?

Dr. DuVAL. Our reference was to the introductory statement to my opening comment, to H.R. 9936.

Senator NELSON. The one that passed the House?

Dr. DuVAL. Yes.

Senator NELSON. Well, does Senator Pearson's bill represent the viewpoint of the FDA?

Dr. DuVAL. Our interests are represented in both bills, Senator.

That is to say, the objective we are attempting to achieve, the resolution as stated by Senator Pearson, the differences between the two works out very satisfactorily.

Senator NELSON. What resolution?

Dr. DuVAL. There are certain differences in substance between the Senator's bill and the bill that came out as H.R. 9936, and we have come down in favor of the 9936 provisions.

Senator NELSON. Would you explain to me what the differences are that you feel have been reconciled or compromised?

Dr. DuVAL. The list is somewhat long.

Would it be appropriate for us to submit for you a copy of the breakdown of the differences between the two bills?

Senator NELSON. Yes, I would like to see a specific breakdown of the differences, and of your interpretation of the differences between the two bills.

The CHAIRMAN. That is to be inserted at this point in the record.
(The information referred to and subsequently supplied follows:)

COMPARISON OF DRUG LISTING BILLS

(S. 2167 and H.R. 9936)

S. 2167 (Pearson)H.R. 9936 (Rogers)Information
Required

Registrant under Sec. 510 shall provide list of drugs produced and for each drug listed the following:

1. Quantitative formula.
2. Copy of all labeling.
3. Copy of all advertising for prescription drugs.
4. Reference to marketing authority for new drugs (Sec. 505) and antibiotics (Sec. 507).
5. Data from which it was determined that it is not subject to Secs. 505 or 507, if it has not been precleared or certified.
6. Production data as the Secretary may require.

Registrant under Sec. 510 shall provide a list of drugs produced and for each drug the following:

1. For nonapproved drugs¹ a quantitative listing of active ingredients (all ingredients if Secretary believes this necessary)
2. All labeling for approved drugs. For nonapproved prescription drugs all labeling; for a nonapproved over-the-counter drug a copy of the label, package insert and representative sample of other labeling.
3. Representative sample of advertising for nonapproved prescription drugs (all advertising if Secretary requests for good cause).
4. Reference to marketing approval under Sec. 505 (new drugs Sec. 506 (insulin), Sec. 507 (antibiotics), Sec. 512 (animal drugs). Note: S. 2167 specifies only Secs. 505 and 507.
5. Brief statement of basis for determining drug not subject to Secs. 505, 506, 507, or 512.
6. Does not provide authority to require production data.

1. "Nonapproved drugs" refers to drugs which have not been approved or certified pursuant to Secs. 505, 506, 507, or 512 of the Federal Food, Drug, and Cosmetic Act.

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S. 2167Drugs containing
particular
ingredient

Does not provide authority to require submission by each registrant of a list of drugs he produces containing a particular ingredient.

Updating

Immediate notification of drugs newly manufactured, but otherwise annual registration in such form and manner as Secretary may require (this could be interpreted to merely require updating each successive year).

Discontinuance

- * Immediate notification of discontinuing a drug and reasons therefore (notice of resumption also).

Notification prior to use
(Labeling and advertising)

If person proposes to use labeling or advertising not previously submitted he shall submit copies prior to using them.

Withdrawal of NDA

For failure to notify as to discontinued drugs.

Registration Numbers

Secretary may assign registration numbers to products.

H.R. 9936

Provides authority to require submission by each registrant of a list of drugs he produces containing a particular ingredient.

Notification in June and December of each year of drugs newly offered for commercial distribution, and of material changes in information previously submitted.

Notification of discontinued drugs in June and December (and resumption thereof)--no reasons need be given.

No comparable provision.

For failure to notify as to discontinued drugs (or resumption thereof), newly offered drugs, or material change in information previously submitted.

Secretary may assign registration numbers, but if he does they shall be the same as in the voluntary National Drug Code Directory.

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S. 2167H.R. 9936Confidentiality

Secretary shall not disclose any list or accompanying information submitted under this Act unless its non-disclosure would be inconsistent with public health (Sec. 510(f)).

Basically the same provision in proposed Sec. 510(f); but H.R. 9936 also amends Sec. 301(j) to prohibit disclosure of information received under Sec. 510. The House Committee Report points out that these provisions should be viewed in conjunction.

Prohibited Act

Failure to provide required information or notice made a prohibited act.

Same.

Drug Imports

Requires that the same information be submitted by foreign manufacturers as by domestic manufacturers.

Same.

Effective Date

First day of sixth month beginning after date of enactment.

Same.

Senator NELSON. In your prepared statement you said:

Additionally the bill would provide that information submitted pursuant to this Act would be confidential.

Now, where do you list the information that would be submitted pursuant to the act.

Are you referring to your prepared statement where you also say:

In addition the following would be required for nonapproved drugs:

1. A quantitative listing of active ingredients (a complete formula if requested).
2. For prescription drugs all labeling and a sampling of advertising (or all advertising if requested).
3. For over-the-counter drugs a copy of the label, any package insert and a representative sample of other labeling.

So then what other information would be confidential?

I take it all of the information that is with reference to nonapproved drugs, under items one, two and three, you would consider to be confidential? Is that correct under this act?

Dr. DUVAL. I will ask general counsel for us to respond to that, so that we could be as exact as possible.

Mr. HUTT. Senator, perhaps I could approach this in a different way, and give you our interpretation of the confidentiality provisions.

First of all, nothing submitted that is already public information would remain in any way confidential, or be something we could not disclose. An example of that would be where we request submission of labeling and advertising. Since this is public information, obviously we would disclose it. Similarly, where a drug contains on its label the active ingredients, as is required, when we receive that information, pursuant to a submission, that would not be confidential information.

Senator NELSON. Does the FDA have the authority to require that the active ingredients of the drugs be shown on the label?

Mr. HUTT. Yes.

Senator NELSON. And do you require it of all prescription drugs?

Mr. HUTT. On the labeling of prescription drugs, it is shown in the prescribing brochure. I did not want to raise the question, if you are alluding to the issue, whether it should also appear on the package that goes to the consumer. I was not raising that issue, but we do have the information on active ingredients through other sources. It simply is not compiled in one place at one time.

Senator NELSON. But that is not a matter of public information?

Mr. HUTT. It would be a matter of public information.

Senator NELSON. Tell me what under this bill would be confidential?

Mr. HUTT. That is the second part of it—

Senator NELSON. And any information that you would conclude to be confidential, that is not now confidential?

Mr. HUTT. Let's go through them one by one.

First, the bill provides that we may obtain a list of drugs with a particular ingredient when necessary for carrying out the purposes of the act. Now, this particular ingredient might well, for example, be an inactive ingredient. That information is considered by the company presently to be confidential information.

Senator NELSON. You say considered by the company to be confidential information.

What about the Food and Drug Administration?

Mr. HUTT. It has always been considered, when submitted through a new drug application, to be confidential information, since 1938, to the best of my knowledge, Senator.

Senator NELSON. Just on that point, is there any good reason for that?

Mr. HUTT. Senator, I suppose there could be arguments made on both sides. Companies spend an enormous amount of capital, and investment in developing particular combinations of ingredients, that will be effective for given indications. This is considered, and I believe has been upheld in the courts, to be the type of confidential information, of valuable trade secret, that would not be given to competitors, and if given to competitors would be quite harmful from a commercial standpoint. It is my understanding that the courts have recognized this as trade secret information, and, therefore, confidential, for example, under provisions of title 18, United States Code, section 1905, as well as perhaps under section 301(j) of our statute.

Senator NELSON. Is that by court interpretation?

Mr. HUTT. Courts have upheld that.

Senator NELSON. If it is a patented item, is not the active ingredient a matter of public information?

Mr. HUTT. I do not know.

Senator NELSON. Would you check that, and submit that information for the record?

I think it is important.

Mr. HUTT. I would be glad to. I have seen patents without it. I cannot say that I could answer the question accurately. I would suggest you might ask the representatives of the pharmaceutical industry, who will be testifying later.

Senator NELSON. Fine, but would you submit that?

Mr. HUTT. I would be glad to.

(The information referred to and subsequently supplied follows:)

The Patent Office informs us that patents are disclosed at the time the patent is issued and copies are available for fifty cents.

The patent must contain, among other things, the following:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." (Emphasis added).—35 U.S.C. 112.

Senator NELSON. What is seen the rationale to the proposition that the active ingredients must be a matter of public information, that they cannot be confidential, but the inactive ingredients can be?

Mr. HUTT. For the reasons I gave earlier, I can see that there is an argument as a public policy matter, Senator. Whether that should prevail or not is an open issue. I believe the Food and Drug Administration has said for so many years they will welcome congressional scrutiny of the present confidentiality provisions of the law, and an open public debate on these issues. Certainly we would continue to encourage that. As we have interpreted the statute, at least since 1938, this type of information has been held to be confidential, and Congress has not told us to change the law in that respect.

Senator NELSON. Does the law refer to processing?

Mr. HUTT. No, sir. Section 1905 of title 18, United States Code, refers to confidential information in general.

Senator NELSON. Well, we will get to this section.

Mr. HUTT. Section 301(j) of the Federal Food, Drug, and Cosmetic Act has a specific confidentiality provision, but there is a more general one that applies to all information submitted to the Government. That is the one to which I refer; namely title 18, United States Code, section 1905.

I might add, Senator, that under the Freedom of Information Act, there is also a specific confidentiality exemption, and I quote:

Trade secrets and confidential financial information obtained from any person is privileged or confidential.

Senator NELSON. Trade secrets?

Mr. HUTT. Yes.

Senator NELSON. What information do you have additionally which would be confidential under this act?

Would it include the information you are talking about?

Mr. HUTT. Yes; some of the information to be submitted will deal with the conclusion of a manufacturer that he falls within the grandfather or old drug status, to which Senator Williams referred just a few moments ago.

Senator NELSON. You mean if a manufacturer asserts the drug he is manufacturing comes under the grandfather clause, as an old drug?

Mr. HUTT. Yes, sir; he may, for example, rely upon data on safety and effectiveness, that he has spent a substantial amount of time and effort in collecting, and which once again is information which, since 1938, at least, has been regarded by the Food and Drug Administration as falling within the confidentiality provisions of 18 U.S.C. 1905. That is safety and effectiveness data.

Senator NELSON. But the fact that the manufacturer asserts it is an old drug is not confidential?

Mr. HUTT. No, sir; I would anticipate the statement, however, would be buttressed, even though it need be only a brief statement, by a brief summary of the data, and the basis on which they rely for that determination. I believe the bill says it would be a brief summary of the basis on which they rely, not just simply a flat statement that they are grandfathered.

Senator NELSON. If it is an old drug, that drug comes under the classification: "generally recognized as safe and effective"?

Mr. HUTT. Or it could come under the grandfather provisions which are somewhat different. It is either a pre-1938 drug, under the so-called 1938 grandfather clause, or a drug put on the market between 1938 and 1962 and not subject to a new drug application under the so-called 1962 grandfather clause.

Senator NELSON. You are saying that with respect to an old drug, the data that the company submits about its safety is confidential?

Mr. HUTT. It could be. I am not saying all of the information would necessarily be confidential. If, for example, they were relying upon generally available information, upon public literature, then quite clearly, as I stated before, anything already in the public domain

would not in some way gather new protection under this provision. I believe the House report made that quite clear.

On the other hand, if they were relying on internal data, which had not become public information, or a collection of data not generally available to the public, and it is considered in the words of the exemption of the Freedom of Information Act, trade secrets, or privileged or confidential information, that would be protected.

Senator NELSON. You refer to data of tests made to show safety or efficacy of old drugs.

Mr. HUTT. Yes, sir.

Senator NELSON. What is the purpose of these tests since the drugs were accepted in the market place without proof?

Mr. HUTT. I would hope, Senator, and I am sure you would, that no one would stop testing, even the oldest of the old drugs.

Senator NELSON. I am not saying I hope. I am saying that is the law, is it not?

Dr. ZAPP. On the old drug, the opportunity to claim it is an old drug exists, but if that statement is challenged by us, there has to be data on which they can substantiate that.

That data may not be public information under the law.

Senator NELSON. How do you define an old drug?

Dr. ZAPP. The easiest thing is to read you the definition. I will submit this for the record.

(The information referred to and subsequently supplied follows:)

The definition of an old drug is simply one which does not meet the definition of a new drug, viz: The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective 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 Drugs 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 (except a new animal drug or an animal feed bearing or containing a new animal drug) the compositions of which is such that such drug, as a result of investigations to determine its safety and effectiveness 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.—21 U.S.C. 321(p)

Dr. ZAPP. The question is, what is the evidence upon which that judgment is made?

Senator NELSON. So anytime somebody proposes to put the drug on the marketplace, the FDA could require that proof of any claims be submitted that it is in fact a new drug?

Dr. ZAPP. Right.

Senator NELSON. And you are saying that studies made to prove that a drug is safe and effective will not be made public, is that correct?

Dr. ZAPP. That is what exists today.

Senator NELSON. This is what I am trying to say.

You say the statutory definition is that if a drug is generally accepted, among experts, as effective and safe, used over a long period of time, then it has a classification of an old drug?

Dr. ZAPP. That is what the law says.

Senator NELSON. Under what circumstances would the FDA say to the manufacturer that you must produce studies to show that it is safe and effective?

Dr. ZAPP. The real question is on what basis have the experts made that judgment, and there may be opposing views of experts, in which case, that kind of information on which they base their judgments has to be made available to us.

Senator NELSON. Then you do have the authority, if there is a conflict among experts, to require the company that claims it is an old drug or generally accepted as a safe and effective drug to produce independent data of its own to substantiate its claims?

Dr. ZAPP. Yes.

Senator NELSON. And then you are saying that the data used to substantiate the claims are confidential?

Dr. ZAPP. That is right.

Senator NELSON. Now, in what way is that type of data a trade secret?

Dr. DUVAL. It may have been a trade secret when it was first developed in 1925. It may still be the same drug.

