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92-22 NOTIFICATION OF INITIATION OR DISCONTINUANCE
OF DRUG MANUFACTURE

GOVERNMENT
Storage

DOCUMENTS

HEARING

AUG 10 1971

BEFORE THE

SUBCOMMITTEE ON

THE LIBRARY
KANSAS STATE UNIVERSITY

PUBLIC HEALTH AND ENVIRONMENT

OF THE

COMMITTEE ON

INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-SECOND CONGRESS

FIRST SESSION

ON

H.R. 4749 and H.R. 8963

BILLS 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

JUNE 10, 1971

Serial No. 92-22

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My dear Sir,
I have the honor to acknowledge the receipt of your letter of the 10th inst. in relation to the above named matter. I am sorry to hear that you are not satisfied with the result of the investigation. I have, however, no objection to your making such use of the facts as you may think proper. I am, Sir, very respectfully,
Yours truly,
J. M. Smith

Very truly,
J. M. Smith

NOTIFICATION OF INITIATION OR DISCONTINUANCE OF DRUG MANUFACTURE

THURSDAY, JUNE 10, 1971

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND ENVIRONMENT,
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10 a.m. in room 2325, Rayburn House Office Building, Hon. Paul G. Rogers (chairman) presiding.

Mr. ROGERS. The subcommittee will come to order, please.

The hearings today are on H.R. 4749, which I introduced for myself, Mr. Kyros, Mr. Carter, and Mr. Hastings; and H.R. 8963, introduced by Dr. Roy.

This proposal would amend the Federal Food, Drug, and Cosmetic Act to provide for the annual registration of all drugs. At present, only the producers and certain wholesalers of drugs are required to register annually with the Food and Drug Administration. The proposal 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.

The bills also require notification when production of any drug is discontinued.

The information filed under this act will not be available for inspection by others, unless a finding is made that the exemption from inspection would be inconsistent with protection of the public health.

The necessity for legislation of this type was highlighted during our recent oversight hearings on the Food and Drug Act, during which all the witnesses that we discussed this with favored enactment of this type of legislation.

At this point in the record, there will be included the text of the bills and the agency reports thereon.

(The text of H.R. 4749 and H.R. 8963 and departmental reports thereon follow:)

[H.R. 4749, 92d Cong., 1st sess., introduced by Mr. Rogers (for himself, Mr. Kyros, Mr. Carter, and Mr. Hastings) on February 22, 1971, and H.R. 8963, 92d Cong., 1st sess., introduced by Mr. Roy on June 7, 1971, are identical as follows:]

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 In-
 4 formation Act of 1971".

5 SEC. 2. The Federal Government which is responsible
 6 for regulating drugs, particularly the safety and effective-
 7 ness of new drugs, has no ready means of determining what

1 drugs are actually being manufactured or packed by estab-
2 lishments registered under the Federal Food, Drug, and Cos-
3 metic Act. Knowledge of which particular drugs are being
4 manufactured or packed by each registered establishment
5 would substantially assist in the enforcement of Federal laws
6 requiring that such drugs are pure, safe, effective, and
7 properly labeled. Information on the discontinuance of a
8 particular drug could serve to alleviate the burden of review-
9 ing and implementing enforcement actions against drugs
10 which, although commercially discontinued, remain active
11 for regulatory purposes. Information on the type and num-
12 ber of different drugs being manufactured or packed by
13 drug establishments could permit more effective regulation
14 by permitting agencies to identify establishments needing
15 greater or lesser surveillance depending on the nature of
16 their production activities.

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 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 a
23 list of all drugs (by established name (as defined in sec-
24 tion 502 (e)) and by any proprietary name) which are
25 being (or, in the case of a person who registers under sub-

1 section (c) or (d), proposed to be) manufactured, prepared,
2 propagated, compounded, or processed in each establishment
3 included in such registration. Such list shall be prepared in
4 such form and manner as the Secretary may prescribe and
5 shall be accompanied by—

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

8 “(B) a copy of all labeling used for each drug
9 listed,

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

12 “(D) in the case of a new drug or antibiotic drug
13 (subject to section 507) listed, a reference to the author-
14 ity for the marketing of such drug and, in the case of
15 any other drug listed, the data from which it is deter-
16 mined that it is not a new drug or antibiotic drug sub-
17 ject to section 507, and

18 “(E) any production data the Secretary may re-
19 quire.

20 If any such person proposes to use labeling or advertising a
21 copy of which has not been submitted to the Secretary in
22 accordance with clause (B) or (C), as the case may be,
23 such person shall, before using such labeling or advertising
24 submit (in such form and manner as the Secretary may pre-
25 scribe) a copy of it to the Secretary.

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

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

21 SEC. 4. (a) Section 510 (e) of such Act is amended by
22 adding at the end thereof the following: “The Secretary may
23 also assign a registration number to each drug or class of
24 drugs listed under subsection (j).”.

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

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

11 (d) Clause (1) of the second sentence of section 505 (e)
12 is amended by inserting “or to comply with the notice re-
13 quirements of the first sentence of section 510 (j) (3)” im-
14 mediately after “subsection (j)”.

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

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

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

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., July 15, 1971.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This letter is in response to your request of March 1, 1971, for a report on H.R. 4749, 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." The bill would require that every person registered with the Secretary of Health, Education, and Welfare pursuant to section 510 of the Federal Food, Drug, and Cosmetic Act shall at the time of registration file with the Secretary a list of all drugs (by established name) which are being manufactured in any drug establishment so registered. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by the formula showing quantitatively each ingredient in each drug listed, a copy of all labeling used for such drug and in the case of each prescription drug listed, a copy of all advertisements of such drug. A reference to the new drug or antibiotic drug approval pursuant to the Act, or data to establish that such product is not a new drug or an antibiotic drug subject to regulation, shall also be submitted. The Secretary may also require production data as necessary.

Any person proposing to use any labeling or advertising which has not been filed at the time of registration shall submit such labeling or advertising to the Secretary before using it. Every person registered under this section shall also immediately notify the Secretary whenever such person begins the production of a drug not previously listed, or ceases or discontinues (in excess of a period of time as the Secretary may prescribe) the production or availability of any drug being manufactured in such establishment and shall notify the Secretary of any resumption thereof. The Secretary may also assign a registration number to each drug listed. Information filed pursuant to this section may be exempted from disclosure. Failure to comply with the notice requirements of this section with regard to discontinuance would be a basis for revocation of a new drug approval and failure to register in accordance with this section would be a prohibited act.

This bill would provide information which is deemed extremely desirable by this Department, specifically: (1) what drugs are being manufactured and by whom, (2) immediate notice of discontinuance of drugs, (3) copies of all labeling and advertising (for prescription drugs) and (4) production data as the Secretary may require. Lack of information on what drugs are being manufactured or which have been discontinued has inhibited full implementation of the efficacy review of drugs marketed from 1938 to 1962, a requirement added to the Act by the 1962 Drug Amendments.

Additionally, the provisions of H.R. 4749 requiring reference to FDA approval or data to establish that a drug is not subject to the new drug or antibiotic provisions of the Act could alleviate enforcement problems such as have been recently encountered with certain drugs which were marketed without going through the new drug approval procedure. Authority under this bill to require production data would facilitate surveillance of particular drugs for which such information could indicate misuse.

Knowledge of all drugs being produced would provide the Food and Drug Administration with a mechanism for notifying all manufacturers, processors, or repackers of warnings or restrictions on certain drugs. FDA is presently unable to determine whether such notices reached all of the manufacturers of drugs affected by the announcements. We believe information on what drugs are being marketed, the claims made therefore, and the basis for their marketing is fundamental to the goal of protecting the public health from unsafe, untested, or ineffective drugs.

In order to reduce potential paperwork, we would desire flexibility in administering the proposed legislation. For example, we believe it would be beneficial to merely require an indication of changes made since the previous annual registration.

Reference to information submitted pursuant to other provisions of the Federal Food, Drug, and Cosmetic Act might also be considered sufficient for part of the registration required under this bill. We believe such flexibility is contemplated in H.R. 4749.

For all of the above reasons, the Department of Health, Education, and Welfare recommends enactment of H.R. 4749.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

ELLIOT RICHARDSON, *Secretary.*

DEPARTMENT OF JUSTICE,
OFFICE OF THE DEPUTY ATTORNEY GENERAL,
Washington, D.C., July 8, 1971.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice on H.R. 4749, 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."

The bill would amend the Federal Food, Drug, and Cosmetic Act by amending Section 510 of the Act to require registrants to furnish to the Secretary of Health, Education, and Welfare a list of all drugs that are being, or are proposed to be, manufactured. For each drug listed the registrant would be required to provide specified additional information and any production data required by the Secretary. The bill would also require all registrants to notify the Secretary immediately upon ceasing to produce a listed drug, or upon undertaking the manufacture of a new drug.

Whether this legislation should be enacted involves questions as to which the Department of Justice defers to the Department of Health, Education, and Welfare.

The Office of Management and Budget has advised that there is no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

RICHARD G. KLEINDIENST,
Deputy Attorney General.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, D.C., June 14, 1971.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to your request of March 1, 1971 for the views of this Office on H.R. 4749, 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."

In its report on H.R. 4749, the Department of Health, Education, and Welfare sets out its reasons for recommending enactment of the bill.

We concur in the views expressed in the report of the Department of Health, Education, and Welfare and, accordingly, support enactment of H.R. 4749.

Sincerely,

C. WILLIAM FISCHER,
Acting Assistant Director for Legislative Reference.

Mr. ROGERS. Our first witness this morning is the Commissioner of Food and Drug Administration, Dr. Charles Edwards.

We are delighted to welcome Dr. Edwards back to the committee, and also see that Mr. Goodrich is with the Commissioner. And I think I could say for this committee, without question, we all regretted your decision to leave Government. Your career has been an outstanding one,

and, certainly, this committee has benefited from the wisdom you have imparted over the years to us, and we are very grateful.

Mr. GOODRICH. Thank you very much.

Mr. ROGERS. Doctor, we are also delighted to see you and know of your fine work.

STATEMENT OF DR. CHARLES C. EDWARDS, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WILLIAM W. GOODRICH, ASSISTANT GENERAL COUNSEL, HEW, AND DR. MARION FINKEL, DEPUTY DIRECTOR, BUREAU OF DRUGS, FDA

Dr. EDWARDS. Thank you, Mr. Chairman and members of the committee.

