

Now as to some of this I may not understand the full scope of what the bill is saying. I am trying to read the wording of the bill and see if I can discover what it means. "Established name" for a drug or for an ingredient thereof means (1), so says the bill, the standard name established under section 508 (the preceding section of the bill), or (2) if there is no such name and such drug, or such ingredient, is recognized in the Compendia, then the Official Compendia name, or (3) if neither (1) or (2), then the common or usual name, if any, of such drug or of such ingredient.

Particular attention must be directed to the word "ingredient." Does the amendment mean that where there is no established name for the drug itself, the ingredients must be given precedent in position over the proprietary name of the article and be displayed in type at least as large and prominent as that used for the proprietary name? The importance of that question is related to the requirement, brought forward from the present law, that articles made up of two or more ingredients must be labeled to disclose the "common or usual name" of each active ingredient. That is all right—and if that is what the amendment would mean, it is all right—unless the amendment has the effect of requiring the names of these ingredients to be given precedence in position over the proprietary name of the article and to be shown in type at least as large and prominent as that used for the proprietary name.

Many proprietary products have many ingredients. Some of them—I am looking at two small ones here, a bottle of Murine and a tube of Mentholatum—have anywhere from 6 to 12 ingredients. Now there is no common or usual name for an article of this sort. It is a combination of ingredients. Murine is its trademark. It may have a descriptive term. It is an eyewash. I guess that is accurate enough. That is a descriptive term that identifies the nature of the article, but there is no name in any book for this article, and it has some nine ingredients. Now I don't know that the bill means this, Mr. Chairman, but there are many people who think that it does; that the way it is worded today, where there isn't a common or usual name, there would have to be these nine ingredients listed, and listed in precedence to the trademark, and listed in type of the same size as the trademark.

I must say to you candidly I can't believe that that is what any one has intended, but we are working on a proposed statute and are trying to revise it to accomplish what is intended by the Congress. So it is a fair question, and it is one which is raised very frequently by people who are studying this bill today. Likewise, with this little package, a little package of Mentholatum, it has no common or usual name. It is a salve. It is a salve for colds. It has seven ingredients, but there is no common or usual name—there is a descriptive term. It is a salve, and you may modify that to call it a cold salve or something of that sort. And so with proprietary medicines there are descriptive terms: Antacids, analgesics, laxatives, and so forth.

The CHAIRMAN: Isn't Mentholatum the name of it?

Mr. HOGE: Mentholatum is a trademark. That is just what I was worried about a moment ago. Suppose under this power without some restraint the Secretary construes, and by regulation declares, that Mentholatum is the "established name" of this article, do we go one step further and inquire whether that would be for this particular article or for any article similar to it.

Now, many articles may be and are on the market similar to it. They may even have the same active ingredients. They might not have the same quantities of the active ingredients or they might have the same quantities of the active ingredients but have different inactive ingredients which would have a material effect upon the action of the article. So quite aside from the injustice that might be done to the owner of the trademark, confusion would be opened up wide. And that is true of practically all of these proprietary articles. Very few of them are single chemicals. That is true frequently with the ethicals, and yet it isn't always true with them. It certainly isn't always true with the ethical over-the-counter items. They too may be combinations.

Mr. Chairman, labeling under these requirements would be difficult at best, and if some of my questions are apt, it would be grotesque at worst. These provisions are an offshoot from the so-called generic name proposals contained in S. 1552 introduced by Senator Kefauver, and H.R. 6245 introduced by Mr. Celler. Both bills having been the same at the time of introduction and both having been entitled "Drug Industry Anti-Trust Act," the avowed purpose for these provisions in those bills was to discourage prescribing medicines by trademarks. It was represented that these provisions in those bills would thus be effective to reduce the price of prescription drugs.

Proprietaries weren't considered in those bills or in the hearings at all, but this was represented and, as I think in a statement just here the other day, it is repeated now that provisions of that sort would reduce the price of prescription drugs.

The proposals were not advanced in the Kefauver and Celler bills or in the hearings on them as being essentially protective of the public health. They were economic in character and were to apply only to drugs sold on prescription. In H.R. 11581, these provisions would apply to all drugs. And this bill is concerned primarily not with price but with the traditional province of food, drug, and cosmetic legislation, i.e., public health. The existing law has ample provision for informative labeling.

I say to you, sir, I am not dogmatic about it. I haven't any objection to some change if the Congress thinks there should be a change, but I say to you for the moment—so we will be informed—the existing law does have provision, and, in my opinion, ample provision for informative language. Section 502(c) provides that a drug is misbranded if any information required by the act—

to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

I can say to you out of my private practice, Mr. Chairman, that the Food and Drug Administration has been constantly diligent and active under this provision of the law. They have been very constructive in the way they have gone about it. There haven't been a great many criminal prosecutions and serious offense charges of that sort, but there have been innumerable situations where manufacturers and distributors are cited to come in before the Food and Drug Administration, hear its criticism and make adjustment. Adjustment is usually made—in my experience almost always made—by revising

the language to conform to what the Department wants in size of type, in prominence of position, in coloring of background, and that sort of thing. That has been, and is today, a very active area of administration, and I think a very constructive one and a very effective one.

Section 112, the one we are discussing, would require formula disclosure of proprietary medicines (p. 18, line 23). Drugs composed of two or more ingredients must under the bill be labeled to show "the established name and quantity of each active ingredient." This is a throwback to the original food, drug, and cosmetic bill introduced on June 12, 1933 as S. 1944 and generally known as the Tugwell bill. It provided (sec. 8(e)) that a drug would be misbranded if its label failed to bear (1) "the common name of the drug, if any there be," and (2) "the name and quantity or proportion of each medicinal or physiologically active ingredient thereof." This was vigorously opposed and the bill was amended and enacted in the form of the present law which, at section 502(e) requires only the listing of the names of the active ingredients and the quantities of certain specified ingredients such as alcohol, chloroform, bromides, strychnine, and perhaps 10 or 12 others.

The quantitative formula is a trade asset—frequently a very valuable one. The label disclosure of it not only destroys the property right of the owner but it opens the door of opportunity for counterfeiting, substituting, and passing off. The bill, therefore, in the provisions of section 112 would—if enacted—seriously impair and frequently destroy proprietary rights. It takes a dual approach to this end: (1) The dilution of the trademark by the labeling predominance for generic names, and (2) the public disclosure of the formulas.