Suppose someone has been marketing a very reputable and useful product for many, many years; and suppose he goes out of business, and delists that drug. Then, suppose he decides to put it back on the market; the question would come, is this a new drug, and the answer is no, it is not a new drug. It is the same as before, in which case it could bypass the FDA procedure, and the manufacturer would then provide us a listing again, with the backup data, to indicate why he is bypassing the new drug application.

If that was in fact a secret or patented medicine, it should still be so treated.

Senator NELSON. I do not understand what is secret about data which demonstrate that a drug is safe and effective.

Mr. HUTT. It is valuable information. Hundreds of thousands of dollars may have been expended by the manufacturer in proving the safety and effectiveness, and in finding support for the general recognition—

Senator NELSON. What aspect of the process is a trade secret? They tested the drug on animals. They tested it on human beings. They got results which showed by controlled studies that it was effective and safe.

Why is it a trade secret?

Why should the public be denied that information?

Mr. HUTT. I think you are taking a somewhat narrower view of trade secret than is indicated in the statutes, and indeed in many cases. The statute itself does not say just "trade secret."

For example, I quoted from the Freedom of Information Act: "Trade secrets and commercial or financial information." What the legislative history indicates is that this covers anything on which a substantial investment has been made, which if given to a competitor, free for nothing, would allow the competitor, you might say, to catch up with his competition, without making a similar investment. Therefore, in effect, you are taking away from one company, and giving to another, highly valuable information.

Now, Senator, I would like to emphasize one thing. The Food and Drug Administration has no particular position on the policy aspect of these congressional determinations. As I mentioned earlier, we have time and time again, over the past 15 years, suggested that the legal status of the confidentiality provisions be reviewed by Congress. This would require review of the various statutory provisions that concern us: the Freedom of Information Act exemption, 18 U.S.C. 1905, and section 301(j) of our act. We believe this is a matter of substantial public importance, that should be debated, and should be looked at very closely on a broad scale basis.

I would suggest that this amendment, which is very critical to our ongoing programs on drugs, should not be the vehicle, hopefully for reexamination of that broader issue, which touches on all aspects of our regulatory authority.

Senator NELSON. Would you be willing to submit a listing of what you consider on page 7 to be information, submitted pursuant to this act, which could be confidential?

Mr. HUTT. Senator, we would be happy to do that. Clarification of the application of the confidentiality statutes to each of the things we listed could then be made in the report.

Senator NELSON. And then would you submit the statutory basis for the confidentiality aspects of the statutes, as they affect the FDA, and the information submitted to it?

Mr. HUTT. Yes.

Senator NELSON. Let me say I would be appreciative of that, Mr. Chairman.

The CHAIRMAN. We will make that a part of the record.

Senator NELSON. I would like to ask you about section 301(j) on, page 7 of the House bill, H.R. 9936.

There are two words added in there, so as to read concerning "any method, process, or information," which as a trade secret is entitled to protection.

Now, what additional information would be barred from public scrutiny?

Mr. HUTT. I would be happy to answer that. The answer is none. Indeed, I believe, if you read in conjunction with the amendment to section 301(j), the explanatory language, and the new section 510(f), more information would be available to the public than has previously been the case.

As I mentioned earlier, section 301(j) is only one of three statutes.

Senator NELSON. In what way would more information be available?

Mr. HUTT. Under the Freedom of Information Act, there is no exception to the rule of confidentiality for this information. Under section 510(f), for the first time, the Secretary would be given authority to make otherwise confidential information available, when preserving its confidentiality would be "inconsistent with protection of the public health." Now, this means that if the Food and Drug Administration determines that public health considerations override confidentiality, we would for the first time have the authority to make public disclosure of the information.

Senator NELSON. I saw this bill for the first time only yesterday, and I hope your interpretation is correct.

That is not, however, the interpretation of Congressman Fountain or the chief counsel of the House Committee on Interstate and Foreign Commerce.

They wrote respecting this matter and took an entirely different position. I ask, Mr. Chairman, that the letter, written by Congressman Fountain and the memo written by Mr. James M. Menger, counsel for the House Interstate and Foreign Commerce Committee, which evaluate this amendment, be made a part of the record.

Mr. HUTT. Senator Nelson, I believe the House report reflects precisely the interpretation which I just gave you, and I would certainly hope any Senate report on this bill would reflect that interpretation also.

Senator NELSON. I see.

The CHAIRMAN. Where in the report? Do you have the House report?

Mr. HUTT. Yes, sir. The House report, pages five and six, states the following and I quote:

(The information referred to and subsequently supplied follows:)

[Excerpts from House Report No. 92-437, August 2, 1971]

* * * * *

Section 4. Other amendments.—

* * * * *

Subsection (b) amends section 510(f) of the Act (relating to inspections by the public of registrations filed under section 510) to exempt from inspection by the public any list submitted pursuant to section 510(j) (3) (relating to lists of all drugs containing a particular ingredient) and the information accompanying any list or notice filed pursuant to section 510(j) (1) or 510(j) (2). Such exemption would not apply if the Secretary finds that it would be inconsistent with the protection of the public health and it is not intended that this subsection prevent the disclosure of information already available to the public, such as advertisements or labeling.

* * * * *

*Section 5. Disclosure of certain information.—*This section amends section 301(j) of the Act (relating to the prohibition of the use or disclosure of certain information relating to trade secrets) to prohibit the improper use or disclosure of (1) any listing submitted pursuant to Section 510(j) (3) (relating to listing of all drug products containing a particular ingredient) or (2) any information required to be submitted with a list or notice filed under section 510(j) (1) or 510(j) (2).

This section makes disclosure of such information a violation of the Act, irrespective of whether or not the information is technically a trade secret. However, the bill does not prevent the Secretary from making public the basic lists of drugs required by new section 510(j) (1) and (2), nor does the bill prevent the disclosure of information already available to the public, such as advertisements or labeling. In addition, section 4(b) of the bill provides that information obtained pursuant to the bill may be made available by the Secretary to the extent the Secretary finds that its non-disclosure would be inconsistent with protection of the public health.

Because section 510(j) makes provision for the Secretary to obtain for the first time certain information as to particular products considered confidential, the extra protection now given to such information by the new 301(j) was thought necessary and desirable. With respect to the matters covered by this legislation, section 301(j) and section 501(f) are to be read in conjunction.

* * * * *

The CHAIRMAN. That paragraph that you just read, it should be read in conjunction with the paragraph before it in the report.

Mr. HUTT. Yes, sir.

Senator NELSON. I am concerned, because you apparently have legal counsel differing about what it means.

Mr. Chairman, I ask that these two letters be printed in the record.

The CHAIRMAN. These will be so inserted in the record.

(The information referred to and subsequently supplied follows:)

L. H. FOUNTAIN, CHAIRMAN
 ROBERT E. JONES, ALA.
 BENJAMIN S. ROSENTHAL, N.Y.
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 BILL ALEXANDER, ARK.

NINETY-SECOND CONGRESS

Congress of the United States
House of Representatives

INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
 OF THE
 COMMITTEE ON GOVERNMENT OPERATIONS
 RAYBURN HOUSE OFFICE BUILDING, ROOM B-372
 WASHINGTON, D.C. 20515

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 CLARENCE J. BROWN, OHIO
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 JOHN H. BUCHANAN, JR., ALA.
 J. KENNETH ROBINSON, VA.

225-2548

September 28, 1971

Honorable Paul G. Rogers, Chairman
 Public Health and Environment Subcommittee of the
 Committee on Interstate and Foreign Commerce
 2417 Rayburn House Office Building
 Washington, D. C. 20515

Dear Paul:

The Subcommittee staff has just had an opportunity to review the details of HR 9936 (the Drug Listing Act of 1971) which was reported by your Committee last month and passed by voice vote in the House on September 16.

The staff had not felt the need to follow this legislation closely after attending the hearing of your Subcommittee on June 10, 1971 and analyzing your original bill (HR 4749), since I and other members of this Subcommittee strongly favored its basic purpose.

Indeed, the astonishing fact that the Food and Drug Administration does not have information on a great many new drugs marketed without approved New Drug Applications was first brought to light by the Intergovernmental Relations Subcommittee. Our investigation led to FDA's taking regulatory action against two such drugs that were the subject of extensive advertising campaigns, and to FDA's initiating a questionnaire survey to obtain at an early date information similar to that specified in HR 9936.

I am distressed to learn that the Drug Listing Act, as it passed the House, contains a general amendment of Section 301 (j) of the Federal Food, Drug and Cosmetic Act which could deprive the

Honorable Paul G. Rogers
 September 28, 1971
 Page Two

Congress of essential information for evaluating FDA's administrative performance. This amendment was not included in your original bill, HR 4749. It should be noted also that the report to accompany HR 9936 describes the amendment of Section 301 (j) on page 6 of the section-by-section analysis, but does not disclose the full extent of the amendment. Rather, it conveys the impression that the amendment is concerned solely with the information to be submitted pursuant to the new section 510 (j) pertaining to the listing of drug products.

At present, Section 301 (j) prohibits employees of the Food and Drug Administration and the Department of Health, Education and Welfare from using to their 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, information obtained under the authority of specified sections of the Act, including section 505 (the new drug section) and 704 (the factory inspection section). Section 301 (j) currently limits the prohibition to any information acquired which concerns any method or process which, as a trade secret, is entitled to protection. HR 9936 amends this section by broadening the provision to include "any method, process or information" which is entitled to protection as a trade secret. The effect of the amendment would be to prohibit FDA from revealing to the Congress and the GAO any information, whether or not it concerns a method or process, which FDA construes to be a trade secret.

The amendment contained in Section 5 of HR 9936 is precisely the same provision which the Executive Branch sought unsuccessfully to obtain through HR 11581 in 1962. On that occasion I appeared before the House Committee on Interstate and Foreign Commerce in opposition to this provision and described in some detail the efforts of FDA to deny essential information to the Government Operations Committee on the grounds that it was confidential. FDA at that time took the untenable position that all information submitted in connection with a New Drug Application is entitled to protection as a trade secret and therefore unavailable to the Congress. Your Committee wisely rejected this interpretation and did not in 1962 alter Section 301 (j). As a result, FDA has had no grounds for denying requests for information, other than information on methods or processes which are entitled by law to protection as trade secrets, from duly authorized committees of the Congress.

Honorable Paul G. Rogers
September 28, 1971
Page Three

In view of this history, there can be no doubt as to the consequences of the amendment of Section 301 (j) contained in HR 9936 if it were to become law. This amendment would make it virtually impossible for the Committee on Government Operations to perform its duties under the House rules and the Legislative Reorganization Act with respect to the Food and Drug Administration. Moreover, it would deny other committees of both the House and Senate access to the information in FDA's possession which is vital for the discharge of their legislative responsibilities.

One of the great challenges facing the Congress today is that of making and keeping the vast Federal bureaucracy responsible to the people. It would be ironic in this context if the Congress were to make the Food and Drug Administration less, rather than more, accountable by denying to itself the information concerning FDA's operations which could and would be withheld as a result of the proposed amendment of Section 301 (j).

I would appreciate an opportunity to meet with you at your earliest convenience to discuss how the House action on HR 9936, as it pertains to Section 301 (j) of the Food, Drug and Cosmetic Act, can be reversed.

With kindest personal regards and best wishes,

Sincerely,

L. H. Fountain, Chairman
Intergovernmental Relations Subcommittee

NINETY-SECOND CONGRESS

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W. E. WILLIAMSON, CLERK

Congress of the United States
House of Representatives
Committee on Interstate and Foreign Commerce
Room 2125, Rayburn House Office Building
Washington, D.C. 20515

DATE: September 28, 1971
TO: Lee Goldman
FROM: James M. Menger, Jr. *jm*
SUBJECT: H.R. 9936

I missed an important point in the preparation of the amendments which became H.R. 9936, as passed by the House, and the language contained in section 5(3) and (4) of the bill can operate to make inaccessible to congressional committees, such as yours, ours, and Government Operations, to list a few, information which is now accessible to them in FDA files.

This inadvertent oversight can be corrected by an amendment to section 5, which inserts "(a)" immediately after "Sec. 5.", and by adding at the end of section 5 the following language:

"(b) Nothing contained in the amendments made by this section shall authorize the withholding of information by the Secretary, or by any officer or employee under his control, from the duly authorized Committees of the Congress."

Language virtually identical with this is contained in the Radiation Health and Safety Act, presently set forth as section 360A(e) of the Public Health Service Act. I have discussed this amendment with Members of my Committee and they are quite anxious to have it included in the bill to correct the error.

JMM:al



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor and
Public Welfare
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

I would like to take this opportunity to thank you for holding hearings on the Drug Listing Act, a bill which I believe is urgently needed to fully protect the consumer.

A serious question was broached during the hearing concerning the provisions in section 5 of the bill which would purportedly restrict access of Congress to information received under the Federal Food, Drug, and Cosmetic Act. I would not support any legislation which further limits the disclosure of information.

During deliberations on this bill in the House of Representatives, my staff and I were concerned about this provision and recommended its deletion. The Committee staff stated that our problems could be resolved in the Committee's report, and we therefore did not interpose serious objection to it.

I would recommend that section 5 of the bill now be deleted, and that the Senate Committee Report emphasize that this bill is not intended to restrict disclosure of information to resolve any possible confusion on this point. I am enclosing a letter prepared by counsel on the technical legal aspects. My strong support of this legislation, with that one change, is based on the urgency with which I view the provisions providing a list of drugs and notice of marketing or discontinuing a drug. This information is essential to enforcement of the law. My overriding concern is that we be granted authority to know what drugs are on the market with the minimum possible delay.

I sincerely appreciate your attention to this matter and your interest in the Food and Drug Administration.

Sincerely yours,

Charles C. Edwards, M.D.
Commissioner of Food and Drugs



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20852

OFFICE OF THE
GENERAL COUNSEL

December 21, 1971

Honorable Harrison A. Williams, Jr.,
Chairman, Committee on Labor and
Public Welfare
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

This letter is submitted pursuant to the request of the Committee made during the testimony of the Department of Health, Education, and Welfare on December 8, 1971, with respect to the proposed Drug Listing Act of 1971, H.R. 9936.