We do very sincerely appreciate the opportunity to testify on H.R. 4749, a bill to require a current listing of all drugs on the market. We strongly support this legislation, because in our judgment it will give the Food and Drug Administration information essential to our effective administration of the Federal Food, Drug, and Cosmetic Act.

Several times, since becoming Commissioner of the Food and Drug Administration, we have been asked, on occasion, how many drugs, both prescription and nonprescription, are on the market, who makes them, and what their ingredients are.

These questions have arisen before this committee, before our present Appropriations Committee, and before other committees of the Congress. They 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, and on a number of other occasions.

We have found it not only embarrassing but frustrating that this agency does not have the information to answer the questions, and I would suggest that we are perhaps the only regulatory agency that does not have this kind of basic information that is so vital to our mission.

I have stated publicly that it is highly unrealistic to expect the Food and Drug Administration to fully accomplish its mission without a mechanism which will provide us with the immediate data on all drugs that are commercially available.

We have just recently prepared a questionnaire and cleared it through the Office of Management and Budget to take an inventory of the Nation's drug supply. We can proceed in that direction, seeking voluntary cooperation for all registered drug producers and following up through our inspectional authority but we believe that is not the most effective way to get the job done.

H.R. 4749 would require the manufacturers and repackers of drugs to register their products with us, to supply copies of promotional material, and to identify for us the applicable new drug applications or antibiotic drug approvals. Without such approvals, they would have to provide data which established that no new drug approval was required.

We know, Mr. Chairman, that there are a great many drugs on the market that have not been submitted to this agency for such ap-

proval. 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 several months ago, in connection with thyroid-amphetamine combination drugs. We had to go through the catalogs 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. Several hundred producers were affected. None of them had undertaken to establish the safety of the product for the intended uses before marketing them.

More recently, we have noted a growing tendency in the industry to market new products without obtaining preclearance on the mere basis of a manufacturer's decision that new clearance was not required. We are developing policy statements and regulatory actions to deal with this particular problem. But meanwhile we urgently need to have product registration as called for in H.R. 4749 so that we can ascertain the magnitude of our problem and develop effective plans to cope with the situation.

This bill would require annual registration of all drug products produced by registered manufacturers. Presently, establishments which manufacture, prepare, propagate, compound, process, or re-pack drugs must register their names, but they do not have to identify the drugs they produce. In addition, the bill would require that the quantitative formulas and labeling of all drugs be included in the registration. Also required to accompany the registration would be advertising for prescription drugs, production data as necessary, and reference to the FDA approval, or in lieu thereof the data from which it is determined that the drug was not subject to such approval.

The provision that the quantitative formulas of drugs be included in the registration is necessary in determining whether changes have been made and their significance. Formula information is presently required to be submitted prior to new drug approval.

We do not expect to force a duplication of effort in this area and would anticipate that reference to the new drug approval would be sufficient for registration under this act. We believe the language in the bill that the "list shall be prepared in such form and manner as the Secretary may prescribe" contemplates such flexibility. We might also want to require that changes in the formula be indicated.

Copies of all labeling and advertisements for prescription drugs would obviously help us insure that drugs are honestly and accurately promoted. Again, there should be flexibility to permit us to require advance notification and perhaps exempt certain classes of products, if not inconsistent with our goals.

In fiscal year 1970, 66 corrective actions were initiated to deal with serious omissions, unsupported claims, and promotionally biased statements which could seriously mislead the physician and affect the safety of patients.

The regulatory measures included requests for cancellation of violative advertisements and publication of corrective advertisements in medical journals. In most cases these called for a boxed statement to

appear in direct association with the corrective material. The statement said: "Published to correct a previous advertisement which the Food and Drug Administration considered misleading."

In some cases, FDA also required the mailing of "Dear Doctor" letters to physicians across the Nation, pointing out the violations in the original advertisement.

We are not able to proceed against every deceptive promotion, and it is questionable if corrective measures really overcome the initial misleading statements. But it certainly would impose no undue hardship, in our judgment, on drug producers to send in to the agency the promotional material they are using to sell the drugs. In our opinion, this would not constitute registration of such approval.

Other information required for registration is reference to the new drug approval or antibiotic approval for the drug listed, or data from which the firm determined that such approval was unnecessary. This provision, of course, would eliminate the present situation in which drugs are marketed without FDA's knowledge. We would also be apprised of the data the firm used in determining the drug's status under the act.

I would like to emphasize that this bill in no way is a licensing law. We could not refuse registration to deny marketing. Registration would merely notify us of facts we are entitled to have under the law on request. The bill would facilitate more expeditious enforcement, but would not otherwise restrict the marketing of drugs or change our basic legal framework.

The bill also would solve another troublesome problem. Except for new drugs and antibiotics, a firm need not notify FDA when it discontinues a prescription or over-the-counter drug. Nor does it have to give us reasons for such discontinuance.

We have, as you know, devoted considerable effort in reviewing the effectiveness of drugs approved before 1962 for safety only.

It is unfortunate that we also had to review drugs which were no longer marketed and yet had effective applications. We have also been criticized for publishing notice of ineffectiveness regarding such drugs because the firm said they had already withdrawn them from the market.

Our prime concern is 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.

Under our present authority, FDA can issue warnings about products, but may not be able to identify the manufacturers of the preparations. This is a paradoxical situation. Examples of such warnings or restrictions include drugs containing mineral oil, tannic acid, phenacetin, aminopyrine, calamus, and stramonium. And there are others.

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

H.R. 4749 will provide these answers and enable FDA to more adequately carry out its responsibilities. We believe the public is entitled to this increased protection.

This legislation, in our judgment, is crucial to enabling the Food and Drug Administration to carry out its regulatory responsibility. Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

Dr. Roy?

Mr. ROY. Thank you for your statement. I have no questions.

Mr. ROGERS. Mr. Nelsen.

Mr. NELSEN. I notice that in the reports you are asking to be filed that you are asking advertising material be included. You say this is not a policing process but merely informational; but in the event that the advertising material is out of line, you would certainly have the authority to call a halt to it, would you not?

Dr. EDWARDS. We already have that authority, so this would not be asking for additional authority.

Mr. NELSEN. What about the voluntary national drug code. Has it worked out? Have you had participation in it? Is there not some code that you now have?

Dr. EDWARDS. We do have a national drug code; that is correct.

Mr. NELSEN. Is it voluntary?

Dr. EDWARDS. It is voluntary, and it has worked, to the best of my knowledge, very well.

Dr. FINKEL. Yes.

Mr. NELSEN. Is some of the same information supplied that you ask for under this provision?

Dr. EDWARDS. Some of the same; yes.

Mr. NELSEN. And how many have participated in the voluntary code? Is it general or is it spotted?

Dr. EDWARDS. I think it has been fairly good.

Doctor, would you have any specifics on it?

Dr. FINKEL. I do not have any figures, but most manufacturers have participated.

Mr. NELSEN. What percentage of the prescription drugs now on the market are covered by the code?

Dr. FINKEL. I think most of them are, but I do not have the exact figures.

Mr. NELSEN. I see.

Mr. Goodrich, I join our chairman in expressing our "regrets" that you are leaving the agency, because all of us over a period of many years really depended on you for your expert information. Of course, occasionally we kind of walk on you a little bit hard, but you always had a smile.

I notice the reference to the grandfather clause and some of the drugs on the market, so again, getting back to my problem in Minnesota with this little laboratory, this is the problem which is the same one I think we face in this proposal. It is where a major company puts together something which at a later time is also put together by a small company, where all of the products in it and all of the component parts, are the same as used by the big company. And, again, we get into this new drug-old drug deal. Have you made any progress on checking out my little laboratory?

Mr. GOODRICH. I have not heard from their counsel since I talked with him here in Washington. We did set out a program for the laboratory to do, on tissue residue in animals, and we assured the firm that

if they could come up with this test, concerning which one of their scientific people went over with us, someone at the University of Minnesota, that there would be no problem of clearance. The counsel is to call me as soon as he had the data available, and I gave him every assurance that it would receive prompt attention in the Department.

It is simply an issue of whether or not there are unexpected or unwanted residues of one of these tetracyclines in the animals that are fed or treated with the drugs. I have forgotten which it is.

Mr. NELSEN. Now, getting back to this voluntary code. Under the legislation that is being proposed, would there be any overlapping of voluntary code and the requirements under the provisions of this bill?

Mr. GOODRICH. There are some, Mr. Nelsen, but the code itself is a cataloging of drugs by category. It does not include the kind of material we are talking about here; that is, the labeling, the advertising, the scientific data, or the reference to the new drug applications. This code is a listing of all drugs by names, by numbers and names, so as to give an overview of what is available, and also is for some assistance in recordkeeping and payments, and it is not the same sort.

Mr. NELSEN. Now, does this reach out to the drugstore?

Mr. GOODRICH. No.

Mr. NELSEN. Merely to the manufacturer?

Mr. GOODRICH. This would cover the same people that have to register under the other provisions. These are basically the manufacturers and repackers. There are about, I believe, 6,400 companies registered. Now, there would be a good many more, a good many more, drugs than that, but we have an idea of the magnitude of the people who have registered. It does not go down to the drugstore level, except where they make up a drug of their own. Some drugstores have a little manufacturing going on of a product, but otherwise not.

Now, the registration under the Comprehensive Drug Abuse Control Act which this committee passed last year made some changes in that.

But the registration we are talking about here has to do with manufacturers, packers, and reproducers, all of which is spelled out here in the law.

Mr. NELSEN. Do you find any extensive opposition to this bill? Is there any feeling that so many reports are required that it gets to be an undue burden—or what do you find?

Mr. GOODRICH. Well, the other people can speak for themselves, because they are here; and the point we want to make is all we are asking for here is information. We are going to deal with the information under the existing provisions of the law. Now, we are asking that the promotional material, that the advertising of all drugs, be sent to us.

Under the Drug Amendments of 1962, of course, the new drug advertisements or the advertisements for approved antibiotics are required to be sent in with the regular reports. There are no reporting requirements applicable to producers of other drugs, so we are asking them to send us the same kind of material that they are sending out to the doctors to sell the drugs.

Now, that does not seem to us asking too much. We are asking for them to reference the new drug applications or the antibiotic approvals. There is no problem with that. We are asking them in the case of a

product, which was not approved, to either identify the grandfather clause under which they are operating or to give us a reference to the data on which it could reasonably be concluded that the product was generally recognized as safe and effective and no approval was required.