I emphasize the word "public" there, Mr. Chairman, because in a moment when I come to factory inspection I am going to suggest our willingness to expose to the inspectors quantitative material on the formula. That is one thing. It is another thing to put it on the label.

Now, quite aside from giving up trade assets, a favorite way of counterfeiting or substituting or even price competition is for competitors to take two packages and say: "You see, they are the same thing. The ingredients on each package are the same and even the quantities are the same, this one is cheaper, so buy this one." That is quite common in fields of unfair competition other than this.

The monetary value of trademarks and trade secrets is very great indeed. The value of them for purposes of identifying desired products, guaranteeing their quality and uniformity, fixing responsibility, and protecting consumers against spurious goods, is even greater. Trademarks and proprietary rights are vital parts of the private enterprise system and much of our economy has been built upon the recognition and protection of them.

I understood, Mr. Chairman, there was a witness before you last night—I didn't hear him—speaking of the turn in Russia, turning back to trademarks for identified merchandise and names.

Let me say to you that trademarks constitute one of our most ancient economic institutions. Etruscan vases found in Italy today bear the trademarks of people long ago. So do things unearthed at Pompeii. I am thinking of one in particular that was labeled—it would seem modern—Scaurus' brand of jelly. That is on an exhibit

in Naples today out at Pompei. Heraldry merged with trademarks because a knight going into battle had to be identified with his visor down and so he had to be marked with a color or emblem. Hallmarks for silver came from being registered in the Guild Hall in London. Thus we have "hallmarks."

Trademarks have figured as long as we have any record for fixing responsibility, for identifying. They were important in the old days in the case of shipwrecks. And so when we talk on this bill, and on the bill in the Senate, about generic names and trademarks, we are dealing with a very ancient institution.

In the making of drugs, some manufacturers are not satisfied with the minimum requirements of the compendiums. They set higher standards for their products and they seek to discover and formulate new products. The incentive to excel is inherent in the system.

The section could be appropriately amended by striking out the words "and quantity" in line 23 on page 18, and by striking out lines 3 to 11, inclusive, on page 19. Those lines have to do with the precedence of position and the same size of type.

I come now to the last section that I ask your indulgence on. Section 201, pages 30-32, "Inspection of Factories and All Things Therein": Here the bill would amend section 704 of the act to authorize employees designated by the Secretary to inspect factories, warehouses, establishments, consulting laboratories—and consulting laboratories I suppose would take in universities, colleges, hospitals, establishments of all sorts—vehicles and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

Up to that point except for the inclusion of consulting laboratories, it is the same as the present law, but now we go on—

And all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded . . . have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations or potential violations of this act.

This would authorize unlimited inspection, and no one—layman or lawyer, manufacturer, consultant, processor, warehouseman, wholesaler, retailer or carrier—could refuse inspection of anything. It is a criminal offense (sec. 301(f)) to refuse "to permit entry or inspection as authorized by section 704." And by the amendment the authorization is so wide that one would be afraid to refuse any inspection. The catchall phrase (p. 31, lines 8 and 9) "otherwise bearing on violations or potential violations of this act" underscores that the proposed power is for carte blanche inspection.

It is important that the discussion of the proposed amendment be introduced by a reference to (1) the fact that the Food, Drug, and Cosmetic Act is a criminal statute, and (2) that the fourth amendment to the Constitution of the United States assures—

the right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures . . .

The statute is indeed a criminal one. Violations of its many complex, technical requirements—many of which are framed by future regulations of the Secretary's making—are punished as crimes by fines or imprisonment or both—as misdemeanors, and as felonies with a \$10,000 fine and 10 years in prison—and guilt does not depend upon

guilty intent and is not avoided by innocence of intent. Indeed, so strict and severe is this statute that criminal punishment may be inflicted upon corporate officers personally even when they have no personal knowledge of the offense or even of the shipments involved, and this may happen even when the officers' corporation is found not guilty. (*United States v. Dotterweich*, 320 U.S. 277; 1943.)

The president of the corporation was convicted on two out of three counts, I think. For some unexplained reason—I believe that it is so stated even in the books—the corporation of which he was the president was found not guilty, but the president was. He had no knowledge whatsoever of the shipment. But he was the president. He was the overall boss of the works, and he was convicted and the Supreme Court upheld the conviction.

Factory inspection, as it is presently constituted in the act, is the result of an amendment in 1953 before this committee following the *Cardiff* case (*United States v. Cardiff*, 344 U.S. 174). At the time of that case, section 704 of the act authorized entry and inspection "at reasonable times" and—this was the important line—"after first making a request and obtaining permission" of the operator. Section 301(f) then, as now, prohibited refusal "to permit entry or inspection" as authorized by section 704.

The Supreme Court held that the statute—in making inspection dependent on consent and making refusal to give that consent a crime—did not give the factory owner fair warning of the criminal nature of his refusal to give consent and was too vague for judicial enforcement. The Court affirmed the Court of Appeals for the Ninth Circuit (194 F. 2d 686) which reversed the district court and ordered an acquittal of the defendant. Amendments to overcome the effect of this decision were proposed in several bills which were the subject of hearings before this committee on May 19 and 20, 1953 (83d Cong., 1st sess.) H.R. 2769, H.R. 3551, H.R. 3604. H.R. 5740 was prepared after the hearings, reported by the committee, and enacted after debate on the floor.

In the *Cardiff* case, Mr. Justice Douglas said—

Before I quote that I want to say to you, Mr. Chairman, that I am sure you and other members of the committee remember the searching consideration given to that amendment in this committee in 1953, and the extensive floor debate which was had in this House. It was more extensive in this House than it was in the Senate, but there was floor debate and a good deal of committee consideration in the Senate too. So, what we have in the law today came as a result of some very searching inquiry and examination by this committee.

Now, in the *Cardiff* case, Mr. Justice Douglas said:

The vice of vagueness in criminal statutes is the treachery they conceal either in determining what persons are included or what acts are prohibited. Words which are vague and fluid (citing cases) may be as much of a trap for the innocent as the ancient laws of Caligula.