Senator Taft asked whether the requirements of the proposed new Drug Listing Act would apply equally to foreign drug establishments and to domestic manufacturers. I replied that, in my opinion, it would apply equally to both. This letter will confirm that interpretation.

Section 510(i) of the Federal Food, Drug, and Cosmetic Act presently provides that a foreign drug establishment "shall be permitted to register under this section pursuant to regulations promulgated by the Secretary." Those regulations are to provide for registration on the condition that adequate arrangements have been made with the foreign government to enable FDA to determine whether the foreign drugs should be permitted entry into the country. Negotiations have been under way for several years with foreign countries in an attempt to arrive at regulations that would be acceptable. We anticipate that regulations under this provision will be proposed in the near future.

It is clear that, under Section 510(i) as now enacted, a foreign drug manufacturer has the option either to register or not to register. The legislative history of the Drug Amendments of 1962 shows that Congress intended to allow the products of those manufacturers who register into the country without delay, and to require a check at the border of all products coming in from unregistered manufacturers.

Page Two - Honorable Harrison A. Williams, Jr.

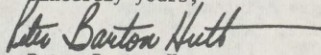
The amendment to Section 510(i) contained in the proposed Drug Listing Act would not change that situation. A foreign manufacturer would still have the option either to register and thus to participate in whatever conditions are required prior to importation to show that the products are not adulterated or misbranded and thus may properly be imported, or not to register and thus not to participate in that program. The proposed amendment to Section 510(i) would change the law to read as follows (new material underscored):

"(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 require such establishment to provide the information required by subsection (j) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs manufactured, prepared, propagated, compounded, or processed in such establishment, if imported, or offered for import into the United States, shall be refused admission on any of the rounds (sic) set forth in section 801(a) of this Act."

Thus, a foreign drug manufacturer could not import any drug into the country unless it had been listed pursuant to the proposed Drug Listing Act, but he would continue to have the option either to have his products checked at the border or to become a part of the program to be established to provide assurance that imported products are not adulterated or misbranded.

The Food and Drug Administration believes there is a sound basis for distinguishing between these two aspects of foreign drug registration, making one mandatory and the other optional. The simple listing of a drug is not burdensome, is essential to the drug inventory that will be undertaken by FDA, and thus should not be optional either with foreign or with domestic manufacturers. The program to be undertaken to help assure that imported drugs are not adulterated and misbranded, however, is a far more complex matter that involves quite different considerations, and we can therefore understand why Congress concluded to make it optional rather than mandatory.

Sincerely yours,



Peter Barton Hutt
Assistant General Counsel
Food, Drugs, and Environmental
Health Division

Senator NELSON. Well, it appears to me that this provision reduces the availability of information to the public, and we have your viewpoint that it expands the information available.

I think it would be helpful to me, and perhaps to the committee, if you would submit a legal memorandum for the record, specifically pointing out how and in what way this amendment makes more information available rather than less.

Certainly if there is any confusion whatsoever, I would think it ought to be directed toward that.

If that is the intent, of course, I think most everybody here would support it, but if there is any confusion of the intent, or lack of clarity in it, so that it may be interpreted in another way, as Congressman Fountain has, then I would suggest clarifying language, and then I would like to have it looked at by a couple of legal experts, so we can be sure we are not passing legislation that further reduces the information available to the public, which is all too small already. While I do not want to get into that subject, it is quite obvious that information that ought to be made public has been interpreted to be confidential.

With respect to processes, I might add that once you get a patent in this country you are protected for 17 years.

The drug industry is the only one I know that can preserve the patent after that period of time, that can preserve its monopoly position by brand name identification after the patent runs out, and by not disclosing sufficient information in the patent application so anyone can produce the drug when the patent expires.

I think this is something Congress has to address itself to.

Once a patent runs out, all of the processes are supposed to be in the public domain. The patent holder has had all of the protection needed, but the fact is that there are all kinds of information the public ought to have, but it is kept from them by ill advised statutes passed by the Congress over the years.

I would like to see a memorandum that demonstrates that clearly.

If it expands the availability of information, I support it.

I cannot tell because I just took a very quick look at the bill.

Mr. HUTT. Senator, we will be happy to submit a memorandum for the record. We would be equally happy to have this committee look into the other issues you have raised. We have urged that be done for some years.

(The information referred to and subsequently supplied, follows:)



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD. 20852

OFFICE OF THE
GENERAL COUNSEL

December 22, 1971

Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor and
Public Welfare
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

This letter is submitted pursuant to the request of the Committee made during the testimony of the Department of Health, Education, and Welfare on December 8, 1971, with respect to the proposed Drug Listing Act of 1971, H.R. 9936.

I

Three Federal statutes prohibit the Food and Drug Administration from disclosing publicly any confidential information obtained from the regulated industries,

18 U.S.C. 1905 contains the following broad prohibition against public disclosure of confidential information by any Government official:

"Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent not authorized by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or return, report or record made to or filed with, such department or agency or officer or employee thereof, which information concerns or relates to the trade secrets, processes, operations, style of work, or apparatus, or to the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures of any person, firm, partnership, corporation, or association; or permits any income return or copy thereof or any

Page Two - Honorable Harrison A. Williams, Jr.

book containing any abstract or particulars thereof to be seen or examined by any person except as provided by law; shall be fined not more than \$1,000, or imprisoned not more than one year, or both; and shall be removed from office or employment."

Section 301(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C 331(j), contains the following more limited prohibited act:

"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, 512, 704, or 706 concerning any method or process which as a trade secret is entitled to protection."

Finally, the Freedom of Information Act, 5 U.S.C. 552(b)(3)-(4), exempts from public disclosure matters that are:

"(3) specifically exempted from disclosure by statute;

"(4) trade secrets and commercial or financial information obtained from a person and privileged or confidential;"

Each of these is pertinent to the questions raised about the confidentiality provisions in the proposed Drug Listing Act.

The most recent of these three statutes is the Freedom of Information Act. In June 1967, the Attorney General issued an authoritative Memorandum interpreting the intended scope of that Act. A copy of pages 31-34 of that Memorandum, which discusses the two exemptions quoted above, is attached to this letter.

The first exemption, for those matters specifically exempted from public disclosure by other statutes, was intended to encompass other existing statutory provisions providing for confidentiality of data submitted to the Government. The provisions of 18 U.S.C. 1905 are explicitly mentioned in the Attorney General's Memorandum as one example of other statutes which the Congress intended not to be disturbed.

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The second exemption, for information given to the Government in confidence, is more directly pertinent to the questions about the scope of confidentiality raised during our testimony. As the Attorney General's Memorandum points out, the Senate Report intended that the Government retain as confidential information "which would customarily not be released to the public by the person from whom it was obtained," and the House Report, after stating the same intent, specifically mentioned "scientific or manufacturing processes or developments." Even more directly in point are the Attorney General's conclusions that:

"In view of the specific statements in both the Senate and House reports that technical data submitted by an applicant for a loan would be covered, and the House report's inclusion of 'scientific or manufacturing processes or developments,' it seems reasonable to construe this exemption as covering technical or scientific data or other information submitted in or with an application for a research grant or in or with a report while research is in progress. Lists of applicants, however, would not necessarily be covered."

* * *

"An important consideration should be noted as to formulae, designs, drawings, research data, etc., which, although set forth on pieces of paper, are significant not as records but as items of valuable property. These may have been developed by or for the Government at great expense. There is no indication anywhere in the consideration of this legislation that the Congress intended, by subsection (c), to give away such property to every citizen or alien who is willing to pay the price of making a copy. Where similar property in private hands would be held in confidence, such property in the hands of the United States should be covered under exemption (e)(4)."

The courts have also broadly interpreted the term "trade secret." In Smith v. Dravo Corp., 203 F.2d 369, 373 (7th Cir. 1953), the court concluded that a "trade secret" includes "almost any knowledge or information used in the conduct of one's business" which represents "in some considerable degree the independent efforts of its claimant" unless

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it is "placed in the public domain." In International Industries, Inc. v. Warren Petroleum Corp., 99 F. Supp. 907, 914 (D. Del. 1951), the court held that:

"A trade secret may consist of any formula, patent, device, plan, or compilation of information which may be used in one's business and which gives a person an opportunity over his competitors."

This broad definition of trade secret was paraphrased directly from Section 757(b) of the Restatement of Torts, which is widely regarded as the authoritative definition.

Since 1938, the Food and Drug Administration has interpreted 18 U.S.C. 1905 and 21 U.S.C. 331(j) to protect from public disclosure, as confidential, the product formulas, identity of ingredients, manufacturing procedures, safety and effectiveness data, and other similar information submitted to FDA by the regulated industries. This has broadly been the practice of other Government agencies. The sole exceptions have been where such information must be disclosed in legal proceedings (as recognized by statute), where it has otherwise become public information, or where the person furnishing the information has consented to such disclosure.

The legislative history of the Freedom of Information Act, as interpreted in the Attorney General's Memorandum, explicitly confirms this earlier interpretation. Much of the information that FDA has regarded as exempt from disclosure under 18 U.S.C. 1905 and 21 U.S.C. 331(j) is mentioned as examples of exempt information: "scientific or manufacturing processes or developments," "technical or scientific data," and "formulae, designs, drawings, research data." Accordingly, we have felt constrained by statute to follow the policy that Congress has established as the legal standard for public disclosure of private information submitted to the Government.

II

The confidentiality provisions contained in Section 5 of the proposed Drug Listing Act of 1971 would amend 21 U.S.C. 331(j), but would not change 18 U.S.C. 1905 or 5 U.S.C. 552(b)(3)-(4). In order to understand how the proposed new confidentiality provisions would apply, as we interpret it, we have listed below the type of information that would be disclosed to the public, and the type of information that would be required to be retained as confidential.

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A. Public Disclosure

1. A list of all drug products.
2. A list of all drug products, broken down by pharmacological category.
3. A list of all products, broken down by manufacturer.
4. A list of a drug product's active ingredients.
5. A list of drug products newly marketed.
6. A list of drug products discontinued.
7. All labeling.
8. All advertising.
9. All data or information that has already become a matter of public knowledge.

B. Confidential Information

1. Any non-public data or information submitted as the basis upon which it has been determined that a particular drug product is not subject to Section 505, 506, 507, or 512.
2. A list of a drug product's inactive ingredients.
3. A list of drugs containing a particular ingredient.

One overall exception to the confidentiality of the information set out above is contained in proposed new Section 510(f), which would be added by Section 4(b) of the Drug Listing Act. This exception would permit the Secretary to disclose such information where confidentiality "would be inconsistent with protection of the public health." None of the three confidentiality statutes discussed above -- 18 U.S.C. 1905, 21 U.S.C. 331(j), and 5 U.S.C. 552(b)(3)-(4) -- contains a public health exception to the rule of confidentiality. Those three statutes require confidentiality even where public health considerations might justify public disclosure. To this extent, therefore, the exception contained

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in proposed Section 510(f) of the Drug Listing Act permits greater public disclosure, rather than greater confidentiality, than has been true in the past.

We can discern no substantive change in the public disclosure of information that would be occasioned by enactment of the confidentiality provisions contained in Section 5 of the proposed Drug Listing Act. The information set out above that we believe would be required to remain confidential information also falls within the prohibitions against public disclosure contained in 18 U.S.C. 1905 and 21 U.S.C. 552(b)(3)-(4). Thus, even if 21 U.S.C. 331(j) were not amended, we would be precluded by these other Federal statutes from making such information public. It is for this reason that we have not objected to enactment of the proposed language. Indeed, as already pointed out, when coupled with the provisions of proposed Section 510(f), the result would permit greater rather than less public disclosure than is presently permitted.

III

We have carefully reviewed the letter of September 28, 1971, from Congressman Fountain to Congressman Rogers, and the memorandum of that same date from Mr. Menger, relating to the confidentiality provisions of the proposed Drug Listing Act. Congressman Fountain and Mr. Menger were concerned not that the amendment to 21 U.S.C. 331(j) would deprive the public of access to confidential information, but rather that it would deprive Congress of access to that information.

The present practice of the Food and Drug Administration is to permit Congressional committees access to confidential information, even though it is protected from public disclosure under 18 U.S.C. 1905 and 5 U.S.C. 552(b). We know of no instances in which granting access to such confidential information has resulted in public disclosure or otherwise contravened the intent of 18 U.S.C. 1905 or 5 U.S.C. 552(b). We would anticipate that Congressional committees would use the same discretion in the future as they have in the past, in their handling of such information. Accordingly, we would not alter our practice in that respect.

We have not granted Congressional committees access to the type of trade secret "method or process" which, under 21 U.S.C. 331(j), we are explicitly prohibited from disclosure outside the Department of Health, Education, and Welfare. Such information includes manufacturing processes, product composition (to the extent not shown in labeling) and specifications, and other highly valuable secret information. We

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discern no reason to expand this provision to include other information not already covered by it. Accordingly, the Food and Drug Administration would recommend that Section 5 of the proposed Drug Listing Act, H.R. 9936, be deleted in its entirety.

IV

We wish to state once again that the Food and Drug Administration takes no position, at this time, on the broad policy issues raised by the various confidentiality provisions contained in present Federal law. There are policy considerations that support public disclosure, and there are policy considerations that support confidentiality. This is an issue of great public importance that deserves substantial Congressional scrutiny and deliberation.

This is not the first time that the Food and Drug Administration has sought to bring this matter to the attention of the Congress and the public. In 1967, in testimony before the Subcommittee on Monopoly, Select Committee on Small Business, United States Senate, the Commissioner of Food and Drugs spelled out the present law and policy and invited Congressional inquiry. Later that year he repeated that invitation before the Subcommittee on Activities of Regulatory Agencies, Select Committee on Small Business, House of Representatives. Subsequently, in several public speeches, he sought to focus public and professional attention on this issue. Just three weeks ago, in a major address to the newly-formed Institute of Medicine of the National Academy of Sciences, Commissioner Edwards again sought to reopen this issue:

"Still another problem involves secrecy of information: Under present law, virtually all material submitted to FDA by a manufacturer to justify approval of a new drug is regarded as confidential, and, thus, cannot be released by us. In effect, we are precluded from telling physicians and the public the detailed basis on which we approve or disapprove a drug. Several FDA commissioners have appealed to the medical and scientific community to suggest ways out of this dilemma. Will this new Institute be as silent on this issue as other medical organizations have been in the past? I hope not."