Now, the companies make the point that this is going to bring to us a lot of information about a tremendous number of drugs that we do not need. If we do not need the information, we can exempt it; but we think we have to have an understanding with the industry of why a product that is put on the market this year without approval was put on there. That seems reasonable to us.

Mr. NELSEN. And any discontinuance, of course, is important to you?

Mr. GOODRICH. Yes, that is very important. We have been trying to clean up a bunch of old files. We have, I believe, canceled something on the order of 3,000 to 4,000, and we have to do it on the grounds that the people deliberately refuse to report. Well, this is abrasive between us and the industry, and it would be better simply to have a system that if the drug file is obsolete or out of date, that it ought to be closed and then brought up to date when the drug is remarketed. That is all this bill calls for—that is, when the product is reentered after the file is closed, that they will update the registration.

Mr. NELSEN. Now, after our hearing has been completed, I presume that you would be available for further consultation. And one of the things we run into here in almost all legislation, for example, drug abuse, the crime bill, health manpower, is so many times we proceed up here without calling in people from downtown, and in some cases when we get out a bill and get all through we find we have made some mistakes, and there needs to be some accommodations made. And I presume that this bill may be similar to that.

And, Mr. Chairman, I am sure that in the event that we need to have a review again with the department people from HEW, that we will have that opportunity.

Thank you.

No more questions.

Mr. ROGERS. Thank you.

Mr. KYROS?

Mr. KYROS. Thank you, Mr. Chairman.

Dr. Edwards, on page 3 of the bill which the chairman has before the committee and of which I am a cosponsor, we state that we would show the formula listing quantitatively each ingredient of the drug listed. Is it actually necessary to show the formula, or should we just list the ingredients? What is the necessity for the formula?

Dr. EDWARDS. Well, I think both are important. It is obviously extremely important that we know what the ingredients of a particular drug are. It is also in terms of the formula extremely important to know when a formula has changed; and if we did not know what a formula was for a drug, then we would not know when it was changed. A formula change will change the basic action of the drug, and, so, I think both of them are really quite important.

Mr. KYROS. Would this create a problem with a legitimate manufacturer divulging any trade secrets?

Dr. EDWARDS. I would not think so.

Dr. Finkel?

Dr. FINKEL. No, I would not think so; for one, they are in repository with the FDA and, for another thing, it will help us evaluate whether the drugs have been altered in such a fashion as to make them therapeutically unavailable to the patient.

Mr. KYROS. You say "repository with the FDA." Isn't this list going to be publicly available?

Mr. GOODRICH. There is a provision, Mr. Kyros, on page 5 at the top, which would authorize the Department to exempt from public inspection whatever in the registration would divulge that kind of information, and we recognize that as the formula would have trade-secret implications, and some of the underlying data, research data, has commercial value, and that would not be divulged.

Mr. KYROS. Do you have any idea how many drug manufacturers there are who are included in this legislation?

Dr. EDWARDS. There are slightly over 6,000.

Mr. KYROS. Is there going to be a problem, Dr. Edwards, in getting notice to all of them? How do you intend to notify all of them about compliance with this legislation?

Dr. EDWARDS. No. You see, as I mentioned in the testimony, all of the manufacturers and repackers and so forth, have to register with us right now, and, so, we do have an up-to-date list of those involved in the process. I do not think it would be any major task for us to notify them exactly what is to be expected of them under the registration.

Mr. KYROS. If we pass this bill, what about all of the paperwork that is going to result? How are you going to handle that with the staff you have? And you are losing, in a short time, my good friend, Mr. Goodrich.

Dr. EDWARDS. Obviously, this would take more staff, and we have anticipated this and would request of the Secretary, Secretary Richardson, additional staff and additional money. We figure for the first year it would cost about a half a million dollars to get this underway. After that, it would run somewhere in the neighborhood of \$2 million a year.

Mr. KYROS. If this is such a valuable tool, why have we not had it before?

Dr. EDWARDS. Pardon me?

Mr. KYROS. If this is such a valuable tool, why have we not had it before? What has prompted it now, besides the chairman's interest in it?

Dr. EDWARDS. I cannot answer that question. It amazes me as to why we have not had it before. I think it is impossible for us, as I also indicated, to, in fact, even monitor the drug system in this country without even knowing what drugs are on the market. I think it is an impossible situation for us to do the job we are supposed to do, and the Congress wants us to do, without having this information.

Mr. KYROS. On page 3 of this legislation, it is indicated that a manufacturer is required to give justification for a drug being simply an over-the-counter drug when, in fact, he has a statutory right to market such a drug. Why is that the case?

Dr. EDWARDS. I am not sure that I understand. Would you repeat your question?

Mr. KYROS. Well, on page 3, where it says, "Articles, subparagraph (d), the data from which it is determined it is not a new drug or an

antibiotic drug subject to section 507." It seems that you are requiring additional justification for an over-the-counter drug which a manufacturer already has justification to market. Or does he?

Dr. EDWARDS. We are not questioning his decision. We are just merely asking for the data on which he based his decision to make it over-the-counter versus prescription or make it a "me, too," and to not go through the new drug application process.

Mr. KYROS. So the legislation does not require any more justification?

Dr. EDWARDS. No. We are merely, as we read this, asking that we have an opportunity to look at the information that he used to make the decision that he had to make.

Mr. KYROS. Thank you very much.

Dr. EDWARDS. Then, we do have the authority after that, if we do not agree, to do something about it.

Mr. KYROS. Of course, that shifts the burden somewhat onto the manufacturer; is that right, Dr. Edwards?

Dr. EDWARDS. Yes.

Mr. GOODRICH. But only to bring the information. We still would have the burden, if a company made a judgment that a product was over-the-counter and we thought it should be a prescription. We say "All right; let us see the data on which you made this judgment." And he sends it in, and we disagree, and we have the burden to go and prove that the drug is one that has high toxicity or some other adverse effect that requires it to be put under prescription, or we would have to sue him if he decided it was not a new drug and did not obtain approval, and we thought that it was one that required approval. Then, we would sue him under the existing law. But this is simply an information type of sharing with us. We think we are entitled to have that to see the basis on which he made this judgment. That is all, and that is all that is in the bill.

Mr. KYROS. Thank you, Dr. Edwards.

Thank you, Mr. Goodrich.

Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. Thank you, Mr. Chairman. I think this has been pretty well covered. But this does provide, this bill does provide, for the current listing of every drug manufactured, prepared, propagated, compounded, or processed to be registered under Federal—or the Food, Drug, and Cosmetic Act, and anytime a drug is discontinued, you want that information also, is that true?

Dr. EDWARDS. That is correct. We feel that it is very important to know why a drug was discontinued; whether it was from purely a marketing standpoint or whether there were, in fact, scientific, medical reasons for discontinuing a drug.

Mr. CARTER. Now, the information on each drug there includes the formula and the labeling and the advertising for prescription drugs, and your intention is to go over that and determine whether the advertising is false or misleading; is that true?

Dr. EDWARDS. We do have a responsibility for reviewing advertising, promotional material, as you know. And while this is not to be construed as a preclearing of promotional material, it does give us an opportunity, or would give us an opportunity, to look at the kind of material that is being used for promotion of these drugs.

Mr. CARTER. And would you be permitted by this legislation to assign a registration number for each drug or class of drug listed?

Dr. EDWARDS. Yes.

Mr. CARTER. I see; it would require quite a few numbers.

Dr. EDWARDS. That is right.

Mr. CARTER. Yes, sir. On foreign drugs, I notice that you will require them to file with the Secretary a list of all of the drugs they put out also; is that not true?

Dr. EDWARDS. That is correct.

Mr. CARTER. The same applies to them that applies to the manufacturers and wholesalers in the United States?

Dr. EDWARDS. That is correct.

Mr. CARTER. Yes, sir. All right.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Dr. Edwards, on page 3 of your testimony, I would like you to enlarge a little bit on the second paragraph, where you state:

More recently, we have noted a growing tendency in the industry to market new products without obtaining preclearance on the mere basis of a manufacturer's decision that new drug clearance was not required.

And you end that with the statement that you urgently need to have product registration so that:

We can ascertain the magnitude of our problem and develop effective plans to cope with the situation.

Do you have any idea how prevalent the practice is today that the manufacturers are making their own decisions that they do not need preclearance?

Dr. EDWARDS. I cannot give you a specific answer in terms of numbers, but we are well aware of the fact that it is extremely prevalent, that we do not, by any stretch of the imagination, have applications on all the drugs that are being marketed—and I am talking both about prescription drugs and over-the-counter drugs. It is a problem.

Mr. HASTINGS. It is rather common that you have the drugs called to your attention and you find, in fact, that you have to take action against a manufacturer once the drugs are marketed. Through one course of action or another, it becomes obvious to you that the drug should have been cleared, and very often you have to get into this type of action?

Dr. EDWARDS. That is right; that is correct.

Mr. HASTINGS. It is the prevalent practice?

Dr. EDWARDS. Again, it is happening, in our judgment, at a growing rate, and I think that this has to be brought under control by the agency.

Mr. HASTINGS. Do you feel that the drug manufacturers are purposely evading, perhaps, jurisdiction of FDA?

Dr. EDWARDS. No, I do not think—Well, it depends on how you use the word “purposely.” I think that—

Mr. HASTINGS. Seeking a loophole, perhaps.

Dr. EDWARDS. I think there is a loophole in the law, and I think it is being utilized some by the industry to get around the usual processes in going through the new drug application.

Mr. HASTINGS. And you are confident that this legislation would cure that problem?

Dr. EDWARDS. No, I do not think it would cure the problem but it would give us at least a handle on the problem.

At this point in time, as I said earlier, we do not, we really do not have a handle on the problem, because we know that this is happening, and we know it is happening with a degree of frequency, but we do not always know when it is happening. It is usually that we find out after the fact; it being brought to our attention, but it is not a very businesslike way to go about having to come up with some of these problems.

Mr. HASTINGS. As a general statement in relation to the use of drugs, legal or otherwise, in this country, do you feel that, in fact, we have what approaches a drug-oriented society today?

Dr. EDWARDS. Well, I do not think there is any question about it. I think we are living in a highly drug-oriented society, and I have said so publicly before.

Mr. HASTINGS. More so than any nation in the world?

Dr. EDWARDS. No question about that.

Mr. HASTINGS. Thank you, Mr. Chairman.