In *Boyce Motor Lines, Inc. v. United States*, 342, U.S. 337 (1952), the Supreme Court said:

A criminal statute must be sufficiently definite to give notice of the required conduct to one who would avoid its penalties, and to guide the judge in its application and the lawyer in defending one charged with its violation.

Does the proposed amendment meet these tests? Will a manufacturer or his lawyer dare refuse the inspection of anything? In an-

swering these questions, we may go back to the *Cardiff* case. Prior to that, the Food and Drug Administration maintained that the comparatively limited inspection of section 704 covered every feature of a factory's operation. The administration contended that the section even then authorized inspection of private formulas, complaint files and qualifications of technical personnel. The following is taken from the Government's petition for certiorari in that case:

Factory inspection of a drug plant may include observation, photographing, and appraisal of the following factors on the premises: (1) Conditions of sanitation, (2) raw materials, (3) formula cards, (4) actual manufacturing work-sheets, (5) batch records, (6) weight and measuring controls, (7) packaging techniques, (8) sterility and pyrogen controls, (9) potency controls, (10) coding system, (11) facilities for maintaining separate identity of each drug, (12) cleaning of equipment between batches, (13) quarantining of drugs until after clearance with control laboratory, (14) qualifications of technical personnel, (15) the complaint file of the firm. In addition, samples and labeling of doubtful materials are purchased from the factory for analysis and appraisal by food and drug scientists, and shipping records relating to sources of raw materials as well as to destinations of finished products are examined and copied to facilitate the removal of offensive merchandise from interstate commerce.

The then Commissioner of the Food and Drug Administration, Charles W. Crawford, testified before this committee that the language of section section 704 did authorize the inspection of numerous items described in that quotation. (Hearings, May 19 and 20, 1953, pp. 84-86.) If the proposed amendment that we have before us now with no limitation in it, should be interpreted in the ratio in which the limited language of the law was interpreted in that certiorari petition, the range of future inspection can be as wide as the imagination.

In these circumstances, it would be better to specify what is subject to inspection. The law, as presently worded, and even more so as administered and as acquiesced in by the industry, already permits extensive factory inspection.

We are not opposed to factory inspection. We would just like to have some limitation, or some security against unwarranted demands for inspection.

With respect to proprietary drugs, we think the inspection provisions of the law are now adequate. But the members of the association are not opposed to inspection except the sort which the bill proposes, the sort which would amount to fishing expeditions and would constitute unreasonable searches.

We suggest the following revision of the proposed amendment—and we make this suggestion, Mr. Chairman, with advice of factory people, in an effort to be constructive and to suggest something that would accomplish what the Food and Drug Administration wants and would give the industry protection.

So we would suggest that the section read:

SEC. 704. FACTORY INSPECTION. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such

factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein—

and this would be new—

*and all pertinent sanitation methods, analytical reports on unfinished materials, quantitative formula data for active ingredients, qualitative formula data for inactive ingredients, facilities for weighing and measuring, packaging facilities, sterility controls, active ingredient assay controls, coding systems, facilities for maintaining separate identity for each drug, cleaning of equipment, methods for quarantine of drugs until after clearance with control laboratory and file of complaints from licensed medical practitioners and licensed medical institutions.*

A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Mr. Chairman, that would give the Food and Drug Administration the substance of what it said it had in the petition for certiorari in the *Cardiff* case.

Some of it would read exactly on it; some other would read in substance, but it is fair to say, I think, that what we have proposed here would give the administration practically everything that they said the law in 1953 gave them in this *Cardiff* certiorari petition, and, at the same time, it would enable a man to know what he must show. It would enable a lawyer to tell his client that you can safely refuse inspection on this without the danger of criminal prosecution.

I include by saying that I hope that I have indicated the sweep and the substance of this legislation, and the need for thoroughgoing and analytical study of it by this committee. Mr. Chairman, it has been my privilege to appear before this committee a number of times over the years, and I know at first hand the care with which this committee studies its legislation, and I thank you for hearing me this morning on this bill.

The CHAIRMAN. Mr. Hoge, thank you very much for your very full and apparently complete statement and your analysis of this proposed legislation.

You have been so thorough in your description that I cannot imagine there will be too many questions to be asked by the members of this committee.

Mr. Roberts, do you have any questions?

Mr. ROBERTS. I agree with the chairman.

I think it has been a very complete and comprehensive statement. I am sorry I was not here when Mr. Hoge began his statement, but I would like to go back to the area where you talk about the over-the-counter items such as Mentholatum, Murine, and similar-type products.

Is it your contention there that present labeling in most instances is sufficient, and that to go with the type of labeling that you think might be required would bring about a very difficult situation. I believe you used some words which I assume to mean that some of these articles are so small in packaging that it would be very difficult to show the ingredients in the same type as you show the trade name.

Is that the point you are making?

Mr. HOGE. This is in addition, Mr. Roberts, if it means what I suggested that it may mean. If it should mean that these seven or eight ingredients had to be shown in letters the same size and type as the word "Murine," it would make a packaging job—I used the word

"grotesque" advisedly. I think it would be grotesque. It might not even be possible to do it. But, at best, it would be a very difficult job, and would literally destroy, I think, the trademark value of the labeling.

Mr. ROBERTS. You made the further point that these requirements are economic in character and have very little to do with public health, in your opinion.

Mr. HOGE. That is my opinion, Mr. Roberts, but it also—I have as my authority for it, the statements made by the gentlemen in the Senate who advocated these provisions which appeared there before they came here. The chairman of the subcommittee there stated, and on numerous occasions, that these provisions were for the purpose of reducing the price of prescription drugs. He had no reference whatever to these proprietary items.

Mr. ROBERTS. Now, go back to this statement that you had with reference to the power sought in the new bill as far as personnel is concerned.

I would like for you to discuss that just a little bit, where you talk about facilities and equipment. I believe you say that, in your opinion, this would give the Administrator a great deal of power over the personnel of a manufacturer, and you propose to strike from (a) (1)—

Mr. SCHENCE. Where are you reading?

Mr. ROBERTS. I am on page 4 of the statement.

You propose to strike subsections 2 and 3?

Mr. HOGE. Yes.

Mr. ROBERTS. Under (B)?

Mr. HOGE. Yes. That is just on labeling.

Mr. ROBERTS. You propose to strike a part of (B) also, do you not?

Mr. HOGE. The word "personnel."