On every pertinent occasion, the Food and Drug Administration has urged scrutiny of the present law in order to define the issues and resolve this policy question in the best interests of the public.

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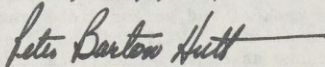
Until Congress changes its mandate to the Food and Drug Administration, we are constrained to follow the provisions of the three statutes quoted earlier in this letter. It is not within our authority to contravene those statutes by instituting policy changes unauthorized by Congress. We have had under consideration, for the past two months, proposals within the Agency to delineate more sharply the parameters of the various confidentiality provisions and their application to the specific information submitted to the Agency. These regulations will be proposed through Federal Register notice in the relatively near future. It must be recognized, however, that they will be designed to implement and define the application of the statutes by which public disclosure of information is limited. They cannot go beyond present statutory requirements.

We would again urge, therefore, that this Committee undertake a study of the confidentiality provisions of Federal law, at least as they relate to the Food and Drug Administration, to evaluate whether they should be retained or modified in any respect. We would cooperate fully in any such review.

V

Finally, we would urge that the proposed Drug Listing Act not be used as a vehicle to review existing confidentiality statutes. As noted above, we would support deletion of Section 5 from the Act, which would then leave 21 U.S.C. 331(j) unamended. With this change, we can discern no substantive change in the law relating to confidentiality that would be brought about by the provisions of this new Act, except for the more liberal exemption from confidentiality in Section 510(f), and we would so interpret and apply those provisions. This letter, as part of the legislative history of the Act, would clearly establish that intent as the controlling interpretation of the Act. Appropriate language in the Senate Report would also make the intended application of the new provisions unmistakable.

Very truly yours,



Peter Barton Hutt
Assistant General Counsel
Food, Drugs, and Environmental
Health Division

Enclosure

[Excerpt from Memorandum of Attorney General (June 1967) interpreting scope of Freedom of Information Act]

(3) STATUTORY EXEMPTION

"The provisions of this section shall not be applicable to matters that are * * * (3) specifically exempted from disclosure by statute;"

Explaining exemption (3) the House report, at page 10, notes that there are "nearly 100 statutes or parts of statutes which restrict public access to specific Government records. These would not be modified by the public records provisions of S. 1160."

The reference to "nearly 100 statutes" apparently was inserted in the House report in reliance upon a survey conducted by the Administrative Conference of the United States in 1962. This survey concluded that there were somewhat less than 100 statutory provisions which specifically exempt from disclosure, prohibit disclosure except as authorized by law, provide for disclosure only as authorized by law, or otherwise protect from disclosure. The reference therefore indicates an intention to preserve whatever protection is afforded under

other statutes, whatever their terms. For examples of the variety of statement of such provisions compare 18 U.S.C. 1905; 26 U.S.C. 6103; 42 U.S.C. 2000e-8, 2161-2166; 43 U.S.C. 1398; 44 U.S.C. 397; and 50 U.S.C. 403g. For a general, but not exhaustive, compilation of relevant statutory provisions, see Federal Statutes on the Availability of Information, Committee Print, House Committee on Government Operations, 86th Congress, Second Session, March 1960.

(4) INFORMATION GIVEN IN CONFIDENCE

"The provisions of this section shall not be applicable to matters that are * * * (4) trade secrets and commercial or financial information obtained from any person and privileged or confidential;"

The scope of this exemption is particularly difficult to determine. The terms used are general and undefined. Moreover, the sentence structure makes it susceptible of several readings, none of which is entirely satisfactory. The exemption can be read, for example, as covering three kinds of matters: i.e., "matters that are * * * [a] trade secrets and [b] commercial or financial information obtained from any person and [c] privileged or confidential." (bracketed initials added). Alternatively, clause [c] can be read as modifying clause [b]. Or, from a strictly grammatical standpoint, it could even be argued that all three clauses have to be satisfied for the exemption to apply. In view of the uncertain meaning of the statutory language, a detailed review of the legislative history of the provision is important.

Exemption (4) first appeared in the bill (S. 1666) following full committee consideration by the Senate Committee on the Judiciary in the second session of the 88th Congress. It then provided for the exemption of "trade secrets and other information obtained from the public and customarily privileged or confidential." The Senate report explained the addition of exemption (4) as follows:

"This exception is necessary to protect the confidentiality of information which is obtained by the Government through questionnaires or other inquiries, but which would customarily not be released to the public by the person from whom it was obtained. This would include business sales statistics, inventories, customer lists, and manufacturing processes. It would also include information customarily subject to the doctor-patient, lawyer-client, and other such privileges." (S. Rept., 88th Cong., 6).

When S. 1160 was introduced in the 89th Congress, exemption (4) differed in two respects from the previous version. The words "commercial or financial" had been substituted for the word "other," and the word "customarily" had been deleted.

While the first of these two changes could be read as narrowing the exemption, a comparison of the Senate reports in the 88th and 89th

Congress indicates, rather, that it was intended to make sure that commercial and financial data submitted with loan applications would come within the exemption. The description of exemption 4 at page 9 of the Senate report in the 89th Congress is the same as that quoted above from the report in the 88th Congress, except that reference to the "lender-borrower privilege" is inserted and the following sentence is added: "Specifically it would include any commercial, technical, and financial data, submitted by an applicant or a borrower to a lending agency in connection with any loan application or loan."

The Senate report in the 89th Congress thus treats the change as expanding rather than contracting the coverage of the exemption, since it not only adds the above language, but also continues to refer to the doctor-patient and lawyer-client privileges, which certainly are not "commercial or financial," and all the other material referred to as exempt in the previous report.

Deletion of the word "customarily" apparently had a different basis. While at first glance the reach of "privileged" might be considered extended by removal of the modifying word "customarily," the change also serves a narrowing function by negating the possibility of a privilege created simply by agency custom. The word "customarily" is still used in the report, but with examples of the kinds of privileges which are protected by the exemption.

The House report on this exemption generally parallels the Senate language with several additions, including such matters as disclosures or negotiation positions in labor-management mediations, and scientific or manufacturing processes or developments. The report states at page 10:

"This exemption would assure the confidentiality of information obtained by the Government through questionnaires or through material submitted and disclosures made in procedures such as the mediation of labor-management controversies. It exempts such material if it would not customarily be made public by the person from whom it was obtained by the Government. The exemption would include business sales statistics, inventories, customer lists, scientific or manufacturing processes or developments, and negotiation positions or requirements in the case of labor-management mediations. It would include information customarily subject to the doctor-patient, lawyer-client, or lender-borrower privileges such as technical or financial data submitted by an applicant to a Government lending or loan guarantee agency. It would also include information which is given to an agency in confidence, since a citizen must be able to confide in his Government. Moreover, where the Government has obligated itself in good faith not to disclose documents or information which it receives, it should be able to honor such obligations."

The last two sentences, in particular, underline the protection afforded by this exemption to information given to the Government in confidence, whether or not involving commerce or finance.

It seems obvious from these committee reports that Congress neither intended to exempt all commercial and financial information on the one hand, nor to require disclosure of all other privileged or confidential information on the other. Agencies should seek to follow the congressional intention as expressed in the committee reports.

In view of the specific statements in both the Senate and House reports that technical data submitted by an applicant for a loan would be covered, and the House report's inclusion of "scientific or manufacturing processes or developments," it seems reasonable to construe this exemption as covering technical or scientific data or other information submitted in or with an application for a research grant or in or with a report while research is in progress. Lists of applicants, however, would not necessarily be covered.

In view of the statements in both committee reports that the exemption covers material which would customarily not be released to the public by the person from whom the Government obtained it, there may be instances when agencies will find it appropriate to consult with the person who provided the information before deciding whether the exemption applies.

One change was made in exemption (4) by the Senate committee in the 89th Congress: the phrase "information obtained from the public" was amended by substituting the words "any person" for "the public." It seems clear that applicability of this exemption should not depend upon whether the agency obtains the information from the public at large, from a particular person, or from within the agency. The Treasury Department, for instance, must be able to withhold the secret formulae developed by its personnel for inks and paper used in making currency.

An important consideration should be noted as to formulae, designs, drawings, research data, etc., which, although set forth on pieces of paper, are significant not as records but as items of valuable property. These may have been developed by or for the Government at great expense. There is no indication anywhere in the consideration of this legislation that the Congress intended, by subsection (c), to give away such property to every citizen or alien who is willing to pay the price of making a copy. Where similar property in private hands would be held in confidence, such property in the hands of the United States should be covered under exemption (e) (4).

* * * * *

Senator NELSON. Let me ask you this; I notice in testimony before Congressman Fountain's subcommittee, Mr. Goodrich testified that the FDA can get the information they are requesting by the method of inspecting the plant, because they have that authority.

Mr. HUTT. That is true with respect to prescription drugs. That is not true with respect to over-the-counter drugs.

Senator NELSON. You have no authority to inspect a plant manufacturing over-the-counter drugs?

Mr. HUTT. We may inspect the plant, but we may not, under section 704, of the act, inspect records except in the area of prescription drugs.

Senator NELSON. Under this bill, you will be authorized to require the same information for over-the-counter drugs that you can require for prescription drugs?

Mr. HUTT. Yes, sir.

Senator NELSON. Now, you have on a voluntary basis proceeded to send out an inventory questionnaire to the drug companies, is that right?

Mr. HUTT. Yes, sir.

Senator NELSON. According to the Washington drug and device letter, dated November 1, the president of the Pharmaceutical Manufacturers Association has protested to the FDA Commissioner that the agency is breaking an agreement in asking for certain categories of information in its drug inventory form.

I submit this item to be inserted in the record.

(The information referred to and subsequently supplied follows:)

Jeanne Anderson, Editor
Jerome F. Brazda, Executive Editor

Washington **drug & device** letter

A MCGRAW-HILL PUBLICATION

November 1, 1971 - No. 139

THIS WEEK: Administration Device Bill Taking Shape....
New Bureau of Drugs View on Phase I Testing Causes Stir....
PMA Voices Objections to Inventory Form....Fountain Schedules
Hearings on Diethylstilbestrol; FDA Reviewing Cancer Findings
....CDC, FDA to Meet on Diagnostic Kit Regulation

STETLER 'DISAPPOINTED' WITH FDA REPLY ON DRUG INVENTORY INFORMATION

PMA President C. Joseph Stetler has protested to FDA Commissioner Charles C. Edwards that the agency is breaking an agreement in asking for certain categories of information in its drug inventory form. In an Oct. 21 letter, Stetler said that certain kinds of data, required in early drafts of the House-passed registration bill (H.R.9936) but omitted in the final version, were to have been dropped from the inventory form as well. The agreement was between FDA, PMA, the Proprietary Association and the House Interstate and Foreign Commerce Committee, the letter said.

Cited as examples of the kind of information being sought are "production data and detailed ingredient information on an across-the-board basis." The fact that the inventory is "voluntary" is moot, Stetler said, since "many manufacturers will not want to incur the displeasure of either local or Washington-based FDA officials" by not cooperating.

The Rogers registration bill is scheduled to be taken up by Sen. Harrison Williams' (D-N.J.) Labor and Public Welfare Committee, but no hearing dates have been set.

Senator NELSON. What does all of that mean in this letter?

Mr. HUTT. What it means, Senator, is that in our voluntary request for information, prior to enactment of this bill, we asked for additional information we thought would possibly be of use to us. It remains our judgment that we would be happy to have the manufacturers submit that information voluntarily. We do not believe we have broken any agreement.

On the other hand, we do not believe it is absolutely critical that we get that information to the extent that we need the legal authority to require that information in that form.

Senator NELSON. What information did you ask for that is objected to?

Mr. HUTT. The financial information, for example, the amount produced in terms of the yearly production.

Senator NELSON. You mean the amount produced?

Mr. HUTT. I believe it was the amount produced.

Senator NELSON. Cited as an example of the kind of information being sought are "production data, and detailed ingredient information on an across-the-board basis."

Mr. HUTT. With respect to production data, first, we already get this information on new drugs. Wherever we have a new drug, we are entitled to receive that information under section 505 of the act.

Second, with respect to controlled substances, those in schedule II of the new Controlled Substances Act, there are quotas set for production.

Senator NELSON. Who sets the quota?

Mr. HUTT. The Bureau of Narcotics and Dangerous Drugs in consultation with the Department of HEW. So that this information is available through two other sources.

In addition, I think, where we actually find a critical need for that information, we will receive the cooperation of manufacturers, and it will be given to us.

Senator NELSON. Why is it objected to by the Pharmaceutical Manufacturers Association?

Mr. HUTT. I would suggest that that question be reserved for them.

Senator NELSON. Do you have the authority under the current law to get the information of how much of the particular compound is being manufactured and put into the market place?

Mr. HUTT. Under the current law we do not, and under this new bill, we would not. As I said earlier, we do not believe that authority is critical.

Senator NELSON. Does this bill, which has been passed by the House, authorize you to collect that information?

Mr. HUTT. No, sir, it does not.

Senator NELSON. That was eliminated?

Mr. HUTT. Yes, sir, and we agreed to the elimination.

Senator NELSON. Cited as examples of the kind of information being sought are "production data and detailed ingredient information on an across-the-board basis."

What does that mean?

Mr. HUTT. That means instead of as is true under this bill, requiring detailed ingredient information only on request, in individual in-

stances, that we ask for it on an across-the-board basis. If that information is not forthcoming on a voluntary basis, we would have authority under the new bill to request it where it was necessary. So that situation is totally taken care of by this bill.

Senator NELSON. You may require that?

Mr. HUTT. Yes, sir, we may.

Senator NELSON. Is information of the ingredients confidential?

Mr. HUTT. Under this bill, if we were to request a list of all drugs by individual active ingredient, it is my interpretation of the confidentiality provision, that that list itself would be confidential.

Senator NELSON. I do not understand.