Mr. ROGERS. Well, presently, I presume a manufacturer can, if he were to decide to put a drug on the market, if he feels it is similar to a drug that is already approved, can he just simply market this?

Dr. EDWARDS. He can go ahead and market that drug. We may or may not agree, and we may not know whether we agree because we may not ever know that the drug is being marketed.

Mr. ROGERS. You might never know, and the only way you might know is if somebody has trouble or your agents go out and say "Well, this drug is in this drugstore, and we do not see any clearance here at all?"

Dr. EDWARDS. Or it is brought to our attention by some of our critics or by some of the other drug firms.

Mr. ROGERS. Yes, or either by an adverse effect on the public?

Dr. EDWARDS. Right.

Mr. ROGERS. So, I would think this is a very necessary tool to have. I would agree with you.

Now, also I presume it will help cut down some of your workload so that even though you may have to have some additional personnel to process the paperwork in order to protect the public, I presume that it would also cut down on some work because you would not have to be checking on the discontinued drugs, and so forth?

Dr. EDWARDS. Absolutely, and, of course, it would also cut down on our work in a number of different areas, not the least of which would be advertising and promotion, and would give us an opportunity to review this on a more organized basis.

Mr. GOODRICH. You see on the top of page 2 we say we have already thought of going with this questionnaire and then following up with the inspectors. Now, that is going to be difficult for us and difficult for the companies. We think it would be better for everyone concerned if the companies would organize their own material in their own way, rather than for us to have to send an inspector to sit down with them and do that. This is why we think there is some savings in this method, and it does allow the company to organize its data

so that it can be reviewed promptly, and it can be handled in a computerized fashion so we will have a real tool to work with.

Mr. ROGERS. Now, I presume if you had to send inspectors, that kind of a system would even cost more than this?

Dr. EDWARDS. No question about that.

Mr. ROGERS. Could you let us have some estimates on what that might cost?

I realize you may not have it here, but if you could, submit it for the record.

Dr. EDWARDS. We do not have it here, but we certainly could supply you with that information.

(See letter dated July 19, 1971, p. 20, this hearing.)

Mr. ROGERS. I think that would be helpful to have.

Dr. EDWARDS. And, too, with the voluntary system we are starting with, there is no question in my mind that the responsible elements of the industry will cooperate and cooperate fully. But, as we have indicated, there are some 6,000 processors of various and sundry kinds, and we would have no particular reason to believe that in this voluntary system we are necessarily going to get an accurate reporting as we get further down into the small firms.

Mr. ROGERS. Yes. Well, I agree. I think most of the companies will cooperate, and they have indicated that in testimony before the committee.

Dr. EDWARDS. I have had a number of discussions with representatives of the industry, and I think for the most part we agree on most of the elements that are in this bill. There are a few things that we disagree on.

Mr. ROGERS. Also, there is an advantage, is there not, in having a listing of drugs, an advantage in the fact I think you alluded to, that if a certain drug is found to be unsafe or not effective, with a registration you can quickly determine who is manufacturing the drug and can quickly notify them; otherwise, it may take years to find out who is manufacturing all the various drugs of that category without such a registration?

Dr. EDWARDS. That is right. With a registration of a dangerous drug we would know exactly where to go to find those manufacturers or those companies that were manufacturing this particular drug. This would be a tremendous service not only to the Food and Drug Administration but to the public generally.

Mr. ROGERS. Let me ask you this?

What about food processors? I wonder if it would be wise to include some similar provisions for food processors, that you have the responsibility to inspect such plants, to let them give you a listing of the foods they produce, and their advertising, such as that, and of the preservatives that they put in it, and so forth—additives?

Dr. EDWARDS. Yes, I think so. We are, of course, as you know, doing a number of things right now. We are now going with an inventory of the food industry in terms of their food manufacturing practices. FDA and the National Academy are going to each of the manufacturers in the study of food additives, finding out what particular food additives a particular manufacturer is using, and getting the background, and scientific information for what is used to establish safety. I think this would all fit into what you are suggesting for the food

industry and would have some very real merit as far as we are concerned.

Mr. ROGERS. Well, I think it would be helpful to the committee if perhaps you could forward to us a suggested draft of such legislation.

Dr. EDWARDS. That we will do.

(The following letter was received for the record:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., July 19, 1971.

Hon. PAUL G. ROGERS,

Chairman, Subcommittee on Public Health and Environment, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. ROGERS: I appreciated having the opportunity to present the views of the Food and Drug Administration on H.R. 4749 before your Subcommittee on June 10, 1971.

We are enclosing a statement on the projected costs of drug registration as you requested during the hearing.

It would also be appropriate to comment with regard to the suggestion that food processing be included in the legislation. As you know, we are able to judge the magnitude of the proposed legislation as presently drafted because all drug establishments must now register; however, registration of food establishments is not presently required. Thus we do not have a means to evaluate the scope of a requirement that all food products be registered.

In addition to the above it should be pointed out that we are not presently entitled to formula data for foods as we are for many drugs. Furthermore, there are obviously many more food processors of a local nature than drug manufacturers.

We have considered the problem of insufficient information on the number and variety of foods produced and have reviewed suggestions regarding increasing our inspectional authority over food plants (our authority to inspect food processors is presently more limited than for prescription drugs). We have also considered records and reporting requirements. As you know, we have developed a pilot survey of the food industry regarding manufacturing practices which should substantially increase our knowledge of this industry.

Although we believe your suggestion has merit, we would need more time to review all alternatives and assess the potential difficulties involved. Thus we do not believe we are in a position at this time to recommend or support legislation requiring the registration of food products or processors.

We again wish to express our support of H.R. 4749 and encourage swift action on this important health legislation.

Sincerely yours,

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

APPENDIX—COST PROJECTIONS FOR H.R. 4749 AND A VOLUNTARY DRUG REGISTRATION

Implementation of drug registration on a voluntary basis relying on information provided by questionnaires to manufacturers, or on a mandatory basis, as provided by H.R. 4749, would require processing and scientific review of the data submitted by manufacturers. Costs for this activity are estimated as follows:

[Amount in thousands]

1972:		
	Positions.....	90
	Man-years.....	23
	Amount.....	\$460
1973:		
	Positions.....	114
	Man-years.....	104
	Amount.....	\$2,125
1974:		
	Positions.....	108
	Man-years.....	103
	Amount.....	\$2,114
1975:		
	Positions.....	104
	Man-years.....	99
	Amount.....	\$2,032
1976:		
	Positions.....	104
	Man-years.....	99
	Amount.....	\$2,032

A voluntary drug registration system would involve additional annual inspection costs estimated at about 200 man-years at \$3,600,000. These costs are associated with followup inspections to obtain information not submitted on questionnaires.

Mr. ROGERS. Are there any other questions?

Mr. CARTER. Mr. Chairman?

Mr. ROGERS. Mr. Carter.

Mr. CARTER. Thank you.

Do you have any specific preparations in mind that you want registered?

Dr. EDWARDS. None that I can think of specifically. I think maybe Dr. Finkel, who, as you know, is the Deputy Director of the Bureau of Drugs, might have some specifically in mind.

Dr. FINKEL. Well, there are certainly some significant drugs that we might be more interested in than others, but I think overall we do want to know, just exactly what is on the market so that we can get some kind of organized way of handling the labeling for particular classes of drugs, making sure that they are all safe and effective, and this would enable us to do it in a very orderly manner.

Mr. CARTER. That includes both over-the-counter drugs and prescription drugs?

Dr. FINKEL. Yes. This is particularly important, as the result of the National Academy of Science's review of the drugs.

Mr. CARTER. Does it include some of the patents we hear so much about?

Dr. FINKEL. The patents?

Mr. CARTER. Patented medicine that has been referred to over the years?

Dr. EDWARDS. Yes.

Mr. CARTER. Lydia Pinkham's pleasant little pellets, or Dr. Pierce's golden medical discovery?

Dr. EDWARDS. We do not refer to them as patented medicines now, but some of them are over-the-counter drugs.

Mr. CARTER. They have called it patented for years.

Dr. EDWARDS. But they would be included; yes, sir.

Mr. CARTER. This, of course, would mean that such formulations as they have would be protected; is that correct?

Dr. EDWARDS. Yes, sir.

Mr. CARTER. Thank you, Mr. Chairman.

Mr. ROGERS. Off the record.

(Discussion off the record.)

Mr. ROGERS. Mr. Kyros?

Mr. KYROS. I have only one more question, Mr. Chairman.

Mr. Commissioner, page 5 of this legislation reads "except where the Secretary may exempt." Would it make it difficult for you if it said "except the Secretary shall exempt?"

Dr. EDWARDS. No problem.

Mr. GOODRICH. No problem.

Mr. KYROS. Thank you.

Thank you, Mr. Chairman.

Mr. NELSEN. Mr. Chairman.

Mr. ROGERS. Yes, Mr. Nelsen?

Mr. NELSEN. I am curious to know, for example, when you require a report from pharmaceutical firms listing all of the ingredients in a drug is there a possibility that trade secrets would escape and become known to others? I presume many of the firms carefully conduct research for years and that they carefully protect a product. I am curious to know how you can guard against the possibility of raiding of information. How can you protect a company's long history of research that might be required in the filing of information with your Department?

Dr. EDWARDS. Well, we do presently, as you know, have confidentiality of the records that are submitted to us on a new drug and I presume we would use the same mechanism basically in this, in the registration, as we currently use in protecting the confidentiality of the current records.

Mr. NELSEN. In the preparation of legislation of this kind, do you have any ad hoc committee on which the industry has representation to discuss what can be done and what cannot be done, what ought to be done and what should not be done? Do you have anything like that?

Dr. EDWARDS. We have a number of ad hoc committees, particularly with the Pharmaceutical Manufacturers Association, and we will over the next week or so, or prior to sending out our voluntary inventory, sit down with PMA and also the Proprietary Association to get any comments or suggestions that they have in terms of the way we are going to go about this.

I think, in the past, we have not always worked closely enough with some of these groups, but I think this is improving.

Mr. NELSEN. Our experience here is that so many times we overlook the opportunity of consulting with HEW or any other agency, and yet if we had had communications with the agencies many of these rough spots could have been eliminated and a more satisfactory piece of legislation would have developed.

Thank you, Mr. Chairman.

Mr. ROGERS. Thank you.

Off the record.

(Discussion off the record.)

Mr. ROGERS. Thank you very much. We appreciate your presence here, and we may be back in touch with you.

Dr. EDWARDS. We would be delighted to provide any information you need.