Mr. ROBERTS. "Controls used for," you propose to strike?

Mr. HOGE. No, sir; only the word "personnel." "Controls used for, facilities, methods," I would leave in.

Mr. ROBERTS. You take out "personnel"?

Mr. HOGE. "Personnel," yes, sir. It seems to me, Mr. Roberts, that there is a big difference in the Government regulating and supervising, to some extent, to the proper extent, let us say, machinery, sanitation, housing. It is another thing to get into the personnel, the qualifications of personnel, how long they have worked for us and whether they have got college degrees or have not got college degrees. We are dealing with people, and I think a different test is indicated.

The CHAIRMAN. You say that is on page 4?

Mr. HOGE. Yes, sir.

Mr. ROBERTS. Page 4 of his statement, the third underscored line which says "facilities or personnel." Also strike subsections 2 and 3 under (B).

Mr. HOGE. Mr. Roberts, I would also strike the power of the Secretary to prescribe these things by regulation. The present law does not do that, and I would strike "personnel," and then two lines below it we have, "regulations promulgated by the Secretary."

Mr. ROBERTS. You would also strike that?

Mr. HOGE. Yes, sir.

Mr. ROBERTS. You want the law to stay as it is at the present time?

Mr. HOGE. Well, no.

The law at the present time comes down to the underscoring. The law at the present time covers unsanitary conditions. Now, the amendment, with the striking that I have suggested, would add to sanitary controls the "methods used in," the "facilities or controls used for;" would put them in the same category with the sanitation control.

Mr. SCHENCK. Will the gentleman yield for a question?

Mr. ROBERTS. I yield.

Mr. SCHENCK. Mr. Hoge, it was my impression that the personnel referred to here was the description of the qualifications of the personnel, their training, experience, and ability of personnel.

Do you object to establishing certain qualifications of that nature?

Mr. HOGE. Yes. I think that is a matter for the manufacturer in employing his people and in studying them over a long period of years to determine whether he has competent personnel. I do not think the Secretary ought to do this.

Mr. SCHENCK. You do not think the matter of competence should enter into this?

Mr. HOGE. Well, necessarily, it enters into it, and it is a part of the manufacturer's responsibility, of course, to have competent help, but I think, to put that under governmental control is a different thing than charging him with the responsibility.

Mr. SCHENCK. Thank you.

Mr. ROBERTS. That is all I have, Mr. Chairman.

The CHAIRMAN. Do you object to giving the Secretary the authority to determine by regulation on the basis of good manufacturing practice as to whether or not a particular person is qualified for the job?

Mr. HOGE. Yes.

The CHAIRMAN. Do you think that the manufacturer should determine the adequacy of the personnel?

Mr. HOGE. Yes; I do.

The CHAIRMAN. And his employment?

Mr. HOGE. Yes.

The CHAIRMAN. That is what this would do, would it? It would permit the Secretary to have that authority?

Mr. HOGE. That would give it to the Secretary; yes.

The CHAIRMAN. Do you interpret this to mean that even though a given person employed by the manufacturer may be well qualified as to background, the Secretary could determine that that person was inadequate—

Mr. HOGE. Well, now, let us see, if he made regulations, I doubt that he could make regulations as to individual persons. He would have to try to standardize. He could not deal with personalities at that point. If he did not have the regulations, then he might in a given case attack the competency of the personnel. But the way it is here, I think it would be a matter of some form of standardization. I do not know what it would be. I would just be guessing.

The CHAIRMAN. It would be based on good manufacturing practices. That would be the key words, I would think.

Mr. HOGE. I have no objection to the language, but I do have objection to the Secretary making the determination. Now, charge the manufacturer, if you please, with having controls and facilities in accordance with good manufacturing practice, and if he does not do it, then make him responsible under the act—his article is adulterated as you have it here—but let us not give the Secretary the authority to standardize these things by regulations.

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Mr. Chairman, just to pursue that a bit further, my impression of the matter of controlling the personnel was the establishment of standards of education or fitness for a given job, not necessarily a personality or a person, but merely broad qualifications, educational and otherwise.

Is this the provision to which you object?

Mr. HOGE. It is the provision, but, Mr. Schenck, I think that it is fair to say that when we are writing this language, we have to consider the growth of it under administration. Now, I happen to know from conversations had respecting this language—I do not think it would be fair for me to quote someone because I cannot document it—that some people advocating this would like to know whether employees had Wasserman tests.

"Well, what has that got to do with it," I asked.

"Well, it may have a lot to do with it."

They would like to know whether the employees had Wasserman tests. They said "We would like to prescribe that they have Wasserman tests."

Well, I am not against Wasserman tests, but I wonder if we are going to have the Federal Government getting into that sort of control. Now, let me say again, Mr. Schenck, that we are not discussing a State or a city ordinance. You might have one situation there. But is Federal, central control to be carried to that extent in this sort of regulation?

Mr. ROBERTS. One more question.

Mr. SCHENCK. Mr. Hoge, it would seem to me that almost all marriage laws require certain health standards. Would you feel that that would be improper in the manufacture of some proprietary medicine?

Mr. HOGE. I think there is a difference.

Mr. SCHENCK. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Friedel?

Mr. FRIEDEL. Mr. Chairman, I am going to be very brief with my questions.

I would like to know what procedure these proprietary drug concerns go through. What standards do they have to have before they can market their product?

Mr. HOGE. The proprietary drugs are subject to the new drug provisions of the law, just as all drugs. I would have to go farther to answer that. A new drug is one which is not generally recognized as safe by experts and so on. Now, if you bring out a proprietary drug today, consisting of ingredients generally recognized, well known, and on good advice there is no question of safety, all you do is bring the drug out, put it up in the proper labeling with directions and warnings and all of the other things that the law requires, and market it, you do not go through any form of pregovernmental control.

Mr. FRIEDEL. You do not have to get the FDA's approval?

Mr. HOGE. No, sir; you do not, unless there is a question of safety. That, of course, poses this situation for the company and its adviser. If there is any doubt about the safety, if one has any question that he may run afoul of the law, then he would file a new drug application, and, very likely, the Food and Drug Administration would report back that: "We do not think the section applies." You then have had your assurance. But that is just a matter of precaution. Now, if you were combining two well-known things and recommending them for time-honored conditions, you would not file any application of any kind.