Mr. HUTT. Very well. Under the bill we have the authority to request specific lists of drugs by individual active or inactive ingredients.

Senator NELSON. From each manufacturer?

Mr. HUTT. Yes. We would have a list of drugs, each one of which contains ingredient X. That list would be confidential. However, a general list, by drug category, or indeed by all drugs, or by drug manufacturer, would not be confidential.

Senator NELSON. What is the rationale of that?

Mr. HUTT. Once again, this raises the trade secret issue.

Senator NELSON. Why is this a trade secret?

Mr. HUTT. Because of the additional factor, that the list is by an individual ingredient, rather than just all drugs. I see nothing confidential about a list of all drugs manufactured by a given manufacturer. But I can see—and again, I think it would be useful at some later time to go into the policy considerations of this—the argument that there are confidentiality aspects of saying that the following list of drugs all contain a certain ingredient. It is information that could have a competitive impact.

Senator NELSON. Would you explain that?

Mr. HUTT. Let me try.

Doctor DuVAL. I see the dilemma that has worked its way into the conversation.

There is more than one issue being treated. Supposing one finds that ingredient A, when added to an open sore as a powder, is very effective as long as it is used in powder form.

Then, suppose a company spends \$2 million, trying to find out how to put it in an ointment form.

It may come up with an otherwise inactive ingredient that succeeds in achieving that objective.

Then he can manufacture and put on the market that ointment.

Under the Freedom of Information Act, the specific process by which he developed that substance, and the ingredient itself (which is inactive), is protected as a trade secret. Then suppose that, 10 or 15 years later, we find that the ingredient is harmful. We would be interested in getting back to identify every product on the market that contains that ingredient.

This has got to be done in some way, under the existing philosophy, that that secret be protected, except and unless the Congress treats that as a separate issue, and that is why I would say it is a compound question.

Mr. Hutt has already invited the Congress to continue to examine that issue, but in order for us to be consistent with the existing law, we have to put that issue in this one.

We have to operate within the constraints of the existing statutes. We have to find a way to put that provision into this statute, until you have addressed the larger question.

Senator NELSON. I think I have not asked all of the questions I want, but I have taken more than my allotted time.

The CHAIRMAN. Senator Taft.

Senator TAFT. Thank you very much, Mr. Chairman.

Doctor DuVal, regarding this patent trade secret problem, when a patent is issued, and then it expires, the information in the patent becomes public, does it not?

Doctor DuVAL. I think the answer to that is yes.

Senator TAFT. Is it public anyway?

Mr. HUTT. It is public. Anything in the patent is public information from the moment the patent is made public.

Senator TAFT. Is it true that the availability or the lack of availability of secrecy, under the trade secrets laws, as compared to this publication of the patent, may well determine whether or not a company will go ahead and investigate and build a particular product?

Mr. HUTT. This is the argument in favor of all confidentiality provisions.

Senator TAFT. How do they decide whether it is a trade secret under the patent rule?

Mr. HUTT. I believe they do both.

Senator TAFT. You cannot do both at the same time; can you?

Mr. HUTT. Yes, sir.

Senator TAFT. As to one product?

Mr. HUTT. I believe Senator Nelson has pointed out that there are two aspects to this.

First, there may be a patent on a new drug. There is also required under our statute to be a new drug application on that drug. Under the way the statute is presently written, the data submitted in support of a new drug application is confidential, and may not be used in support of a competitor's new drug application.

As Senator Nelson has pointed out, this means that, even after the patent expires, the data, if they remain confidential, continue to give an additional term of protection to the drug, that would not otherwise be available under the patent law.

Senator TAFT. Could the patent be complete under those circumstances; could it be a complete patent?

Mr. HUTT. Senator, I regret, I am not a patent attorney. I do not know the law in that respect. I simply cannot answer that question.

Senator TAFT. It is a novel concept to me. I have worked in this field somewhat, and it is a novel concept to me, that a patent, and trade secret protection would be available for the same information, because by definition the patent becomes public.

Mr. HUTT. Senator, we have been concerned about this for several years, and we have urged Congress to look into this matter. We continue to do so.

Senator TAFT. What about the whole area of imports? There is no mention in the bill, as I understand it, about imports, by any inference. I guess if they are marketed, they would be covered under some circumstances, but what is the general impact of the bill with regard to the import of new drugs, say, and old drugs for that matter?

Mr. HUTT. The Food and Drug Act applies equally to imports and to drugs manufactured overseas as to drugs manufactured in this country. One of our difficulties, of course, is that whereas we have an easy access to manufacturing plants in this country, it is very difficult indeed to inspect plants throughout the world. We must therefore rely principally upon the temporary detention of incoming goods, until we can conduct spot checks on sanitation and on the labeling and so forth of any incoming drugs.

Senator TAFT. Would this proposed bill cover the imports?

Mr. HUTT. Yes, it would, as I understand it.

Senator TAFT. Of new drugs, or new and old both?

Mr. HUTT. I see no exclusion that the bill has toward imports, and, therefore, it would be my interpretation it would apply.

Senator TAFT. I see.

Mr. HUTT. Senator, if I could, I might prefer to submit something for the record, after I have had an opportunity to look at it closely.

Senator TAFT. I would like to have that stated a little more closely.

Mr. HUTT. The question that arises in my mind is that this is an amendment to section 510 of the act, which has a specific provision dealing with imported drugs. I am uncertain how that provision ties in with this new amendment, so I will submit a further memorandum for the record.

Senator TAFT. Regarding the listing language, the problem I have, is that the listing language does not seem to cover the importing process, in the various sections of the bill, but if you would check that out and let us have some thought on it, that would be helpful.

I would like to ask Dr. DuVal, generally about imports, why it seems to take so long to get approval of drugs that have a considerable record of testing abroad, and have had apparently favorable effects, but nevertheless seem to take a long time for approval in this country?

Dr. DUVAL. The issue to which I interpret your question is being addressed is not a function of whether the drug itself is an import.

The issue is whether or not under the Federal Food, Drug, and Cosmetic Act, we can permit use for clinical experimentation for a drug that has not gone through the prescreening processes required of all drugs irrespective of their function.

Senator TAFT. But the clinical experience is used, is it not?

Dr. DUVAL. Clinical experience could be used, but it would have to be used with respect to any other experienced use. Ordinarily, most drugs brought forward for consideration by us go through a sequential testing procedure, after having achieved an example of efficacy of one level, and so forth.

Such a drug is advanced through a procedure, the network of which constitutes what we believe to be the protective element to the public, and there are always going to be some drugs, I suppose, which cannot effectively pass that particular screen, and the issue then becomes can

we find a way around that screening, and then should we, because the screening is there to protect the public.

Senator TAFT. There have been quite a number of drugs developed and used abroad for a considerable period, and then coming into this country, but only after considerable delay.

Since I do not know the examples to which you have reference, I might ask Dr. Simmons, if he wants to address himself to that, so that he can perhaps speak on the specific issue.

Dr. SIMMONS. Senator, it is difficult to answer the question of delay, because after all, the Food and Drug Administration can only consider what is brought in for it to consider.

If a manufacturer does not bring to us an application to investigate, or to approve a drug, naturally, we are powerless to do anything. So it is basically that.

Senator TAFT. How about a doctor??

Dr. SIMMONS. A doctor, of course, obtains most investigational drugs from a manufacturer.

Senator TAFT. Suppose he gets it from abroad?

Dr. SIMMONS. That sometimes happens. What he does, usually, is to file an investigational drug application with the Food and Drug Administration.

Senator TAFT. How long does it take to approve it?

Dr. SIMMONS. There is no approval process, but there is a review process of 30 days, after which he is free to proceed with the investigation if he has not been told otherwise by the FDA.

Senator TAFT. What is the individual case?

Dr. SIMMONS. It depends on the drug, and what is trying to be determined.

Various types of protocol would apply to the question, and the type of drug he is dealing with. But the point you are making is the delay. As I said, it is difficult to say that the agency is responsible for the delay, until you could say the agency has been presented with the question. Not infrequently, a firm may decide to test and develop something overseas first, which might take a number of years, and only then comes to the Food and Drug Administration.

Now, that period is not delay due to the FDA. The delay that is appropriately charged to our system is as of the time the material was presented to the FDA.

In answer to your question on the use of form data, the Agency does consider all data submitted on testing for the safety and efficacy of the drug. We do have our own internal policy, which states that without any data produced in this country, which he can in fact prepare, and see in fact its quality firsthand, we would not approve the drug without some confirmatory U.S. studies. But all studies are considered, and the quality of the material would depend on the consideration and weight they carry.

Senator TAFT. Thank you.

Mr. HUTT. Senator Taft, I have an answer to your earlier question. The amendment that is being considered would require that the same information be submitted by foreign manufacturers as by domestic manufacturers. It is absolutely clear.

Senator TAFT. What particular language are you referring to?

Mr. HUTT. I am particularly looking in the House report, on the bill. It shows how section 510(i) deals with foreign drug establishments. It states the FDA regulations dealing with registration of foreign drug companies, and I quote, "Shall require such establishment to provide the information required by subsection (j)."

Senator TAFT. Thank you.

I asked the question of Senator Pearson earlier, with regard to animal drugs. I wonder if we could have some elaboration on that, from the FDA. The bill appears to apply to new animal drugs. What about old animal drugs, and what are animal drugs?

Mr. HUTT. If I may, I would suggest that we insert the definition of a new animal drug here. In the definitional section of the Food and Drug Act, section 201(w), which was added by the provisions of the animal drug amendments, the term new animal drug means any drug intended for use in animals, other than man, including any drug intended for use in animal feed, but not including the animal feed itself. And then it goes on, in somewhat the same way as the definition for human drugs. Section 512 was also added to the Federal Food, Drug and Cosmetic Act, by an amendment for the purpose of consolidating all of the animal drug provisions in the act.

It was not my interpretation of the bill we are considering today, to exclude old animal drugs. Perhaps, Senator, I could ask you the language to which you were referring in your earlier question, so I could deal directly with that.

Senator TAFT. I do not see it immediately at hand. The question I asked is whether old animal drugs are covered.

Mr. HUTT. They are clearly covered in the same way as old human drugs. Obviously, there are some provisions for both new animal drugs and new human drugs that are slightly different. But as set out in the various provisions, I see nothing to exempt old animal drugs any more than old human drugs.

Senator TAFT. Thank you, Mr. Chairman.

The CHAIRMAN. Is there anything further?

Senator NELSON. I have nothing.

The CHAIRMAN. Gentlemen, thank you very much.

When can we look forward to the memorandum?

Mr. HUTT. We will submit it just as quickly as we possibly can, Senator. It should be no more than 2 or 3 days.

(The information referred to and subsequently supplied follows:)



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

MERLIN K. DUVAL, M.D.

ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

BEFORE THE

COMMITTEE ON LABOR AND PUBLIC WELFARE

UNITED STATES SENATE

DECEMBER 8, 1971

Dear Mr. Chairman:

Thank you for this opportunity to testify on H.R. 9936, a bill to require a current listing of all drugs on the market.

This legislation is essential to the effective administration of the Federal Food, Drug and Cosmetic Act. On various occasions the FDA has been asked how many drugs -- both prescription and nonprescription -- are on the market, who makes them, and what their ingredients are.

These questions have arisen in connection with the National Academy of Sciences Drug Efficacy Study, with respect to the regulation of amphetamines and the fat-reducing rainbow pill business, before Congress and on a number of other occasions.

In order for the FDA to fully accomplish its mission, we believe it necessary to have a mechanism at hand which will provide for prompt data on all drugs that are commercially available.

We have begun to take an inventory of the Nation's drug supply by submitting a questionnaire to the industry and requesting voluntary cooperation in this effort. This legislation will complement that survey, and will also provide a mechanism to keep such an inventory current. In fairness to the industry as a whole, legislation will also insure that the inventory will not discriminate against those willing to assist us in this endeavor.

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H.R. 9936 would, first of all, require the manufacturers and repackers of drugs to register their drug products with us and update this list semiannually.

Presently, establishments which manufacture, prepare, propagate, compound, process or repack drugs must register their names and places of business but do not have to identify the drugs they produce. Thus, although FDA can issue warnings about products, we may not be able to identify the manufacturers of all preparations subject to such warnings. This is a paradoxical situation. Over the years we have issued many warnings or restricted certain uses. Examples of such warnings or restrictions include drugs containing mineral oil, tannic acid, phenacetin, aminopyrine, calamus, and stramonium.

Did FDA reach all the manufacturers, processors, or repackers? Were all firms properly notified? These are questions we cannot answer. Yet they are fundamental questions, going to the very heart of our consumer protection program.

In addition, knowledge of which drugs are being produced and where, will assist us in determining inspection priorities.

The bill also provides that for each drug listed which is subject to the preclearance or certification provisions of the Act, the registrant shall provide a reference to the authority for marketing such drug. In the case of drugs which the manufacturer has determined are not subject to those provisions the Secretary may request a brief statement of the basis for this determination.

I think it would be appropriate at this time to explain why we need this information on the status of all drugs. There are a great many drugs on the market today that have not been submitted to this Agency for approval. These are known in the trade as "me too" preparations. This means they are similar to, or identical with, drugs that have the protection of the grandfather clause or drugs that were cleared through the new drug procedures between 1938 and 1962, and later achieved general recognition as to safety.

The complexity of the "me too" problem confronted us during the last year in connection with thyroid-amphetamine combination drugs. We had to go through the catalogues of available drugs to identify and notify producers of these combinations that such drugs could not be regarded as generally recognized as safe or effective for weight control.

The bill would also require persons registering under the Act to provide FDA with additional information for drugs which have not been precleared. This information would include a quantitative list of active ingredients, except that the Secretary may require the complete formula, including inactive ingredients, if necessary for carrying out the purpose of the Act.

For prescription drugs which have not been precleared, a copy of all labeling and representative sample of the advertising would be required except that the Secretary may require copies

of all advertising if necessary. With respect to nonapproved drugs which are not restricted to prescription sale, the registrant would have to submit a copy of the label and any package insert.