Mr. ROGERS. Mr. Goodrich, I am sure we will see you again before you leave.

Mr. GOODRICH. I hope so; yes, sir.

Mr. NELSEN. We will be down for your farewell party.

Mr. ROGERS. Dr. Finkel, thank you so much.

Our next witness will be Mr. C. Joseph Stetler, president, Pharmaceutical Manufacturers Association, and he will be accompanied by Mr. Bruce J. Brennan, PMA vice president and general counsel.

Welcome, again, to the committee. We will be pleased to receive your testimony.

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

Mr. STETLER. Thank you, Mr. Chairman, and members of the committee. We appreciate the opportunity to appear before you today on behalf of the prescription pharmaceutical manufacturers that are members of the PMA for the purpose of discussing H.R. 4749.

I would like to submit our entire statement for the record and present an abridged version.

Mr. ROGERS. Without objection, your statement will be made a part of the record following your summary, and you may proceed as you desire.

Mr. STETLER. The stated purpose of the bill is 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 regulation by readily identifying establishments needing greater or lesser surveillance depending upon the nature of their activities.

The PMA supports, without qualification, those portions of the bill relating to the annual submission of lists of all drugs manufactured or processed. We also believe that manufacturers should be required to submit, within a reasonable length of time, notices of initiation, discontinuance, or resumption of manufacture. 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 drug legislation.

We also have no objection to the requirements in the bill for the annual submission of labeling and advertisements.

Despite comments made this morning as to examples of bad advertisements, I believe in the past few years agency officials having responsibility for prescription drug advertisements have attested to the great improvement of prescription drug ads.

Thus, any need for preclearance would seem to be less now than was the case in 1962. Further, the manpower and other resources currently available to FDA is insufficient to adequately administer present law. Vesting additional responsibilities of this type in the agency would only increase the gap between statutory assignment and performance.

I was glad to hear Commissioner Edwards say this morning that he does not view this provision of the bill as giving the agency preclearance authority. We think that would be a problem, and we think to the extent the bill can be read that way it should be clarified.

PMA also believes that the requirement to submit the formula of each drug showing quantitatively all ingredients, including inert material, should be replaced by a requirement for the name and the amount of each active ingredient. This would, in our judgment, enable FDA to obtain sufficient information to accomplish the purposes of the bill without requiring the divulgence of trade secret information.

We believe that the provision authorizing the Secretary to assign a registration number to each drug should be changed to make it clear that the registration number should be the same as that assigned pursuant to the existing National Drug Code.

We are also uncertain as to the full meaning of the proposed requirement for the submission of "data from which it is determined that * * * is not a new drug or antibiotic drug." There is, of course, no analogous requirement in the Food and Drug Act as it presently exists.

Indeed, under the present act it is clear that there is no statutory burden on the manufacturer to compile data substantiating a claim that a drug is generally recognized as safe and effective. A judgment as to general recognition is required but not substantiating data. The imposition of a requirement for such data would in effect eliminate the present distinction between new drugs and old drugs, a difference carefully drawn in the 1938 Food and Drug Act and reaffirmed in the Drug Amendments of 1962.

We feel strongly that the compilation of such substantiating data for thousands of well-established drugs with the need for FDA to review such data should not be required without a showing of clear need. As in the case with the regulation suggesting the preclearance of prescription drug advertising, the FDA does not have the manpower and resources to carry out the added responsibility.

We assume that the intention of this provision is not to vest authority within the agency either to preclear the marketing of old drugs or to require certain types of data in support of claims for old drug status. Nevertheless, the provision as presently worded would give FDA the color of authority to insist that manufacturers waive their statutory right to a court determination of old drug-new drug status in the event of a disagreement.

Under present law, if a manufacturer markets a new drug without an approved new drug application, he is subject to injunction, seizure, or criminal prosecution. The purpose of the bill as stated, could be accomplished by a notation on the annual submission as to which drugs the manufacturer considers old drugs.

We are also concerned with the provision in the bill for the submission of "any production data the Secretary may require." This provision is so vague that FDA could require volumes of material without a showing of any need. Compiling and submitting requested data could be burdensome and expensive and could extend to trade secret information. Moreover, this material is already generally available to the FDA under its broad inspection authority.

In order to give effect to the suggestions which we have made, the bill would have to be amended in certain respects. Let me offer our complete cooperation and assistance in working with the committee and its staff in the preparation of appropriate language if you agree with the comments we have made.

I would like to thank you for the chance to discuss the bill with you, Mr. Chairman, and we would be glad to try to answer any questions you may have.

(Mr. Stetler's prepared statement follows:)

STATEMENT OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS
ASSOCIATION

Mr. Chairman and Members of the Committee, 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 that are members of the PMA to discuss the provisions of H.R. 4749, 92nd Congress.

PMA is a national association composed of approximately 125 firms, whose production accounts for about 95% of the nation's prescription drug supply, and whose research and development programs constitute the bulk of the American pharmaceutical R&D effort.

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 it manufactures, together with their formulas, all labeling, all advertising for prescription drugs, and such production data as the Secretary may require. In the case of new drugs and antibiotic drugs, the bill would require a reference to the authority for marketing such drugs; and for other drugs, the data from which it was determined that such drugs were not new drugs or antibiotic drugs. The Secretary could also assign a registration number to each drug or class of drugs so listed. The bill would also require the submission of labeling and, in the case of prescription drugs, advertising to the Secretary before such labeling or advertising was put into use. Manufacturers would also have to notify the Secretary when the marketing of a particular drug is initiated, discontinued, or resumed. Failure to comply with the notification requirement could result in revocation of a new drug application. Failure to provide any of the other information required by the bill could subject the offending party to criminal or injunction proceedings.

The stated purpose of the bill is 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 regulation by readily identifying establishments needing greater or lesser surveillance, depending upon the nature of their activities.

The PMA supports without qualification those portions of the bill relating to the annual submission of lists of all drugs manufactured or processed. We also believe that manufacturers should be required to submit, within a reasonable length of time, notices of initiation, discontinuance, or resumption of manufacture. 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 drug legislation.

We also have no objection to the requirements in the bill for the annual submission of labeling and advertisements. Submission of these items is currently required for new drugs, and we see no reason to distinguish between new drugs and well-established drugs in this regard.

We do question, however, the need or the desirability of a provision directing the submission of labeling or advertising prior to use. For drugs which are not generally recognized as safe and effective, and for antibiotic drugs, substantially all labeling is subject to FDA preclearance now. No need has been demonstrated to burden FDA with the additional responsibility of reviewing the vast amount of labeling relating to well-established drugs.

With regard to advertising, the matter of vesting preclearance authority in FDA was debated at great length at the time the Drug Amendments of 1962 were being considered. It was decided at that time that such preclearance was not necessary. In the past few years, agency officials, having responsibility for prescription drug advertisements, have attested to the great improvement of prescription drug ads. Thus, any need for preclearance would seem to be less now than was the case in 1962. Further, the manpower and other resources currently available to FDA is insufficient to adequately administer present law. Vesting additional responsibilities of this type in the agency would only increase the gap between statutory assignment and performance.

PMA also believes that the requirement to submit the formula of each drug showing quantitatively all ingredients, including inert material, should be replaced by a requirement for the name and the amount of each active ingredient. This would enable FDA to obtain sufficient information to accomplish the purposes of the bill without requiring the divulgence of trade-secret information.

We believe that the provision authorizing the Secretary to assign a registration number to each drug should be changed to make it clear that the registration number should be the same as that assigned pursuant to the existing National Drug Code.

For a number of years, the Department of Health, Education, and Welfare, the Pharmaceutical Manufacturers Association, the Food and Drug Administration, the American Society of Hospital Pharmacists, and several members of the National Drug Trade Conference engaged in discussions and negotiations for the purpose of establishing the format and operations of a voluntary national drug coding system. Such a code was finally accepted and published in the Federal Register on July 2, 1969. This code was the result of extended, harmonious, and successful joint Government-industry efforts, and its use is being continually expanded. The assignment of an additional registration number would serve only to undermine that effort, with no commensurate gain.

We are uncertain as to the full meaning of the proposed requirement for the submission of "data from which it is determined that * * * [the drug] * * * is not a new drug or antibiotic drug." There is, of course, no analogous requirement in the Food and Drug Act as it presently exists.

Indeed, under the present act it is clear that there is no statutory burden on the manufacturer to compile data substantiating a claim that a drug is generally recognized as safe and effective. A judgment as to general recognition is required but not substantiating data. The imposition of a requirement for such data would in effect eliminate the present distinction between new drugs and old drugs, a difference carefully drawn in the 1938 Food and Drug Act and reaffirmed in the Drug Amendments of 1962.

In our opinion, such data compilation would constitute an unnecessary and difficult burden on the sponsor of the drugs involved. To compile and submit the required data would necessitate a review of the opinions of a great number of physicians and scientists, and a study of the scientific literature which led to the conclusion of general recognition of safety and effectiveness. The futility of such an undertaking is one of the principal reasons for the historic distinction between "new" and "old" drugs.

We feel strongly that the compilation of such substantiating data for thousands of well-established drugs with the need for FDA to review such data should not be required without a showing of clear need. As is the case with the regulation suggesting the preclearance of prescription drug advertising, the FDA does not have the manpower and resources to carry out the added responsibility.

We assume that the intention of this provision is not to vest authority within the Agency either to preclear the marketing of old drugs or to require certain types of data in support of claims for old drug status. Nevertheless, the provision as presently worded would give FDA the color of authority to insist that manufacturers waive their statutory right to a court determination of old drug-new drug status in the event of a disagreement.

On February 23, 1971, FDA issued a proposal which indicates its desire to remove the distinction between old and new drugs. Consider briefly these excerpts from the published statement by FDA for an understanding of the true scope of the pronouncement: "Most, if not all, of these products are new drugs." "New drug approval will be required in essentially all cases."

The proposed regulation suggests that FDA should review data submitted by the manufacturer to determine new drug-old drug status. In other words, the proposal would require the manufacturer to prove to the Agency's satisfaction that a drug was an old drug rather than leaving the manufacturer the option of requiring FDA to prove that the product was a new drug. If the FDA proposal is finalized, the Agency could, for all practical purposes, require premarketing clearance of all drugs. We have urged the Agency to amend its basic philosophy on this point to reflect the fundamental scheme of regulation which was previously established by Congress.