Mr. FRIEDEL. You would have to have no proof of tests to show that the article is—

Mr. HOGE. You would not if you were dealing, as I say, with these old drugs which are, to use the words of the act, generally recognized.

Mr. FRIEDEL. For example, you just had some salve there. What is that?

Mr. HOGE. One is the Mentholatum salve.

Mr. FRIEDEL. And you stated that it might be a cold salve or it might be a pain salve. Who would determine that?

Mr. HOGE. It is an external ointment according to its directions, "to be used as a vaporizing unguent and balm applied for relief."

Well, the manufacturer determines it, but he does it, of course, on the advice of his chemists, his pharmacologists, and others that he seeks out. And, of course, he may make tests, Mr. Friedel, and probably does. But the law does not require him to file for a new drug unless it is not generally recognized as safe.

Mr. FRIEDEL. This leads to my question. On page 15 of your statement, the bill, pages 8 and 9, authorizes the Secretary to withdraw his approval if it later appears to him that there is substantial doubt as to the safety or efficacy of the drug, to authorize the suspension of approval prior to the hearings when the Secretary finds that there is imminent hazard to the public's health.

Now, are you opposing that?

Mr. HOGE. The place I have it there in my statement, Mr. Friedel, would apply to a drug which is on a new drug application. Now, these proprietary articles, most of them now are not on new drug applications. My point along there was that if you change the definition to include efficacy, so that a new drug is now one which is not generally recognized as efficacious and safe, it might bring in some of these proprietary articles on which no one has any question of safety, but some expert, as the law calls him, might say, "Well, I don't think it will do you any good; I don't think it is harmful; I don't think there is anything unsafe about it, but I don't think that it will do you any good, and, therefore, it is a new drug." And now you have got to go through all of this new drug procedure. Now, those matters on page 15 apply to a drug which, however it got there, is under a new drug application.

Mr. FRIEDEL. Getting away from the proprietary drugs, to a new drug, if the Secretary of Health or the Food and Drug Administration would find that it would be an imminent hazard to the public health he could order suspension of approval without a hearing?

Mr. HOGE. That is right.

Mr. FRIEDEL. That you are opposed to?

Mr. HOGE. Yes.

That is an awful lot of authority.

Mr. FRIEDEL. Do you not think the Secretary would notify you that they have complaints on it or something, prior to withdrawing the drug?

Mr. HOGE. Well, it puts in one man an awful lot of power to say that without a hearing he can just pull this article off the market, on which one has invested, well, somebody said yesterday, I think, about \$5 million to get a new drug on the market.

Mr. FRIEDEL. I do not want to prolong this, but I think in your testimony here you said you had such wonderful cooperation with the Food and Drug Administration?

Mr. HOGE. Yes, we do.

Mr. FRIEDEL. Very few cases have gone to court. They just come in and notify you.

That is why I cannot understand why you are opposed to this, when they have shown in the past that they do cooperate.

Mr. HOGE. I am glad you said that because, in my considered opinion, having worked with this law for many years, I think the great cooperation that the industry has with the Government is due to the fact that this law back there in the 1930's was worked out as a law which stated the obligation of the industry and gave the power, gave power to the Administrator to enforce it, so that both parties have approached this work over the years with respect for each other.

The Food and Drug has assumed its burden and gone about its duty, and the industry has tried to assume its burden and gone about its duty under the law.

I think this statute has been one of the finest statutes that I have ever had any experience with for the reason that it was worked out so carefully back there in the 1930's, and does so clearly state the requirements that are upon us and the duty that is upon the Administrator.

That is what I am asking you to do now with this amendment, is to keep the law that way by revising it—I am only asking for revision, Mr. Friedel. I am not opposing amendment to the law at all except in the details which I have discussed.

Mr. FRIEDEL. That is all, Mr. Chairman.

I would like to pursue it further, but I know we have other witnesses and other members want to ask questions.

The CHAIRMAN. Do you think there should be some procedure, Mr. Hoge, whereby a drug, if there are obvious reasons, could be temporarily withdrawn from the market until after a hearing and such other procedure as may be necessary to determine its safety?

Mr. HOGE. I think you can do that now by injunction, Mr. Chairman.

The CHAIRMAN. Do you think that would be sufficient authority for the Secretary to go to court?

Mr. HOGE. Well, I think so, and I would say this:

That if there is any doubt about it, then I think the act might be revised to make it clear that he could go to court.

You mentioned yesterday the cranberry incident. It is no criticism of the Administrator to say that these things can happen. He is only human, and he has to delegate with this large organization to

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people all down the line, and they are just as likely to go off sometimes as we are.

I think that, just generally, to have a court or to have somebody that is not immediately interested in it, either from the industry's standpoint or the Food and Drug standpoint, to pass upon it is a safeguard which we have long recognized in our system of jurisprudence.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Thank you, Mr. Chairman.

Mr. Hoge, you made the statement that your relationship with the FDA was very satisfactory and with the industry and under the law you knew your responsibilities, they knew theirs, and you have gotten along very well and produced good drugs.

Mr. HOGE. That is correct, yes.

Mr. YOUNGER. Is that a fair statement?

Mr. HOGE. That is a fair statement.

Mr. YOUNGER. Then why, in your opinion, are these changes proposed?

Mr. HOGE. You mean the changes that I have proposed?

Mr. YOUNGER. No, the changes which this law proposes.

Mr. HOGE. Oh, well, I think that they, like ourselves, learn by experience, and, as we go along, we see need for updating the law. We did it here in 1951 with Durham-Humphrey. Experience had taught us that some different controls were needed with respect to prescription drugs and we worked them out. We were here on factory inspection in 1953 because of the Supreme Court decision.

We have been here on food additives because of what we learned in those respects. I think it is just a matter of growth, a larger industry, a larger population, and the things that Food and Drug has learned in administering and the things we have learned in trying to obey the law.

As with this unfortunate thalidomide case, we have all learned something. I am not sure, and, in fact, I have read that it perhaps could not have been prevented. I do not know whether the regulations which the Government has adopted now will prevent it in the future, but on what we have learned the Food and Drug Administration has now proposed some regulations which have been shaped in the light of what has been learned, and it is hoped that they would prevent anything—well, it really did not happen, but it might have happened—and they would prevent anything like it happening again.