Presently it is mandatory that formula information and proposed labeling be submitted with applications for new drug approvals. This bill would, however, extend our jurisdiction, by authorizing FDA to acquire the formula and labeling of drugs not subject to the premarket testing provisions of the Act. It also provides that the Secretary may require each registrant to submit a list of drug products he produces which contain a particular ingredient thus facilitating notification of the appropriate manufacturers when a particular ingredient presents a potential health hazard.

FDA is, as you know, responsible for regulating advertising for prescription drugs and reviews advertising copy as part of the new drug approval process. However, our responsibility to regulate advertising extends to all prescription drugs whether approved or not. The bill would provide greater access to advertisements for prescription drugs which have not been approved or certified and therefore assist in our effort to provide uniform regulation of all prescription drug advertising.

The bill also would solve another troublesome problem. Except for new drugs and antibiotics, under the present requirements a firm need not notify FDA when it discontinues the marketing of a prescription drug or over-the-counter drug.

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Prompt notice of such discontinuance will aid us in determining the reasons for such withdrawals -- reasons which might assist us in evaluating other products and otherwise assessing the safety of the drug supply. Moreover, we need this information to reduce our paperwork burden. Old files on discontinued drugs should be closed, and no such drugs should be remarketed until their registration is made current.

The bill would also authorize the Secretary to assign registration numbers to products provided they correspond with the numbers assigned in the National Drug Code Directory. This Directory, a voluntary effort of FDA in cooperation with industry, contains descriptions of more than 34,000 prescription and over-the-counter drugs marketed by more than 260 labelers. The Directory identifies the drug products listed by product or generic name, manufacturer or labeler name, dosage form, strength, route of administration, and legal status and package forms and sizes.

The Directory and its magnetic tape counterpart were established to meet the needs of present and potential users, in Government, and the private sector, for a standard drug product data processing code.

Through the drug industry's voluntary efforts, the standard codes required for the automated processing of drug product information have been made available for use in inventory control

applications, drug utilization review studies, hospital billing activities and, in particular, for application to prescription drug reimbursement plans underwritten by third party insurers. It would also have application in Government agencies for such diverse purposes as an adverse reaction reporting system, drug utilization review, poison control center operations, and drug product recalls.

In summary, the bill would require that all manufacturers, processors, or repackers of drugs, whether or not engaged in interstate commerce must supply FDA with a list of all drugs they produce. They must also notify us on a semiannual basis of drugs newly introduced or drugs which have been discontinued.

All drugs listed must refer to the authority for marketing or the Secretary may request a brief statement as to why clearance was not necessary.

In addition the following would be required for nonapproved drugs:

1. A quantitative listing of active ingredients (a complete formula if requested).
2. For prescription drugs all labeling and a sampling of advertising (or all advertising if requested).
3. For over-the-counter drugs a copy of the label, any package insert and a representative sample of other labeling.

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The bill would also permit the Secretary to obtain information on which drugs contain a particular ingredient.

Additionally the bill would provide that information submitted pursuant to this Act would be confidential. Importers could also be covered by the provisions of the bill.

This bill is in no way a licensing law. We could not refuse registration to deny marketing. Registration would merely notify us of facts we are entitled to acquire under our inspectional authority. The bill would facilitate more expeditious enforcement, but would not otherwise restrict the marketing of drugs or change our basic legal framework.

I would be pleased to answer any questions the Committee may have.

The CHAIRMAN. Mr. Joseph Stetler, president, Pharmaceutical Manufacturers Association, and Mr. James Hoge, general counsel, the Proprietary Association.

You have heard the emphasis has been on the House passed bill here rather than the Senate introduced bill of Senator Pearson.

Mr. HOGE. Mr. Chairman, I am James Hoge, and I have with me Mr. O'Keefe, Mr. Daniel F. O'Keefe, Jr., who is secretary and vice president of the Proprietary Association.

I would like him to be with me.

The CHAIRMAN. Fine.

Mr. STETLER. Mr. Chairman, members of the committee, Mr. Bruce Brennan and I are representing the Pharmaceutical Manufacturers Association.

We are happy to appear here to support and to discuss H.R. 9936.

The CHAIRMAN. Thank you very much.

We will hear from Mr. Stetler first.

STATEMENT OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, ACCOMPANIED BY BRUCE J. BRENNAN, VICE PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, AND GENERAL COUNSEL

Mr. STETLER. I am C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association.

With me is Bruce J. Brennan, PMA vice president and general counsel.

We appreciate the opportunity to appear before you today on behalf of the prescription pharmaceutical manufacturers, which are members of the PMA, to support and discuss the provisions of H.R. 9936, 92d Congress.

PMA is a national association composed of over 100 firms, whose production accounts for approximately 95 percent of the Nation's prescription drug supply, and whose research and development programs constitute the bulk of this effort by the American pharmaceutical industry.

The legislation in question would require each drug manufacturer, at the time of annual registration to file with the Secretary of HEW, a list of all drugs, not previously reported, which it manufactures.

In the case of new drugs, new animal drugs, antibiotics, and drugs containing insulin, the list would be accompanied by a reference to the marketing authority and copies of all labeling.

When a manufacturer determines that a drug is not in one of the categories just described, he would submit, if requested by the Secretary, a brief statement outlining the basis for the decision.

Also to be submitted with the listed drugs would be a statement as to the active ingredients and an indication of all ingredients for those drug products made subject to a finding by the Secretary that such submission is necessary to carry out the purposes of the act.

Copies of the labels, package inserts, and representative samplings of any other labeling would be submitted along with the list of over-the-counter drugs.

The list of prescription drugs would be supplemented by copies of all labeling and a representation sampling of advertisements. If needed, the Secretary could request a copy of all advertisements for the particular drug products specified.

The Secretary could assign a registration number to each drug or class of drugs so listed.

The number would be the same as that assigned pursuant to the National Drug Code.

Manufacturers would have to notify the Secretary every 6 months of material changes in information previously submitted as well as information concerning the initiation, discontinuance, or resumption of commercial distribution of particular drugs.

Under the bill, the Secretary would be authorized, in particular situations, to require manufacturers to submit a list of products which contain a particular ingredient.

In the case where a manufacturer failed to comply with the notification requirements relating to a particular new drug, FDA would be empowered to revoke the new drug application involved.

Failure to provide any of the other information required by the bill could subject the offending party to criminal or injunction proceedings.

The stated purposes of the bill are threefold: First, through the acquisition of complete information as to which drugs are being manufactured, to assist in the enforcement of Federal drug laws; second, to alleviate the burden of undertaking enforcement actions against drugs no longer marketed; and third, to insure more effective and timely regulation by, among other things, identifying which drugs are new drugs or are antibiotic drugs.

The PMA is pleased to lend its unqualified support to this bill. It is and has been the view of our association that the Food and Drug Administration must have knowledge of all manufacturers and all drugs on the market if it is to effectively administer the drug laws of this Nation.

As you know, H.R. 4749, an earlier version of this bill, was the subject of hearings before the Committee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce last June.

We appeared at that hearing and presented PMA's view on the bill. We supported H.R. 4749 in principle and suggested the adoption of some amendatory language.

We are pleased that accord was reached in the House committee and that the House passed bill provides additional protection to the public health, is not difficult to administer, and does not place an unwarranted burden on manufacturers.

The Food and Drug Administration has consistently maintained that it has no way of ascertaining the number of drugs currently on the market. Passage of this bill will solve that problem.

In addition, the Agency will be able to ascertain whether or not manufacturers believe their drug products are subject to the new drug, new animal drug, insulin, or antibiotic provisions of the Federal Food, Drug, and Cosmetic Act.

In the vent there is a difference of opinion between the Food and Drug Administration and a particular manufacturer with regard to

the status of a drug, the bill should enable the issue to be resolved expeditiously.

The submission of information on ingredients as well as the submission of labeling and advertising should materially assist FDA in determining the status of a particular drug.

The requirement in the bill that any registration number assigned will be the same as that issued pursuant to the National Code will system.

We urge the committee to approve H.R. 9936 as passed by the House.

The additional information this bill would make available to FDA will not in itself insure more effective regulation by the Food and Drug Administration.

But it is certainly a vital and timely step to take, and one that is clearly in the direction of giving the FDA the tools it needs to do its job.

In our opinion, it is also important that increased appropriations be made available to the FDA to enable it to use this additional information in a more complete and efficient enforcement of the act.

We would wholeheartedly support such budgetary increases.

Thank you, Mr. Chairman.

THE CHAIRMAN. Thank you, Mr. Stetler.

I only have one or two points I would like to raise.

The legislation as it was originally introduced, as I understand it, in the House, and the legislation introduced here, did not differentiate between active and inactive ingredients.

The listing required the information on both the active and inactive ingredients, is that right?

Mr. STETLER. Yes, it did. It would require the complete formula for each drug.

THE CHAIRMAN. Well, the inactive ingredients, that suggests that whatever the ingredient is, it does not have any effect beneficial or harmful, but as I understand it, the inactive ingredient can have harmful side effects?

Mr. STETLER. It can.

Also, of course, the inactive ingredients are important in terms of the effectiveness of the drug, the way it acts in the body.

The question was asked earlier about why it might be important for the public to know the active ingredient, and not the inactive ingredient.

The active ingredient has the direct effect on the disease, or the case being treated. Knowledge regarding the inactive ingredient is important to the manufacturer, in terms of perfecting his product, or assuring its quality.

THE CHAIRMAN. Then the consideration here, it is commercial and competitive considerations which are involved on their decision of active or inactive?

Mr. STETLER. That is part of the background, yes.

THE CHAIRMAN. This particular change in the legislation that occurred in the legislative process over there in the House, I gather, you gentlemen, in your organizations, associations, were part of that determination?

Mr. STETLER. We were part of it. The Food and Drug Administration was part of it, and the staff of the House committee. We were

called together to discuss the bill, as it was introduced. We being all who testified.

I think three parties were part of that discussion. The changes were agreed to by all parties that expressed an interest.

The CHAIRMAN. Do you know what the genesis of this new listing requirement was?

The bills were introduced in late spring. How long was this discussed with the FDA, and with you?

Mr. STETLER. We did not have any discussions with the Food and Drug Administration on this proposition prior to the hearings.

The CHAIRMAN. On the bill itself, the requirement of listing?

Mr. STETLER. No discussion prior to the time of our testimony in June before the House committee.

The CHAIRMAN. You did not know the FDA was going to seek legislation in this area?

Mr. STETLER. I did not really know.

I presumed it was an FDA drafted bill, but the sponsorship was not attributed at the time. The bill introduced by Congressman Rogers and several other members of his committee, but even at the time of the hearings, it was not identified as an FDA bill.

The CHAIRMAN. Before we go to you, Mr. Hoge, Senator Nelson, do you have any questions?

Senator NELSON. I have no questions.

The CHAIRMAN. Mr. Hoge, you may proceed.

STATEMENT OF JAMES F. HOGE, GENERAL COUNSEL, THE PROPRIETARY ASSOCIATION; ACCOMPANIED BY DANIEL F. O'KEEFE, JR., SECRETARY AND VICE PRESIDENT OF THE PROPRIETARY ASSOCIATION

Mr. HOGE. My name is James F. Hoge. I am a member of the bar of the State of New York, engaged in the practice of law as senior member of the firm of Rogers, Hoge & Hills, at 90 Park Avenue, New York City.

My appearance on these bills is on behalf of the Proprietary Association, the offices of which are at 1700 Pennsylvania Avenue NW., Washington, D.C.

The association was organized in 1881 and has been in continuous existence since.

Its active members—79 in number—are engaged in the manufacture and distribution of proprietary medicines—medicines which are completely compounded, prepackaged, and labeled for use by consumers.

Generally speaking, I think we represent the nonprescription business.

Mr. Stetler in substantial part represents the prescription business.

These products are classified as over-the-counter medicines, that is, medicines which are not restricted by law or practice to sale on prescription.

They are distinguished from some over-the-counter preparations in that proprietary medicines are promoted primarily to the public rather than to the medical and pharmacy professions.

There are also 124 associate members—companies which do not manufacture or distribute proprietary medicines but which are interested therein as suppliers of materials and services.

Mr. Chairman, I would like for my first expression to be one of appreciation—an expression of thanks on behalf of my client and of myself for the opportunity of this appearance.

Earlier this year, the distinguished Commissioner of Food and Drugs, in testimony before the Subcommittee on Public Health and Environment of the House Interstate and Foreign Commerce Committee, said:

I think the most urgent need that we have, Mr. Chairman, is for some drug registration law.

He said that the FDA was at a real disadvantage by not knowing what drugs are actually on the market.

We could understand that disadvantage, and we desire to assist in overcoming it.

Accordingly, on June 10, 1971, we appeared before that House subcommittee and expressed our support of the concept of an inventory of all drugs and of the purpose of legislation to accomplish that.

We requested certain revisions of the bill then before the subcommittee which we thought made it more agreeable to the stated concept. The bill at that time was H.R. 4749.

After the hearings, the bill was revised and reintroduced as H.R. 9936, which was then unanimously reported by the full committee and passed by the House.

We now support the bill as so passed and propose no amendments. S. 2167 corresponds to H.R. 4749. We recommend that it be conformed to H.R. 9936. I was here this morning, and I, of course, heard Senator Pearson make that request.

We think that this legislation would then accomplish the purpose as stated in the report of the House committee which is to provide the Secretary of Health, Education, and Welfare with a current listing of all drugs on the market.

This would be accomplished by requiring each drug manufacturer to provide an initial listing of the drugs he is marketing and then to provide a semiannual update of changes in the list.

The Secretary will then know how many drugs are on the market; who makes them; what their ingredients are; the conditions and directions for their use; and the particular provisions of law to which they are subject.

We endorse the purposes as so stated and corresponding provisions of the conformed bills.

We pledge our support of such a bill and our compliance with such legislation if enacted.

We recommend that such a bill be favorably and expeditiously reported.

The CHAIRMAN. Thank you, Mr. Hoge.

My concern is a layman's concern, I guess, but I still have a concern about the change of the requirement from all ingredients, to only active ingredients, and are you representing your association, were you part of the discussions that led to the change of the bill?