We know of no health hazards that would justify such a radical departure from the statutory scheme of the Food and Drug Act. Under present law, if a manufacturer markets a new drug without an approved new drug application, he is subject to injunction, seizure, or criminal prosecution. The purpose of the bill as stated, could be accomplished by a notation on the annual submission of the list of drugs as to which drugs the manufacturer considers old drugs.

We are also concerned with the provision in the bill for the submission of "any production data the Secretary may require." This provision is so vague that FDA could require volumes of material without a showing of any need. Compil-

ing and submitting requested data could be burdensome and expensive and could extend to trade secret information. Moreover, this material is already generally available to the FDA under its broad inspection authority.

In order to give effect to the suggestions which we have made, the bill would have to be amended in certain respects. Let me offer our complete cooperation and assistance in working with the Committee and its staff in the preparation of appropriate amending language.

Thank you, Mr. Chairman. If you or the members of the committee have any questions, we will be glad to attempt to answer them.

Mr. ROGERS. Thank you, Mr. Stetler.

Mr. KYROS?

Mr. KYROS. Thank you, Mr. Chairman.

Mr. Stetler, I just heard Dr. Edwards say that it would be helpful to have the formula of the drug, because if there were changes in the drug they could be compared. What is your judgment on his comment?

Mr. STETLER. I think if changes in the formula are made, this could be made a reporting requirement, and then the FDA would have first-hand information about the change. I do not think it would be necessary to have the formula on all of the drugs. I think the important thing is a listing, as we say, of the active ingredients and the amount and the name of them.

Mr. KYROS. You also indicate in that same paragraph that one of your concerns about this listing of the formula would be the problem of divulging trade-secret information. Section 4(b) states: "The Secretary may exempt from inspection any list" et cetera. What if that were to read "shall exempt"? Would that not give you the kind of protection you need?

Mr. STETLER. The only thing that bothers me about that is the effect of another bill passed recently, known as the Freedom of Information Act. That statute is still a little vague, frankly, as to what is or what is not available under its provisions. I am not sure that even if we made this "may" "shall," what the effect would be on the provisions of the Freedom of Information Act. I think, if it is not absolutely necessary for you to accomplish the purpose of the bill, why submit additional data, why run the risk if you do not have to run it and still can accomplish the purpose of the bill?

Mr. BRENNAN. Mr. Kyros, I might say that the section of the current Food and Drug Act, the portion of this bill that you refer to, is section 510(f), a section concerning inspection, not really divulgence of information. It is inspection of the plant that registers; so if something along this line were to be accomplished, I think a new provision would have to be written into this bill.

Mr. KYROS. Is the formula given on new drugs?

Mr. STETLER. Yes.

Mr. KYROS. So, that is already in the application?

Mr. STETLER. They do have it on a great number of these drugs already.

Mr. KYROS. They would already have that. Of course, trade secrets are specifically exempted from the Freedom of Information Act.

Mr. STETLER. What is and what is not a trade secret is also something subject to debate.

Mr. KYROS. I understand.

Mr. STETLER. And there is a variety of opinions on that subject.

Mr. BRENNAN. We just went through sending the department a request for disclosure under the Freedom of Information Act, and in reviewing some of the recent cases, I might say that the tendency of the Federal courts is to give a very broad application to the Freedom of Information Act, and limit the exemptions.

Mr. KYROS. If the bill is passed as currently drafted, would FDA really be flooded with materials, including television tapes which are used as commercials?

Mr. STETLER. If we could restrict, as we have suggested, the submission of some of the data which we think is already there or is superfluous to the bill's purpose, we do not really see major problems with the bill. In other words, we are generally in agreement. We think it is important that we have a listing, a registration of the manufacturers of drug products. I would agree completely with Dr. Edwards on that. I do not know how we can expect them to do their job without it. We do not see the need, however, and we think you could accomplish that purpose without flooding them with a lot of other material.

The bill would require the submission of labeling and advertisements, and I frankly think they will have a very difficult time coping with all that volume of material. Much of it comes to them in other ways, but still, as long as it does not involve preclearance, they should have a right to it. Whether they can handle it or digest it is an administrative problem.

Mr. KYROS. Does he not have some discretion as to what material he requires initially so as to control the data coming to him?

Mr. STETLER. Theoretically, that is possible under the act, I would imagine. However, if the bill is passed, unless there was some limitation imposed, it would pretty much all be submitted. The decision would probably be made after the fact as to how it would be handled.

Mr. BRENNAN. Commissioner Edwards' statements just a few moments ago, as I understood them, did not seem to give any limitations toward it, or in his view would they; nor does the bill seem to incorporate any limitation at this point.

Mr. KYROS. Thank you.

Thank you, Mr. Chairman.

Mr. ROGERS. Mr. Nelsen.

Mr. NELSEN. Only this: I gather from what you say, and also from the objectives that have been cited by the Food and Drug Administration, we are not very far apart; it is a matter of clarification as to just what we mean, so that you have the proper guidance?

Mr. STETLER. Yes, I would say that the bill should be amended to make it clear that it does not involve preclearance of advertising. If it is adequate to submit the principal ingredients and not the complete formula, that would be a second point. I would say that a major point that we would make—and this is one where we may be in disagreement with FDA—deals with what you have to submit when you have marketed an old drug, one that is well recognized as safe and effective. We think it would be completely adequate and sufficient in submitting the listing to specify "old drug," and if the FDA wants to come back and require that you submit your justification for that judgment which you have made and can make under the law, they could proceed that way. We would not like to see a provision in the bill where it was an absolute mandatory requirement that data substantiating that decision

be submitted. This data is not already compiled for many of these drugs.

In other words, the present statute contemplates a manufacturer can determine that a drug is generally recognized as safe and effective and market it without a new drug application. If you were to require that the manufacturer now submit to FDA, on all of his old drugs, all of this data, you would impose a very significant burden on him. We think the objective of FDA could be accomplished by indicating it was an old drug. If they had a question about it, go back to the manufacturer and make him furnish it. Not on every old drug. That, to us, is a big burden, and really is our principal objection to the wording of this bill.

Mr. NELSEN. In other words, it is your feeling that if an old drug has already made the hurdles of the investigation, research, and had clearance, and if it is a continuation of what has already been approved, there is no need of submitting information already available as could be required by this bill.

Mr. STETLER. Certainly not for all of them. However, if there is an occasional one, when a question exists, let the FDA go back on it individually. Under this bill, they would have full knowledge of all drugs that are so classified, and they would have a right to go back under the present statute.

Mr. NELSEN. Thank you.

Mr. ROGERS. Dr. Roy?

Mr. ROY. Thank you, Mr. Chairman.

You object to the "any production data the Secretary may require," clause. This is vague to me also. What do you think it means?

Mr. STETLER. Well, obviously, it could mean anything that the current administrator of this statute wanted to require. If you look at the wording under the present statute, as far as what is accessible to them under their inspection authority, it really is already very broad. This wording, in our opinion, could impose a significant burden on manufacturers.

Mr. ROY. Has there ever been a problem in regard to inert material and active material?

Has that been difficult to define on any occasion?

Mr. STETLER. I think not. In other words, to define it is not so difficult. To have to submit all of the information would seem to be kind of a useless exercise.

Mr. BRENNAN. The law presently requires such definition. You have to list on your label what your active ingredients are. So that is clear to everyone.

Mr. ROY. This has not been a problem; this has not been contested in the past?

Mr. BRENNAN. No, that is true, whether you are talking about over-the-counter or prescription drugs, or whatever.

Mr. ROY. I have no further questions.

Thank you.

Mr. ROGERS. All right.

Dr. Carter?

Mr. CARTER. No questions.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Only one, Mr. Stetler. You say PMA represents about 95 percent of the national prescription drug firms. Can you give me a number so I have an idea of what we are dealing with, how many individual products are we dealing with or talking about?

Mr. STETLER. Well, let us talk about manufacturers first.

The figures cited this morning indicated that there are something like 6,200 manufacturers or processors.

Mr. HASTINGS. Right.

Mr. STETLER. We have, in our Association, 125 members. That means that our 125 members make up to 95 percent of all of the prescription drugs supplied. Five percent of the drugs supplied are made by the remaining 6,000 manufacturers, which means they are pretty small operators and pretty hard to get to. All of the drugs manufactured, and all of the dosages and formulas run to something like 12,000 to 15,000. This is a kind of a guess, because I do not think anybody really knows with great assurance.

Mr. HASTINGS. Do you have any idea what the retail sales would be annually of your 95 percent?

Mr. BRENNAN. I think the last figures were a little over \$3 billion.

Mr. HASTINGS. About 12,000 or 15,000 items that the FDA would have to deal with for registration on some \$3 billion in annual sales.

Mr. STETLER. Yes. I should mention, too, I think Dr. Carter alluded to the drug code and the extent of cooperation and compliance. I can tell you that all of our 125 companies are participating under that drug code on a voluntary basis, and all of their products do have registration numbers. But you still have a larger number of manufacturers, and you may still have to get them through another way.

Mr. CARTER. If you gentleman will yield on that?

You disagreed, I believe, a little bit in your statement with the registration numbers?

Mr. STETLER. We do not disagree that there should be one. It is just that we don't think there should be a new one for each drug when we already have a good code system. So, let us not change the numbers and create a lot of number duplication.

Mr. CARTER. You do have a code?

Mr. BRENNAN. It is a joint industry-Government code published in the Federal Register. It is an active program of HEW, and industry participates on a voluntary basis.

Mr. ROGERS. Well, I think that makes sense.

I would suggest that the suggestions you made be given to us in the appropriate language so that the committee can consider them when we go over the bill.

Mr. HASTINGS. I have no more questions.

Mr. ROGERS. Any other questions?

Thank you so much. We appreciate your being here.

I note in the audience one of our former colleagues and former distinguished Members of the Congress who was chairman of this subcommittee, Mr. Kenneth Roberts. The committee is pleased to recognize your presence here today, Mr. Roberts. Good to see you.

Mr. ROBERTS. Thank you, Mr. Chairman.

Mr. ROGERS. Our next witness will be Mr. James F. Hoge, general counsel of the Proprietary Association.

I might say that Congressman Preyer of North Carolina, who is an old friend of yours, wanted to be here to introduce you again to the committee—not that you need any introduction; but he is detained in chairing another committee at this moment, and we are delighted to see Mr. Cope here who is also with you.