That is the reason for it, and I am quite in sympathy with updating this law. Mr. Younger.

Mr. YOUNGER. Primarily, if I understand your statement, you want these changes expressed in the law?

Mr. HOGE. Wherever possible.

Mr. YOUNGER. And not left to administrative regulations of some kind that may change at any time without hearing or without due process?

Mr. HOGE. That is quite true, and I will say to you that there have to be exceptions. I know that, that you cannot deal by express statute with every detail. We have to have regulations. We have to have food standards, as an illustration.

But wherever we can write these matters into law, let us do it and let us not avoid it simply because it may be a little inconvenient to the Food and Drug Administration, or it may be easier for them to do

it themselves rather than to go to the court. Those are not good reasons. They can give you good reasons why they ought to make food standards, rather than have them enacted here in the statute. But, wherever we can, we should write the requirements in the law. That would be the only way I can answer that question without being dogmatic about it.

Mr. YOUNGER. Just one other question.

It is not clear in my mind what you mean when you say that under this law the Administrator or the Commissioner may say that the trademark is the name of the drug. Is that true?

Mr. HOGE. Yes.

There is nothing in the bill, as prepared, that would prevent it, and, as I said in my statement, my anxiety about it is born of experience, because they did attempt that very thing 20 years ago.

Mr. YOUNGER. To follow that just one step further, if the Commissioner were to say that Mentholatum is the name of this product, then would it follow that any manufacturer could take those same ingredients and produce Mentholatum and violate the trademark which the original manufacturer had?

Mr. HOGE. If the Commission declared that Mentholatum was the name of that product, however he would describe the product, if he declared that that was the name of the product, then every manufacturer who put out that product would have to call it mentholatum.

Mr. YOUNGER. Regardless of the trademark?

Mr. HOGE. Yes, sir.

Mr. YOUNGER. Regardless of the protection which the trademark gives to the original manufacturer?

Mr. HOGE. If the law is amended this way, he would have to. As the law is today, no.

Mr. YOUNGER. That is all, Mr. Chairman. That was not clear in my mind.

Mr. SCHENCK. Mr. Chairman?

Mentholatum or Murine or other products you mentioned are compounds, are they not, Mr. Hoge, not drugs?

Mr. HOGE. Yes.

Mr. SCHENCK. Is a compound a patentable item?

Mr. HOGE. Well, practically not today, sir. I do not know of any of these things that are patented. We call them patent medicines frequently, but they are not.

Mr. SCHENCK. In other words, it is a proprietary compound, the knowledge about which is a complete and personal knowledge held by the manufacturer who produces it under a trade name or a brand name or a trademark name, is that correct?

Mr. HOGE. That is true.

It is know-how, we call it, which is so important, and which sometimes is reflected in such unexpected places. For instance, as I said to you in factory inspection, it is one thing to let the inspector see the quantitative formula. It is another to let him see the qualitative formula because the effect of these things is frequently materially influenced by the inactive ingredients, the binders that are used, or the diluents, and much of the trade secret is in those things, the temperatures, the batch controls and so on.

Mr. SCHENCK. Thank you.

The CHAIRMAN. Did I understand you to say, Mr. Hoge, that if this law were to be enacted, that hereafter Vick's salve would become Mentholatum?

Mr. HOGE. Mr. Chairman, I ardently hope that would not be the case. I have represented Vick's salve for a great many years.

The CHAIRMAN. Mr. Roberts?

Mr. ROBERTS. No questions.

The CHAIRMAN. You have been very responsive to the questions, and certainly have shown you know your subject, Mr. Hoge.

The committee wishes to compliment you for it and extend our thanks.

Mr. HOGE. Thank you, Mr. Chairman and gentlemen of the committee.

The CHAIRMAN. The committee will recess until 1:30.

(Whereupon, at 12:05 p.m., the hearing was adjourned, to reconvene at 1:30 p.m., of the same day.)

AFTERNOON SESSION

Mr. ROBERTS (presiding). The committee will please be in order. The next witness is Mr. D. L. Bruner, executive secretary of the Animal Health Institute, 512 Shops Building, Des Moines, Iowa.

You may proceed, sir.

STATEMENT OF D. L. BRUNER, EXECUTIVE SECRETARY, ANIMAL HEALTH INSTITUTE, DES MOINES, IOWA, ACCOMPANIED BY B. H. LEBEIS, COUNSEL

Mr. BRUNER. Thank you.

Mr. Chairman and members of the committee, I am appearing today on behalf of the Animal Health Institute, of which I am executive secretary, to express the views of AHI on H.R. 11581.

AHI is an association of more than 80 firms engaged in the manufacture and distribution of animal drugs—animal health and nutrition products. Our membership accounts for the major share of the production of these products in the United States, the sales value of which approximates \$300 million annually.

Mr. Chairman, the Animal Health Institute is deeply committed to the principle of protecting the health of consumers by legislation requiring manufacturers to establish the safety and effectiveness of new animal drugs. At the same time, we submit that any such legislation should encourage the development and marketing of animal drugs for all safe and effective uses.

The health and productivity of our livestock and poultry populations are dependent, in great measure, on the flow of our industry's products to the farm. Research has made that flow of safe and effective animal drugs possible. Continued research will provide even better products for the future, and help to lessen the tremendous annual livestock losses which, in 1959, were \$2.5 billion. The research effort required to develop these products and make them available

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must be encouraged, if we are to have an adequate food supply at reasonable prices for our expanding population.

For further information concerning the economic importance of animal drugs to the farmer and to the consumer, the members of this committee may wish to refer to the testimony of Dr. Don Paarlberg, Hillenbrand professor of agricultural economics, Purdue University, given August 7, 1962, before the Subcommittee on Health and Safety of this committee on H.R. 12437 and H.R. 12420. Dr. Paarlberg's testimony is brief and I have attached it to my statement for easy reference.

Mr. ROBERTS. It may be received for the record.  
(The statement referred to is as follows:)

[Attachment to statement of D. L. Bruner]

TESTIMONY OF DR. DON PAARLBERG, HILLENBRAND PROFESSOR OF AGRICULTURAL ECONOMICS, PURDUE UNIVERSITY

My name is Don Paarlberg. I am a professor of agricultural economics at Purdue University where I engage in research and teaching in a number of fields including livestock economics. During the previous administration I held various positions: Assistant Secretary of Agriculture, Special Assistant to President Eisenhower, and Food-For-Peace Coordinator.