Mr. HOGE. Yes, and I recommended that change.

Mr. Chairman, this has been an interesting development in this field of regulation.

Many years ago, none of the ingredients of these products—certainly of the over-the-counter ones—was disclosed in the labeling, or anywhere else. It was quite a step forward, when it was proposed back in the 1930's, and the Congress then required that the active ingredients should be listed with respect to these over-the-counter products; also certain specifically named ingredients, whether active or not. But the formulas—the quantities of active ingredients—need not be disclosed.

Now, this bill would require quantities, and we have withdrawn all opposition.

There was a time years ago, when we were against disclosing quantities, but now we would go along with disclosing the quantities of active ingredients.

We did ask that the inactive ingredients which usually have something to do with the trade secret—the processes and property rights—that they not be disclosed, unless there was some real reason in the public interest. The bill provides, with respect to “a particular product” that the Secretary may require listing of those ingredients—and their quantities—if he finds that necessary to carry out the purposes of the act.

The CHAIRMAN. How does he become alerted to his need for knowing what the inactive ingredients are, unless that information comes from the manufacturer?

Mr. HOGE. Well, the bill, of course, would not disclose the inactive ingredients, unless he asked for them, and presumably, the bill contemplated there might be an occasion when he would have reason to inquire if certain inactive ingredients were processed. If there was some reason, he might then require that the manufacturer disclose them. But unless there was some reason, I think it was the concept of the committee in doing what it did, that he would not ask for the disclosure of these property rights, unless there was some public interest.

The CHAIRMAN. How about a middle ground here, would this make any sense, the active ingredients, in that connection, you would be required to inform through your listing of the quantity of the active ingredients, is that right?

Mr. HOGE. Yes, sir.

The CHAIRMAN. How about rather than the quantity of the inactive ingredients, the presence of these inactive ingredients.

I do not see how he will know he has a problem, and he ought to require information on it, how the Secretary will know.

Mr. HOGE. I would imagine that there are a variety of ways of which he learns of his problems: things that arise in the trade, maybe as to some product, or he gets a report, and that alerts him, and he has the authority to go forward. But so many of these inerts are what we call solvents—things of that sort—which over the long period of time and experience, do not present health problems.

There are exceptions to everything, of course, but I think what I am saying is accurate; that over the period of years, most of these things are accepted as being safe.

Mr. O'KEEFE. Senator, the Secretary might find he has a problem with a given drug product, for example, if there was some reason to think that some adverse reaction was being caused, he would want that information.

Alternatively, he might want to know of a possible problem with a specific ingredient, and then he would want to find out what drugs contain that ingredient, he could get that. So, where there is a problem that he can then see, or have reason to see, there is a provision in the bill for him to get the information.

Senator NELSON. On that exact point, we have received somewhere around a dozen letters in the past year or so from doctors, saying that the labels ought to include the so-called inactive ingredients, because of the allergy problem. As you are aware, there are people allergic to probably every matter there is on earth, including water and sand, and sunlight, and what have you, so physicians feel that they ought to know what the so-called inert matter is, so that if they have a patient that is allergic to it, they will not be prescribing it for them.

Mr. HOGE. I do not know if there is any absolute answer to it.

I am not a doctor, but I am informed that what you said a moment ago is true, that perhaps there are allergies, or idiosyncracies for all of our food, all of our drugs and all of our medicines—practically everything—so how we get at these questions is by the relative importance, and most of these things—if I am correctly informed by people in the industry—most of these things that are used do not have an allergic effect for any appreciable number of people.

Senator NELSON. I am not sure I understand just what is the trade secret or trade process involved in the question of disclosure of the ingredient, whatever the inert material may be that is used.

Hr. HOGE. Well, Senator, the question, what is a trade secret is not an easy one.

That requires briefing, and involves a good deal of uncertainty.

Competitively, we have this situation—as a trademark lawyer which was my basic role, I was in that until I got into this field—we have this sort of situation: Competitively, here is a man that puts out a package, and he can list on the front of it the identical ingredients, and perhaps the percentages of them, and he can then say: “you see, it is exactly the same,” but he does not have the same thing, because even if you put the same ingredients on the outside of the package, there is no assurance that the article will turn out to be the same.

The slightest change in the quantity, or the temperature, or other elements of procedure, will change the ultimate effect of that article. We have actual cases in the books of that sort of competition. We have to stand it, if there is a public interest in it, but we do not think we should otherwise.

Senator NELSON. That is not a very persuasive case. I think I remember in testimony before the Senate Small Business Committee

that the FDA, after a 14-month study, thereabouts, reached the conclusion—and this is my language, not theirs—that any two products, or any product in the marketplace using the same active compounds, and meeting official standards, such as the USP, have with rare exceptions the same therapeutic effects. If they are correct, and I think we have heard that from enough experts in the field, then what is all of the great secrecy about the inactive ingredients?

Mr. HOGUE. I think you are opening up the question of generic equivalency, and nobody knows better than you of the long story on that.

I am not qualified to get into that. I am told, however, that just because the same ingredients are put in an article, that does not assure the same—or “equivalent,” is the word they use—the same therapeutic equivalency.

Senator NELSON. We know what that argument is all about, and we have heard it: You can take aspirin and compound it in a tablet, and it will pass through the alimentary canal, and is finally expelled without being absorbed, therefore, you cannot say that aspirin is aspirin. That is a nonsensical argument, and even Time Magazine fell for that approach from one of the drug manufacturers, and ran their propaganda in its science section, saying aspirin really is not aspirin.

The conclusion of the experts, who have testified year after year, is that if you have the same compound, and you meet official standards, the therapeutic or clinical effect is equivalent.

Now, you can find some exceptions. There is no question about that. But it makes no sense to take the rare exception and make a general rule out of it, rather than the other way. For my part, I would like to see something more persuasive than I have heard; or see something more persuasive than I have read, before I would be willing to accept a proposal that says the public is not to know what the inactive ingredients are.

Mr. HOGUE. Senator, I do not think aspirin is a good example. That is a single entity for one thing. Most of those over-the-counter medicines are compounds.

Senator NELSON. I am talking about a study by the FDA, on prescription drugs.

I just used aspirin off the top of my head. The testimony, quite regularly—and there was testimony before the Senate Small Business Committee for 4½ years—has been roughly what I mention. The USP said the same thing. They all say the same thing, but the drug industry without using any evidence, says something else.

Mr. STETLER. I would like to discuss this subject very briefly.

It is one we have been discussing with Senator Nelson for 4½ years. It was alluded to in a 1966 drug potency study of the FDA.

If you want to allude to study, you should also discuss the rebuttal, which has appeared in the Congressional Record, and other places.

There are two sides. It was a drug potency study of 1966, and it has been rebutted.

Senator NELSON. This has been the conclusion by our experts, including the FDA, and I do not know of any medical scientists that have come to a different conclusion.

Mr. STETLER. We can give you a long list of people that have come to a different conclusion. If the record is open, we will submit a whole book of references.

Senator NELSON. I would like to see something more persuasive. As one of the individuals of the committee I will argue for including the provision.

Mr. HOGE. I wish I could supply something. I read a great deal as do you. I try to understand it. I wish I had the qualifications for understanding it better, but do have to believe what I am told by people I trust in the field, that generic equivalency is not conclusive; does not follow by just putting in the same ingredients.

The CHAIRMAN. Wait a minute. We are talking about ingredients.

Senator NELSON. I did not hear what you said.

Mr. HOGE. Well, I just said that I wish I could answer out of my own mind some of the questions you have about equivalency; of getting an equivalent product through use of the same ingredients.

You know—and I know—the articles that have been written. You have read them, and I have read them, and I wish I were an informed scientist, informed enough to offer a judgment of my own.

I have to rely on the people that advise me in this respect, and they say that putting in the same ingredients alone, does not bring the equivalent result.

Senator NELSON. Just so the record is complete on that, we have asked all companies in America, and the pharmaceutical associations to produce all of their samples of drugs which meet official standards, and have a different therapeutic effect. The witnesses have testified that there is an insignificant number, maybe eight or 10 examples that have been demonstrated.

So what you are talking about is an exception which tests the rule, and tests it very well.

The CHAIRMAN. This takes in a broader concept, but on the active and inactive, the manufacturers reluctance to accept the bill that includes the requirement of listing of the inactive ingredients, is it competitive and commercial reasoning?

Mr. HOGE. That is part of it.

The CHAIRMAN. Part of it?

Mr. HOGE. Well, yes, sir.

The CHAIRMAN. What other elements are present here?

Mr. HOGE. I think that is it.

Mr. STETLER. In our situation, as far as prescription drugs are concerned, that information, or a large part of it is already known to the Food and Drug Administration.

If you remember, Mr. Hutt testified, the FDA already acquires that data from us. So part of our reasoning, is that if you have it once, why go through the whole business again.

We felt, and they felt later that for the information they really need, they should have the facility and the authority to get it.

Senator NELSON. Well, I just ask a question: If it is a fact that the inactive ingredients of a prescription drug are a matter of public information, why is it so important that the inactive ingredients be a matter of confidentiality?

Mr. STETLER. It is not a matter of public information. It is a matter for the Food and Drug Administration. They have not made it a matter of public information?

Senator NELSON. Did I misunderstand the testimony? Is there anything illegal about making it a matter of public information?

Mr. BRENNAN. Section 301(j) presently prohibits the employees of the Food and Drug Administration from disclosing certain information, and that includes information concerning any method or process which is collected under section 704, the investigational process of inspection, so this is currently considered confidential under the law.

Senator NELSON. Is the inactive ingredient a method or process?

Mr. BRENNAN. It is part of it.

Senator NELSON. Is that part of interpretation?

Mr. BRENNAN. It is information concerning a method or process, and Mr. Hoge mentioned that this is vital information, and I think for that reason, it was historically protected in this manner. This is nothing new.

Senator NELSON. Just for my own information, is there a specific exception in the statute for the active ingredient in the prescription drug?

Mr. BRENNAN. No, that is included, along with inactive ingredients.

Senator NELSON. It is on the label?

Mr. BRENNAN. Yes, it is the label.

Senator NELSON. Is that a specific statutory exception from the protection of confidentiality in the statute, or is that an interpretation?

Mr. BRENNAN. That is a specific part of the statute. It is displayed publicly.

Mr. HOGE. I would like to add one word—there is a difference between the prescription item and the over-the-counter item in the disclosure of ingredients, in that the prescription item goes through the pharmacist, whereas the over-the-counter one goes direct to the layman. What is disclosed reaches the ultimate consumer; it goes right into the home.

We do not have any other business than over-the-counter business that I am representing.

Mr. O'KEEFE. Senator, as Mr. Hoge indicated, the reason we feel it is appropriate to have inactive ingredients, in effect, excluded from disclosure requirements, is for trade secret ingredients. However, first of all, on page 4 of the bill before you, H.R. 9936, it provides specifically that the Secretary may require quantities of all ingredients to carry out the purpose of the act.

Furthermore, when you get to public health areas, section 4(b) on page 6 of the bill would provide that the exemption of the inactive ingredients being made public would be overcome if the Secretary finds such an exemption would be inconsistent with the protection of the public health.

The CHAIRMAN. That was helpful.

Thank you very much.

At this point I order printed any pertinent material submitted for the record.

(The information referred to follows:)



THE UNITED STATES PHARMACOPEIAL CONVENTION, INC.

12601 TWINBROOK PARKWAY, ROCKVILLE, MARYLAND 20852
(301) 881-0666

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EXECUTIVE DIRECTOR AND SECRETARY

William M. Heller, Ph.D.

December 8, 1971

Committee on Labor and Public Welfare
United States Senate
Washington, D.C. 20510

Re: S. 2167, "The Drug
Information Act of 1971"

Gentlemen:

We have reviewed S. 2167 with a view toward its potential effects on the responsibility of the United States Pharmacopeia in establishing legally enforceable standards for drugs. This Bill provides for the registration of drugs under the Federal Food, Drug, and Cosmetic Act. We believe that the Bill is a significant step forward. However, we wish to call to your attention one further point that would add to the advances in drug quality and drug control that would result from the enactment of this Bill.

Section 2 of S. 2167 amends Section 510 of the Federal Food, Drug and Cosmetic Act to provide for the submission of the full quantitative formula of the registered drug. Such information will not only be helpful to the F.D.A., but would also be extremely valuable to the Pharmacopeia in defining a drug's identity; in improving the standards for strength, quality, purity, and packaging; in establishing tests and assays free of interference from non-therapeutic ingredients; and in revealing non-therapeutic ingredients which also need standardization. All these factors are tremendously important in the promulgation of standards that will ensure quality medication and optimum therapeutic effect. The advancement in the development of compendial standards that this information would provide would have numerous benefits to the F.D.A. in its enforcement activities, to the medical community, and to the public which they serve.

Section 3(b) of S. 2167 provides that the Secretary may exempt from inspection information filed under such subsection (1) unless he "finds that such an exemption would be inconsistent with the protection of the public health." It is hard to imagine that the Secretary would not always find the work of the U.S. Pharmacopeia to be necessary for the protection of the public health and thus make available to the Pharmacopeia the information supplied by the manufacturer. On the other hand,

THE UNITED STATES PHARMACOPEIA

Committee on Labor and Public Welfare

December 8, 1971

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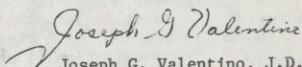
a question could arise about the propriety of the Secretary making this information available to the Pharmacopeia without also making the information available to the general public. To avoid such question, it would be more straight-forward to refer to the U. S. Pharmacopeia directly in S. 2167 as a recognized recipient of information that it needs. Adequate precedent for such a provision already exists. For example, under Section 707 of the current Food, Drug, and Cosmetic Act, the Secretary is specifically authorized to cooperate in the revision of the U. S. Pharmacopeia and in the development of methods of analysis; and other provisions of the Food, Drug, and Cosmetic Act establish the Pharmacopeia as an official compendium.

We respectfully request that such recognition be extended in S. 2167, and that Section 3(b) be amended to read as follows (the proposed addition is underlined):

(b) Section 510(f) of such Act is amended by inserting before the period the following: "; except that the Secretary may exempt from inspection any list filed under subsection (j) and any information accompanying such list unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health. Upon request, the Secretary shall make available information necessary for the revision of the United States Pharmacopeia.