**STATEMENT OF JAMES F. HOGE, GENERAL COUNSEL,
PROPRIETARY ASSOCIATION**

Mr. HOGE. Thank you, Mr. Chairman. I would have been delighted to have been introduced even “again” by Richardson Preyer. I would liked to have said—if it did not embarrass him—that I have known him since he was a very young fellow, and that one of the chief boasts of my wife is that she was one of his teachers in the high school. So, I am sorry that he was not here for my pleasure in seeing him.

Mr. Chairman, as you have said, I am general counsel to the Proprietary Association. Its address is 1700 Pennsylvania Avenue NW., Washington, D.C. My address is 90 Park Avenue, New York City. I am a partner in the firm of Rogers, Hoge and Hills, and I am appearing on behalf of the Proprietary Association which is made up of manufacturers of proprietary medicines.

Dr. Carter—as you say—I suppose, they are sometimes called “patent” medicines. I wish we could outgrow that. “Patented” medicine really is a different thing. It is a medicine that is patented in the Patent Office. “Patent medicine” was the term applied generally to these products. We have tried to outgrow that term and grown into proprietary medicines.

They are medicines which are sold over the counter. They do not require a prescription. They differ from some over-the-counter products in that they are advertised to the laity. The ones I represent are advertised directly to the public whereas other over-the-counter items are advertised only to the professions—pharmacies and doctors.

Mr. Chairman, I would like to make my first expression one of appreciation; an expression of thanks on behalf of my client, and of myself, for the opportunity of being here. I have been counsel to The Proprietary Association since 1934, and, as such, have had the privilege of appearing before this subcommittee, and before the full committee, many times over the years.

I am sorry that Mr. Goodrich has gone. I might not have been in order, Mr. Chairman, but I would have liked to have associated myself with the compliments and sentiments expressed with respect to him. I have known Mr. Goodrich since he came up from law school in Texas. A good deal of the time he has been my adversary, but always a respected brother lawyer and a valued personal friend.

POSITION

Now, Mr. Chairman, our position is stated in this fashion:

I want to allude first to what Commissioner Edwards said on April 30 of this year before this committee. He 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 in not knowing what drugs—or how many drugs—are actually on the market. He

said that again this morning. We can readily understand such a disadvantage, and we desire to assist in overcoming it.

Our hope has been that the desired end might be accomplished by voluntary action, and we have expressed that hope to you, Mr. Chairman, and to the FDA.

You and the FDA think that—in this connection—good industrial intentions and desires, such as we profess, should be encouraged and delineated by legislation. Somebody asked me what I meant by that. Well, it might take too long, to answer. Just let me say that although you did not say this, Mr. Chairman, I thought you might have meant that faith without works is dead, and that, as sometimes said in the vernacular, hell is paved with good intentions.

So, we think we understand what you and the FDA mean, and we accept the judgment, and we are here this morning to support this legislation.

VOLUNTARY ACTION

But let me, please, nevertheless, linger just a moment on the subject of voluntary action, for it is pertinent to the immediate subject, and it is pertinent to long-range regulation in this field.

On the 26th of last month, the Honorable James Grant, Deputy Commissioner of Food and Drugs, testified before another committee that the FDA is involved in an inventory under which it would develop a list of all drugs on the market, and the Commissioner alluded to that this morning.

Mr. Grant said that FDA had developed a fairly extensive questionnaire which is now in its final stages of approval, that it would soon be mailed to all drug manufacturers, that FDA would keep a record of who received it and would then proceed with a field force to follow up directly with manufacturers on their responses.

Although that questionnaire is still in a tentative form, we have enough information about it to permit my saying that we have little, if any—and I really think that we have no—objection to it, and that we will cooperate and will encourage our members to be responsive.

May I say that our knowledge about the questionnaire has been received through the courtesy of the FDA, and they have asked that, if we refer to it, we refer to it as “tentative” and that we not disseminate it. We have done as requested.

I think that this questionnaire will aid—and it does not, in view of what you and FDA have told me, it does not take the place of your bill, but we think it will aid and speed the accomplishment of the desired inventory.

One final word on the voluntary approach—and this is with particular regard to the long-range view, which I think is very important to regulation in the drug field: this committee has been very effective in the past in directing voluntary industrial action. In 1966, this committee was responsible for a conference, under FDA auspices, on the prevention of accidental ingestion of salicylate products by children.

You, Mr. Chairman, and other members of this committee were active and very prominent in bringing about that development. The conference agreed that children's aspirin should be $1\frac{1}{4}$ grains per tablet and should be put up in packages of not more than 36 tablets per package, and should bear stated warnings in the labeling. These

agreements have been carried out, I think I may say, to the satisfaction of this committee. And the memory of that conference encouraged us just a little to say something to you about the voluntary approach.

LEGISLATIVE ACTION

But now for the legislation and legislative action; as just indicated to you, we endorse the concept of an inventory of all drugs on the market. We, therefore, are not opposed to the purpose of this bill, H.R. 4749, or to the bill itself insofar as the bill is agreeable to that concept.

Our petition to you this morning is that the bill stay with that concept, that it not go beyond providing the needed inventory. We think some of the provisions in it now might—if enacted in the present form—be later construed as going well beyond product listing.

THE BILL

Now, for the bill itself.

We request that it be revised, and we offer these suggestions:

The bill is entitled as an amendment of the Food, Drug, and Cosmetic Act to provide for a current listing of each drug manufactured by a person or firm registered under the act, and, as you have been told, we all have to register. We suggest that section 1 be revised to provide that the act may be cited as the "Drug Listing Act of 1971." This conforms not only to the title but to references generally—and I have counted not less than 10 in the bill itself—references to the word "list" and to the word "listed." We also think this change better describes what we understand is the real purpose of the bill, that is, a listing or an inventory.

Section 3 is designed to amend section 510 of the Federal Food, Drug, and Cosmetic Act. That is the section which requires the registration of establishments in which drugs are prepared, and, as to some drugs, depressants and stimulants, places such as wholesale establishments, in which they are held for distribution as in wholesale plants. The bill would add a new subsection (j). Each establishment registrant would be required to file with the Secretary a list of all drugs which are manufactured in the establishment.

The list must be accompanied by certain specified information as follows—and this is where I have some comment:

On the listing of drugs, per se, no comment at all. But, under "A," the bill would require the formula showing quantitatively each ingredient of each drug listed. We ask that the filing be restricted to a quantitative showing of each active ingredient.

Mr. Chairman, I want to say here that this is an advance. We have come a long way on this. There was a time when the proprietary manufacturers did not want to disclose the quantities of any of their ingredients. The law of 1938 required them to disclose the active ingredients, and they have done that.

We have come now to the point where we are agreeable to disclosing the quantities, but we do not want to disclose the whole formula with all of the inerts and all of the other things that contribute to trade secrets. I am not a chemist, but I am told that much of the secret—trade secret, if you will—is in the know-how, the inerts, and

the processes. So, that is our only point there: to limit the disclosure of quantity to the active ingredients.

Under "B," the bill requires a copy of all labeling used for each drug listed. We suggest that that should be amended to: "a representative sampling of the labeling used for each drug listed."

We have no objection, sir, to the FDA seeing all of the labeling. They have ways of doing that now, and perhaps have already seen it. And we have no objection to their seeing it. But on the quantum of the matter—on the logistics of it—we feel that the bill imposes a burden on us, and—though I am not entitled to speak for it—a burden on the administration.

In the case of each prescription drug—and Mr. Stetler has just spoken concerning, and I should leave this to him. But we would have suggested there also that a representative sampling of the advertising used for such drug would be enough rather than all of the advertising as the bill provides.

The next requirement in section 3—or rather "j", of the bill, is that we supply data from which it is determined that the listed drug is not a new drug or an antibiotic drug subject to 507. I think I can just skip over the antibiotics, because I do not think my people get into that at all, but the new drug sections, of course, are applicable. We think that this provision has the potential for involvement and for ramification beyond our ability to foresee. There has been discussion of it here this morning, and perhaps I can abbreviate what I want to say.

The basic act, in section 201 (p), defines a new drug, as you know, as one which is not generally recognized among qualified experts as safe and effective for use under the conditions recommended in the labeling. The oldness of a drug is not determined solely by the presence or the absence of data, and the provisions as to newness are susceptible of varying definition and application; so that whether or not the drug is new is a factual matter, determined—in the event of challenge—by any probative evidence going to the issue of general recognition.

With old over-the-counter drugs—and that is all I am speaking for at the moment—it usually is a matter of long use, common experience and common knowledge to require a filing of "the data from which it is determined" that such an over-the-counter drug "is not a new drug" opens practical difficulties which, we submit, are not necessary in accomplishing the basic purpose of the act to provide an inventory.

For example, would compliance with the law—if this provision is enacted—require the filing of such data for aspirin, Sloan's Liniment, milk of magnesia, Vicks Vaporub, Epsom salts, Castoria, and many others?

And for my friend, Mr. Preyer, I will put in Bengay which he mentioned in one of your recent hearings.

The final thing that this particular section of the act requires is any production data the Secretary may require. I emphasize the expanse of that: "any production data the Secretary may require." As has already been said this morning, section 704 of the basic law provides for factory inspection. The FDA is authorized to inspect the factory, warehouse, establishment or vehicle, and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

In the case of a factory and/or establishment in which prescription drugs are manufactured and packed, the inspection, the law says, "shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this act, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this act."

Now, there are some takeouts there as to financial figures and other things set out in section 704, but my point is that section 704 is a very thorough, ongoing factory inspection section in the law as it now stands, so presumably the bill seeks something different or additional. Thus, the present wording is limitless, as I said a moment ago—"any production data the Secretary may require."

Now, if a provision of this sort is retained, then we think there should be some specificity and some limit.

The bill as now drawn, we think, is susceptible of being construed to provide for preclearance of labeling of all drugs, whether new or not, and no matter how old, and of the advertising of prescription drugs. With respect to prescription drugs, the basic act now provides in section 502(n), that "except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement."

Now, while the bill does not expressly provide for preclearance of the labeling of old drugs, it does provide that before using any new labeling the manufacturer must submit it to the Secretary. It is not clear in the bill what the Secretary is to do, or may do, upon such submission, but we apprehend that in the practicalities of the matter, the procedure—in time and under administrative development—will resemble, if indeed it does not actually become equivalent to, preclearance.

We suggest revision to provide that if the person making the required listing later makes material changes in the labeling, or in the advertising of the prescription drugs, as submitted to the Secretary, such person shall promptly notify the Secretary of such changes.