I am here as a professor of Purdue University, at the expense of the University. The Animal Health Institute invited me to attend but has no financial stake in my presence or in what I shall say. My purpose is to make clear to this subcommittee the importance of the livestock industry and the importance of medicants and other drugs to that industry. In making this statement I have in mind the well-being of our Indiana farmers, who receive nearly three-fourths of their income from the sale of livestock. Nationwide, more than half the gross income of American agriculture is from sales of livestock.

In 1960 the various classes of livestock accounted for farm receipts of the following magnitude:

Cattle and calves .....	\$7,396,000,000
Dairy products.....	4,737,000,000
Hogs.....	2,857,000,000
Eggs.....	1,728,000,000
Chickens.....	1,125,000,000
Turkeys and other poultry.....	431,000,000
Sheep and lambs.....	329,000,000
Wool.....	111,000,000
Other livestock and products.....	224,000,000
Total.....	18,938,000,000

Modern methods of livestock production make the use of pharmaceuticals absolutely imperative. Efficient large-scale production of broilers, for example, with thousands of birds kept in close confinement, would be impossible without medicants. Epidemic disease would decimate these flocks in short order. According to the Journal of Animal Science, 70 percent of the beef cattle on feed are either fed or implanted with diethylstilbestrol, a hormone known to have a favorable effect on the rate of growth. Benefits, according to this same source, are of the magnitude of a 17-percent increase in weight gains and a 12-percent improvement in feed efficiency, as compared with untreated animals.

In hogs, Professor W. M. Beeson of Purdue University found that the inclusion of streptomycin produced an 11-percent increase in daily gains.

One economic effect of these pharmaceuticals is to lower livestock production costs and reduce the price of meat, milk, and eggs to the consumer. At the lower prices, more meat is purchased. Much of the improvement in the nutritive level of the American diet in recent years is attributable to the efficiencies which have resulted from the tremendous strides made in the use of pharmaceuticals.

The following brief table is an indication of the advances in efficiency for various classes of livestock:

	1925-29	1959
Pigs saved per litter.....	5.7	7.0
Lambs saved per 100 ewes.....	86.0	96.0
Calves saved per 100 cows.....	76.0	87.0
Live weight of hogs produced per sow.....	1,154.0	1,487.0
Live weight of lamb produced per ewe.....	58.0	76.0
Live weight of cattle produced per cow.....	890.0	629.0

These striking increases are attributable, to some indefinable degree, to better disease control, better nutrition, the use of hormones, better breeding, better management, and the use of better equipment. Pharmaceuticals relate directly to the first three of these.

No one can say for certain how much higher would be the price of beef roast without veterinary drugs. No one can say how much the cost of poultry meat would rise if there were no medicants, or how much pork prices would increase if there were no antibiotics. Farmers and, I am sure, consumers, hope there never will be need to learn. One thing is sure. Whatever price increase occurred would come from higher production costs, the result of greater mortality and morbidity, and slower rates of gain. All of these would be abhorrent to the farmer.

It is perfectly clear that many veterinary drugs are not in question and are not affected by the legislation before this committee. But some of them are.

The health and safety of the consuming public is properly the major responsibility of this committee. Even though this is the major and indeed the overriding concern, it cannot very well be the only consideration. My purpose is to emphasize that economic considerations also are important. They are important from at least these views: Production costs to farmers, food costs to consumers, and incentives for research in the pharmaceutical industry.

There is undoubtedly a very large sector within which efficient production and human health are wholly compatible. I am sure this committee will do its best to define and protect this area of mutual interest.

Mr. BRUNNER. The AHI associates itself with the testimony provided by PMA on H.R. 11581. My comments, accordingly, will be limited to (1) describing the unique impact of existing law and of H.R. 11581 on animal drugs as distinguished from drugs for human use, and (2) suggesting means for correcting the regulatory nightmare which now seriously impedes the clearance of new animal drugs and which would worsen substantially if H.R. 11581 were enacted without amendment.

The adverse impact of existing law on the clearance of new animal drugs was discussed in considerable detail in my statement submitted August 7, 1962, on behalf of AHI to the Subcommittee on Health and Safety of this committee on H.R. 12437 and H.R. 12420, with particular reference to pages 4 to 14 of my statement. At this time, I will briefly discuss the operation of existing law in this field.

#### TRIPPLICATION OF CONTROLS

A major problem, shared by drug manufacturers, feed manufacturers, livestock and poultry producers, and, ultimately, the consumer, is the triplication of controls under the Federal Food, Drug, and Cosmetic Act as presently interpreted and administered. We feel that such triplication is consigning to oblivion the incentive to conduct research and to develop new animal drugs.

Duplication and triplication of legislative provisions applicable to the clearance of new animal drugs has created a top-heavy superstruc-

ture of administrative regulations. This is not necessary in order to adequately protect the public health, and is completely unjustifiable from the point of view of the public welfare or sound legislation.

New animal drugs are subject, first of all, to the clearance provisions of the new drug section, section 505, of the act. As applied to animal drugs, this section requires manufacturers to demonstrate the safety of new animal drugs under the conditions of use proposed for such drugs, which includes establishing their safety when mixed in animal feeds and fed to animals.

Second, the same new animal drugs, when used in combination with certifiable antibiotics, must also be cleared under the regulations promulgated pursuant to the antibiotic section, section 507, of the act. This section requires the batch certification of certain specified antibiotic drugs. It does not purport to create duplication in regulations, but it has led to this result, even though the statute authorizes FDA to exempt any drug or class of drugs from the requirements of section 507. We believe this statute has been distorted because the FDA regulations on the one hand do exempt animal drugs from batch certification but on the other hand subject many of them to detailed clearance procedures, even when such drugs have already been cleared under section 505.

As the law is construed and applied by FDA, every feed and formulation must be cleared under regulations promulgated under section 507, if it contains, among other drugs, a certifiable antibiotic drug. The feed formulation thereupon becomes exempt from batch certification and only then may be marketed.