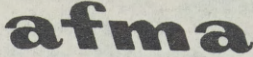
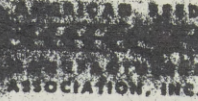
We cannot overemphasize to you our concern that the U.S. Pharmacopeia needs to advance in unison with the F.D.A. The contributions to the public health and welfare that will result from S. 2167 can be most fully realized if the standards-setting organization and the enforcement agency both have access to the information supplied by the manufacturer in registering each drug.

Sincerely yours,



Joseph G. Valentino, J.D.
Executive Associate

JGV:jhc

December 8, 1971

WASHINGTON OFFICE
1725 K STREET, N.W.
WASHINGTON, D.C. 20006
TELEPHONE: 202: 296-1760

The Honorable Harrison A. Williams, Jr.
Chairman, Committee on Labor and Public Welfare
United States Senate
Washington, D.C.

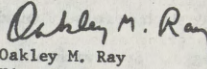
Dear Senator Williams:

Attached please find a statement concerning H.R. 9936 and S. 2167. I would appreciate it if you would make the statement a part of your official hearing record.

This request has been discussed with Dr. C.D. Van Houweling, Director of the Bureau of Veterinary Medicine, FDA. It is our understanding that the Bureau of Veterinary Medicine (which has jurisdiction over animal feeds) has no objection.

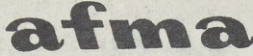
Your consideration of this request would be appreciated.

Sincerely yours,



Oakley M. Ray
Vice President

OMR/meg
Attachment


afma
AMERICAN FEED MANUFACTURERS ASSOCIATION, INC.

WASHINGTON OFFICE
1725 K STREET, N. W.
WASHINGTON, D. C. 20006
TELEPHONE: 202: 296-1760

STATEMENT

CONCERNING S. 2167 AND H.R. 9936

SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE

DECEMBER 7, 1971

Members of the American Feed Manufacturers Association produce more than 70% of the feed which is sold by primary feed manufacturers for the production of meat, milk and eggs. Following is some background information which will indicate our interest in this proposal.

Animal drugs are used to protect and improve the health of animals and to lower the cost of producing meat, milk and eggs. Animals, like humans, suffer from various diseases. Healthy animals produce higher quality and lower cost food products. This is important to all of us. Without animal drugs consumers would have to pay much more per pound (gallon, dozen) for a smaller supply of meat, milk and eggs. Even with animal drugs, the U.S. Department of Agriculture estimates that annual losses of livestock and poultry due to diseases, insects, parasites, etc. total \$2.8 billion.

In 1970, U.S. farmers produced about 3 billion broilers, more than 100 million turkeys, more than 100 million hogs, kept an average of more than 300 million laying hens, more than 100 million cattle and calves, etc. Comparable numbers are being produced or maintained this year. Even larger numbers will be needed in the future if the current rates of per capita consumption of meat, milk and eggs are to be maintained.

-2-

In most cases feed provides the most feasible and economical means of administering animal drugs to these animals. It is simply not practical to administer drugs to large numbers of individual animals by injection or other means or to prescribe "two tablets every four hours."

There is obviously a great difference between a relatively pure or highly concentrated drug product and an animal feed containing only a minute amount of that drug. However, it is our understanding that the legislation which you are considering is worded in such a manner that an animal feed which is used as a method of administering a drug to an animal might be treated the same as the drug product itself.

We have discussed this legislation with Dr. C.D. Van Houweling, Director of the Bureau of Veterinary Medicine, FDA. It is our understanding that the information not presently available to the Bureau which he desires from animal feed manufacturers is a list of the drugs and drug combinations used by such manufacturers -- and not a list of the individual feeds which are used as a means to administer the drugs. It is also our understanding that the Bureau of Veterinary Medicine does not wish to ask animal feed manufacturers to duplicate any information which the Bureau already has available from feed and animal drug manufacturers, or which will be made available by the drug manufacturers through this legislation.

Attached please find suggested amendments to H.R. 9936 which we understand would provide the information from animal feed manufacturers which is desired by FDA. This would be accomplished without the filing of a great deal of additional duplicative-type information which FDA does not desire, and which would result in unnecessary effort and expense for both the industry and the Agency.

Thank you for the opportunity to present this statement.

Oakley M. Ray
Oakley M. Ray
Vice President

PHARMACEUTICAL MANUFACTURERS

*Association*C. JOSEPH STETLER
PRESIDENT1155 FIFTEENTH STREET, N. W.
WASHINGTON, D. C. 20005
AREA CODE 202-296-2440

December 10, 1971

The Honorable Harrison A. Williams, Jr.
Chairman, Senate Committee on Labor and
Public Welfare
United States Senate
Old Senate Office Building, Room 352
Washington, D. C. 20510

Dear Senator Williams:

This is in pursuance of our testimony before your Committee on December 8 concerning S. 2167 and H. R. 9936, 92nd Congress. Based on questions presented by Senator Gaylord Nelson, a story in the Washington Post on December 9, and our subsequent inquiries, it seems that there is some concern that the present wording of Section 5 of H. R. 9936 would prevent committees of the Congress from obtaining information previously available to them.

We agree with testimony presented on December 8, by counsel for the Food and Drug Administration that the provisions of H. R. 9936 would not authorize the Food and Drug Administration to withhold any information which Members of the Congress or other parties are now entitled to receive. However, if there is any question in this regard, we would support an amendment to Section 5 of the pending bill, which would eliminate the cause for concern.

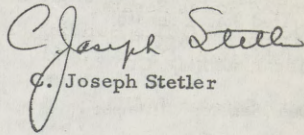
Let me assure you that it was not suggested nor intended by representatives of the PMA that in the revision of H. R. 4749 (the predecessor of H. R. 9936) there be included any provision which might interfere with the Congress obtaining information from the FDA. As we read these various legislative proposals, nothing more was suggested in H. R. 4749 and H. R. 9936, with respect to the subject of confidentiality of information, than the protection afforded under Section 704 of the Food, Drug, and Cosmetic Act (factory inspection) and other sections designated in Section 301(j) of that Act or otherwise covered by 18 U.S.C. 1905.

Representing manufacturers of prescription pharmaceuticals

- 2 -

We trust that the above discussion will clarify the understanding and intentions of the PMA with respect to this matter. We would not want this issue to prevent the passage of a piece of legislation by the Senate, which is needed by the U. S. Food and Drug Administration and supported by the Government and by responsible, ethical and proprietary drug manufacturers. We urge that the Committee report this legislation to the Senate for approval just as soon as possible.

Sincerely,


C. Joseph Stetler

cc: Congressman Paul G. Rogers



THE PROPRIETARY ASSOCIATION

1700 PENNSYLVANIA AVENUE, N.W. • WASHINGTON, D.C. 20006 • PHONE (202) 223-5866

December 28, 1971

JAMES D. COPE
Executive Vice President
and Treasurer
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JOSEPH M. PISANI, M.D.
Vice President for
Medical and Scientific Affairs
ALAN W. MERCILL
Director
Trade and Public Relations

Honorable Harrison A. Williams, Jr.
Chairman, Senate Committee on Labor and Public Welfare
United States Senate
352 Old Senate Office Building
Washington, D. C. 20510

Dear Senator Williams:

We are writing concerning S. 2167 and H. R. 9936, the proposed "Drug Listing Act of 1971." Our General Counsel, James F. Hoge, of Rogers Hoge & Hills, and I appeared in support of H. R. 9936 at hearings held before your Committee on December 8.

One of the principal issues raised at those hearings was the matter of confidentiality of information which would be submitted to the Food and Drug Administration under the provisions of the bill. We share the view of Peter Hutt, Counsel for the Food and Drug Administration, that H. R. 9936 would not authorize the Food and Drug Administration to withhold information which Members of Congress or other parties are presently entitled to receive. We certainly have no intention or desire to prevent Congressman Fountain or other Members of Congress from obtaining information which is now accessible to them in FDA files. We would, of course, have no objection to an appropriate amendment to the bill to clarify that point.

As we tried to point out at the hearing, H. R. 9936 would simply protect legitimate commercial trade secrets from disclosure, but specifically provides that the Secretary may disclose any information received under the bill to the public if he finds that failure to disclose would be inconsistent with the protection of the public health.

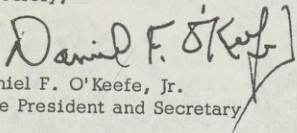
In our view, H. R. 9936 is a straight-forward bill. Its purpose is to provide to the Food and Drug Administration a current listing of drugs which are on the

market in order to assist that agency in implementing the Food, Drug, and Cosmetic Act. We would like to reiterate our support of H. R. 9936 as carrying out that intent and as being a constructive step in the public interest. We hope it can be speedily enacted.

We offer to you, members of your Committee, and your staff our assistance on the bill in the weeks ahead.

Again, we thank you for the privilege of appearing before your Committee; and we wish you a very happy holiday season.

Sincerely,

A handwritten signature in dark ink, appearing to read "Daniel F. O'Keefe, Jr.", with a stylized flourish at the end.

Daniel F. O'Keefe, Jr.
Vice President and Secretary

DOK:sh



NATIONAL ETHICAL PHARMACEUTICAL ASSOCIATION

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Drug Exchange
LIONEL SMITH
Medco Supply Co.
Muncie, Ind.

Executive Secretary
MRS. EDITH K. HARRIS
P.O. Box 13547
St. Petersburg, Fl. 33733

January 21, 1972

The Honorable Harrison Williams
Room 232, Old Senate Office Bldg.
Washington, D.C. 20510

Dear Senator Williams:

As members of the above association, which is composed of small drug manufacturers and distributors, we wish to acquaint you with our position in reference to (1) The Drug Listing Act of 1971; and (2) The FDA Survey of Marketed Drugs. We will confine ourselves in this letter to the former subject, outlining our support along with constructive criticism, so that our total opposition to the latter will not obscure the issue.

It is necessary to preface our comments with a statement that we do not know the exact status of the proposed legislation. We have a copy of HR9936 as originally submitted on 7/20/71. We also have F-D-C reports of 12/13/71, page 24, stating that the final House-passed bill deleted the following requirements:

Disclosure of inert ingredients
Copies of drug ads
Submission of production data
Medical justification for marketing

Assuming this to be correct, the bill is reduced to its original purpose which is simply a listing of drug products on the market. Then our only remaining objection is not at all with the intent but rather with the mechanics of implementation.

Now, our position is as follows:

(1) We agree in principle with the basic intent of the bill, i.e., to provide FDA with an up-to-date listing of currently marketed drugs.

(2) We disagree with the mechanics of producing such a listing.

(3) We propose a constructive suggestion on modification of the bill that would save both the industry and the government, hence the taxpayers, a considerable sum of money.

2.

Senator Harrison Williams

Referring back to HR9936, we believe that the statement made in Section 2 is a false premise upon which much of the bill's support is based. The statement is made that the Federal government has no ready means other than periodic inspections to determine what drugs are actually available.

First, upon each of these numerous inspections, they usually request and receive product listings and labeling, ordinarily three copies of each. If it is assumed that there was a purpose in collecting all this data, what have they done with it that they are unable to compile a listing of products from such voluminous documentation?

Second, and most significantly, the data essential to the stated objectives of the bill have already been submitted to the FDA by a majority of the members of NEPA, as well as by hundreds of other pharmaceutical companies throughout the United States. This was done in 1969 on a voluntary basis under the National Drug Code Directory system. All of this data is being constantly updated and is stored in the FDA computer memory banks, ready for reproduction at the touch of a button.

Since they have all this information on computer tape for most of the products marketed in the U.S.A., why have us do it all over again? Why spend all this time and money, and thus increase health care costs further in unnecessary repetitive efforts? Where is the commonsense in such an operation? Is it possible that their objective is other than that stated in the bill? Or is it possible that the FDA (or Congress) does not know what information is presently available?

The only flaw in the National Drug Code Directory is that it is voluntary and thereby compliance is less than total. It is our recommendation that the stated intent of the proposed law will be fully met by simply making the NDC system compulsory rather than voluntary. This is a simple yet practical recommendation which would save the industry as well as the government untold numbers of man-hours and dollars in complying with and regulating a redundant system.

A copy of the 500 page National Drug Code Directory as produced by the FDA in June, 1970 contains all the data we are currently being requested to furnish. There may be a more recent edition which would be even more comprehensive than this, however it does demonstrate the extent and availability of the information which they now have. Paradoxically, our district FDA officials are unable to explain why they have not used this data and, in fact, were not even aware of it when promoting their recent "Voluntary Survey of Marketed Drugs". Neither is it referred to in the agency's support of the proposed legislation.

We have a computer print-out of our particular company's products as received from the FDA. We are enclosing a copy of the computer input form designed by the FDA for the more recent "voluntary survey" and you will note the marked similarities as well as being able to sense the

3.

Senator Harrison Williams

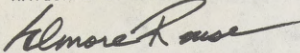
frustration engendered by such an obvious bureaucratic repetition of efforts. May we call you attention particularly to the FDA's own evaluation of the NDC listings in the preface to the Directory. If what they have said is true, then why is it now being stated that they have no ready means to determine what drugs are available?

One final observation, if our interpretation of HR9936 is correct, it would be limited to those companies who register with the FDA and therefore would exclude all who do not market stimulant or depressant drugs. Hence, the proposed law would still not provide an all-inclusive listing. Let us know if this is correct.

In summary, we do not object to providing a listing of currently marketed drugs. It is our conviction that we have already complied and we do therefore object to an expensive repetition of work. Simply convert the voluntary NDC system into a compulsory NDC system and you will have expeditious, economical enforcement of the intent and purpose of the proposed law at a minimal cost to the people who ultimately pay all the bills - the American taxpayers.

With best regards.

NATIONAL ETHICAL PHARMACEUTICAL ASSOCIATION



Elmore Rouse
President

The CHAIRMAN. The hearing is now adjourned.
(Whereupon, the committee was adjourned at 12:30 p.m.)

○