(4) The last point I have relates to section 3(j)(2). It provides that "upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug not contained in any list filed" pursuant to the act, the person shall immediately notify the Secretary of the fact and supply the required information.

Now, we presume that the purpose of that provision is to keep the list current, and we certainly support that objective. The present wording of the bill at this point causes us concern lest it be so construed as to make listing a condition precedent to engaging in business or to producing new products which are not—in the law's definition—"new drugs." We suggest that the provision be revised to require periodic—annual or semiannual—notification to the Secretary of any drugs marketed in addition to—or other than—those presently or previously listed.

Mr. Chairman, I close, as I began. I express again my appreciation to the committee and our hope that we may assist you and the staff in revising this bill.

Mr. ROGERS. Thank you very much, Mr. Hoge, for your statement which sets forth, I think, very clearly the position of your people, and it will be helpful to have this information, and we would be glad to receive specific language. I think you have stated some of it already.

Mr. HOGUE. Yes; I will supply it to your staff.

Mr. ROGERS. Mr. Kyros?

Mr. KYROS. Thank you, Mr. Chairman.

Mr. Hoge, it is a pleasure to see you here. Anyone who is a friend of Judge Richardson Preyer, our distinguished colleague, is particularly welcome.

On page 6 of your statement, you have made a case against the inclusion in this legislation of the broad provision that the list is to be provided by the manufacturer to include under item (e) any production data the Secretary may require.

Now, what is there in the history of the FDA, and particularly in regard to Commissioner Edwards, that gives you pause for consideration about giving him such broad power?

Mr. HOGUE. Well, I do not think that my concern has anything to do with Commissioner Edwards as a person. I do not know how long he will be the Commissioner. Commissioners come and go. And, then, Mr. Kyros, beneath the Commissioner level the work is done, of course, by the staff. My only point is that if we are writing a law for the future, without regard to any given person, we ought to have the language in a more limited fashion.

Mr. KYROS. Well, let us look at the FDA. Give me an historical reference, a concrete instance, where language such as this has been harmful in the past.

Mr. HOGUE. I do not believe I can do that right at the moment. I have been in this a long while, and there have been times when, as an advocate, I have thought they exceeded the limits. I really would have to go to my file to document it, to be prepared to substantiate it with illustrations. I do not want you to think I am criticizing the FDA as such. I would say the same of almost any bureau or of any given group of men that were given such authority in legal matters.

Mr. KYROS. Do you think it is just that kind of discretionary language with such a broad mandate that is simply not necessary for the effective carrying out of this bill?

Mr. HOGUE. That is right. Well, Mr. Kyros, I really do not know what they are getting at. Now, in this questionnaire they asked us for production data to which I have no objection. They ask how much or how many batches of the particular product to which the questionnaire applies were manufactured in the last 3 months or 6 months.

Now, "production data" can get into practically anything when you are dealing with complicated factory and medical processes and machinery. That is my point with it. I merely want some limitation, some boundary put here, sir.

Mr. KYROS. Thank you. Thank you, Mr. Hoge.

Thank you, Mr. Chairman.

Mr. ROGERS. Dr. Carter.

Mr. CARTER. It is certainly a pleasure to have the distinguished gentleman appear before us today. It is my feeling that perhaps there is some worry on the part of the industry that you will, again have to clear such drugs as you have sold for many years like Sloan's

Liniment, Milk of Magnesia, Vicks Vaporub, and so on, and that they might be taken from the market and would affect the industry adversely quite seriously; is that true?

Mr. HOGE. That is true, Dr. Carter, but I would not put it only there. I think unless there is some public purpose really to be served, those old products should not be required to go through the rather involved, lengthy, and complicated processes under the new drug provisions. And, again, I am not criticizing the provisions, I am just simply telling you—I think I brought it with me—the code of regulations has some 15 pages of fine print as to what one must do when he applies under the new drug section.

Mr. CARTER. Certainly, as a youngster I was brought up, as many of us in the South, the area that I came from, on Vicks Vaporub—Vicks Croup Salve, as it was called at the time. I believe it was psychologically effective, at least to a certain extent. I would hate to see it removed from the market.

Mr. HOGE. Dr. Carter, I began my career in this work as a lawyer for the Vick Chemical Co., and its Vicks Vaporub.

Mr. CARTER. Yes, sir. Again, I notice that you do not object to naming the active ingredients, but you do object to naming the inert substances, and I believe this would be, I should think, because of the fear that the method of manufacture or the formulation of this drug might be revealed. Actually, you have certain ingredients which make a cough syrup more palatable, a different kind of vehicle in many instances; is that true, which really is a trade secret?

Mr. HOGE. That is true, and I am doing what lawyers frequently have to do, and that is, take what my client tells me, and that is what I am told, sir.

Mr. CARTER. Well, yes, sir. Thank you, sir, very much.

Mr. HOGE. Good to be with you, sir.

Mr. ROGERS. Dr. Roy?

Mr. ROY. I have no questions. Thank you, Mr. Chairman.

Thank you, Mr. Hoge.

Mr. ROGERS. Mr. Hastings?

Mr. HASTINGS. Very briefly, Mr. Hoge, can you tell me the number of products involved in the Proprietary Association, the same question I asked before?

Mr. HOGE. I thought you were going to ask that. I do not know, sir, but I do think that we would like to know and maybe we can find out. It would be a large number, yes; a great number.

Mr. HASTINGS. Do you think you might be able to provide that information for us for the record?

Mr. HOGE. Let me just put it this way: I will make an effort and will provide with what I get or tell you if I do not get anything.

Mr. HASTINGS. How about the retail sales; do you have any idea?

Mr. HOGE. I really do not, but I will do the best I can to get you both.

(The following information was received for the record:)

PRODUCTS MANUFACTURED BY MEMBERS OF THE PROPRIETARY ASSOCIATION

As to the number of products manufactured by members of The Proprietary Association, we do not have complete information. We do have some information, and the members of this Association do account for a very large percentage in volume of the proprietary medicines made and distributed in this country.

We have an actual listing of approximately 500 products made by our members, but there are many more than that. These are over-the-counter medicines which are advertised direct to the public. As to the number of such products made by others than our members, any figure would be just an estimate or a projection based upon a variety of samplings. And, the number would include products of limited production and distribution: regional or local.

It must be made clear, too, that any stated number of products—whether made by our members, or others—would include competing brands of the same or similar products (as with aspirin) as well as different dosage forms, such as liquids and tablets, and also different sizes.

Practically all of the articles produced by members of The Proprietary Association are brand name products. That is, they are sold under trademarks. As pointed out earlier, there are many over-the-counter medicines which are advertised only to the professions.

There is an excellent listing of non-prescription drugs published by the American Pharmaceutical Association. It is entitled "Handbook of Non-Prescription Drugs." It includes 1,122 items. These would be the better known ones. This figure would have to be projected by some multiple to get at the total of all products. Many of the items would be quite similar (often the same) as other items listed. This figure includes many items made by manufacturers other than those in The Proprietary Association's membership, and it includes items which are advertised only to the health professions.

RETAIL SALES OF PRODUCTS MANUFACTURED BY MEMBERS OF THE PROPRIETARY ASSOCIATION

We do not have accurate figures on the retail sales of products made by members of The Proprietary Association. A special *Drug Trade News* report on 1969 retail sales includes "packaged medication" at \$2,592,050,000. From that figure must be subtracted the amount of \$480,000,000 as duplication. A footnote (No. 44) explains "duplication" as "the estimated amount received when packaged medications and other health aids of the types listed above are supplied as prescription." The figure thus arrived at is \$2,112,050,000. This includes sales of products other than those manufactured by members of The Proprietary Association but, as stated, the members do make a very substantial proportion of the packaged medication sold other than on prescription.

Mr. HASTINGS. Thank you.

No more questions.

Mr. ROGERS. Thank you so much, and I think your position is quite clear, and we are grateful to you for being here to set forth your position.

Mr. HOGE. I was very grateful to have the opportunity to be here, Mr. Chairman, and I thank you all.

Mr. ROGERS. Thank you.

Any other questions?

That concludes the list of witnesses, and the committee will stand adjourned.

(The following letter was received for the record:)

ANIMAL HEALTH INSTITUTE,
Washington, D.C., July 2, 1971.

HON. PAUL G. ROGERS,
Chairman, Subcommittee on Public Health and Environment, Committee on
Interstate and Foreign Commerce, House of Representatives, Washington,
D.C.

DEAR MR. ROGERS: The Animal Health Institute, the national trade association representing manufacturers of veterinary pharmaceuticals and animal health products, supports the concept of a continuing inventory of marketed drugs and supports enactment of H.R. 4749 with the changes suggested in this letter.

The institute supports the establishment by FDA of an inventory of all drugs, including animal drugs, presently on the market. It therefore endorses those

portions of H.R. 4749 relating to periodic submission of lists of all drugs manufactured for commercial distribution. It also supports a requirement that such manufacturers submit, within a reasonable length of time, notice of the initiation, discontinuance, or resumption of manufacture of drugs. The Institute believes that knowledge of the drugs, including animal drugs, currently on the market is important to FDA's mission and that the agency should be given authority to obtain this information.

The Institute does not support, however, some of the provisions of the present bill which go beyond the listing and recording of drug products and which might be the basis for assumption by the agency of licensing control of drug products not presently subject to such control. In particular, the Institute objects to requiring the submission of labeling and advertising (other than for human prescription drugs) prior to their use. Nor does it see the need for requiring the registration of drug products before they are placed on the market. The Institute has no objection to a requirement that this material be furnished on a periodic basis so long as it does not operate as a preclearance requirement for the products registered.

The Institute particularly wishes to register its strong opposition to the requirement in the present version of H.R. 4749 that FDA be furnished with "the data from which it is determined that (a product) is not a new drug" as it would apply to animal drugs not covered by approved NADAs. Requiring such data compilation would constitute a difficult and unnecessary burden on the manufacturer or distributor of the drugs involved. In the case of many old, well-recognized remedies, it would unnecessarily present great practical difficulties. The requirement in effect would eliminate completely the distinction in the present Act between "new animal drugs" and those not subject to Section 512 of the Act. Certainly, in the case of animal drugs, we are aware of nothing that would justify such a radical departure from the present, recently enacted, statutory scheme of the Act.

Very truly yours,

FRED H. HOLT, *Executive Vice President.*

(Whereupon, at 11:50 a.m., the committee adjourned.)