Third, new animal drugs are subject to the clearance procedures contained in the food additives section, section 409, of the act. This section was intended to apply mainly to chemicals added to human food, which are not otherwise subject to any clearance procedures. Like the antibiotic section, the food additives section was not designed to produce duplication in regulations. Thus, the statute exempts from food additives regulation articles which have been granted prior "sanction or approval" under the act. However, this exemption is so strictly construed that drugs having such a "sanction or approval" by virtue of prior clearance under sections 505 or 507 nevertheless must be cleared under section 409 when used in animal feeds in combination with new drugs not having such an exemption. And the exemption does not apply to any drug whatsoever developed after 1958.

Accordingly, animal drugs are subject to three separate statutory procedures for the same uses involving three separate regulatory divisions of the FDA. These three sections of the law have differing provisions, are subject to differing interpretations, and the actions taken under one are not always consistent with the actions taken under the others.

As a result of this situation, there has, in our opinion, developed an unreasonable distortion of regulatory effort which is totally unjustified and which may seriously retard further progress in agricultural technology.

FDA construes the law to require feed manufacturers, as well as drug manufacturers, to file new drug applications. In effect, this enables FDA to license the use of individual feed formulations of individual feed manufacturers even though the drugs used in those

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formulations have previously been cleared as safe for such use. Thus, the regulations go beyond the establishment of safety of drugs in animal feeds and actually undertake the licensing of the feed manufacturing industry.

Not one of the three preclearance sections of the act was designed primarily to cover the use of animal drugs. However, their combined operation in this field has produced unreasonable delays, overlapping jurisdiction, and extreme confusion within the drug and animal feed manufacturing industries. They can produce serious dislocations, particularly for small manufacturers. Because of the cost and time involved to obtain the multiple-type clearances presently required by FDA, animal health products of a demonstrable utility will sometimes die at their inception.

#### A PROPOSED SOLUTION

Accordingly, we urge Congress to enact a new section to the Federal Food, Drug, and Cosmetic Act which would govern the preclearance of new animal drugs. A bill for this purpose could be entitled "Pre-marketing Clearance of New Animal Drugs." It would amend chapter V of the act by adding thereto a new section, and it would contain other conforming amendments to the act, as well as appropriate transitional provisions. Under our proposal, new animal drugs would henceforth be exempt from the preclearance requirements of the food additives, new drug, and antibiotic sections of the act, inasmuch as the preclearance of such drugs would be governed by the newly created section of the act specifically geared for animal drugs.

By such an amendment, Congress can establish a proper basis for the accomplishment of both of the following purposes:

(1) To protect the health of consumers by requiring manufacturers of new animal drugs to pretest any potentially unsafe drug for use in animals other than man; and

(2) To advance agricultural technology by permitting the use of animal drugs at safe levels.

At the present time, the second of these purposes is being unreasonably thwarted. This second purpose should be specifically recognized by Congress now, in the same manner that Congress adopted a similar purpose in connection with the Food Additives Amendment of 1958. (See H.R. 2284, 85th Cong., 2d sess., July 28, 1958.) Under present circumstances, it is imperative for Congress to take positive steps to reestablish its intention to provide for advancement of agricultural technology.

The new section of the act governing the preclearance of animal drugs would be patterned after the new drug law, section 505 of the act, so that the firm intending to market a new animal drug would be required to present evidence of safety for the proposed use or uses of the drug and obtain an effective new animal drug application prior to marketing the drug. Other provisions necessary to fully protect the public health would also be incorporated in the section.

In addition, we would recommend that the bill we are suggesting for enactment contain provisions which would require the registration of all establishments manufacturing animal drugs or mixing such drugs in animal feeds for sale. Each registered establishment would be subject to inspection and would be required to be inspected at least

once in each 2-year period. We would also support a provision in the bill that an animal drug or feed containing such a drug would be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug or animal feed has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Under these provisions, it would no longer be necessary to require the filing of new animal drug applications for individual feed formulations needed by individual feed manufacturers once the safety of the basic drug and combinations of drugs had been established.

#### IMPACT OF PROPOSED LEGISLATION

Section 105 of H.R. 11581 proposes to extend batch certification procedures under section 507 of the act (now limited to five specified antibiotic drugs) to all antibiotic drugs and to products such as animal feeds containing such drugs. We strongly oppose such a change.

Under existing procedures, such extension will only lead to the imposition of more meaningless clearance within FDA for antibiotic-containing feed products, with no concomitant gain to public health. A number of additional feed formulations not now covered by the antibiotic regulations would be brought under these regulations in addition to other regulatory procedures to which they are subject.

There is no justification for the application of batch certification requirements to animal drugs. No batches of antibiotics used in animal feed are actually certified, even today, and none would be certified under extension of batch certification as proposed in H.R. 11581. But, as discussed earlier in my statement, the so-called exempting regulations issued by FDA amount to licensing controls over individual feed formulations.

As has been previously pointed out to this committee, the original law providing for the batch certification of penicillin was adopted as a temporary measure until satisfactory manufacturing methods, tests, and controls to assure uniformity among batches of different manufacturers could be established. The legislative history of section 507 clearly shows that batch testing controls were to be discontinued when no longer necessary to accomplish this objective. Since today antibiotics can be produced with the same assurance of uniformity and quality as other drugs, the entire batch certification procedure has become an anachronism.

In any case, H.R. 11581 should be amended so as to make it clear that section 105 thereof be limited in its operation to drugs for human use, in the event this committee decides to retain this section in the bill.

Mr. Chairman, may we emphasize that prompt action by Congress is necessary to clarify the legislation and regulations applicable to the use of animal drugs. We appreciate the opportunity of appearing before you today and presenting our views on this important legislation. You may be assured that AHI stands ready to assist this committee in any manner possible.

The CHAIRMAN. I notice you have a document attached to the statement. Do you desire that to be included in the record?

Mr. BRUNER. Yes, sir; if you please.

The CHAIRMAN. It will be included in the record. Does that conclude your presentation?

Mr. BRUNER. Yes, sir.

The CHAIRMAN. Any questions?

Mr. YOUNGER. Just one.

Mr. Bruner, as far as the Animal Health Institute is concerned—and I take it you speak for the industry—

Mr. BRUNER. Yes, sir.

Mr. YOUNGER. You would prefer to have a separate section in this bill dealing solely with the preparation of animal foods?

Mr. BRUNER. Right.

Mr. YOUNGER. And drugs?

Mr. BRUNER. Yes, sir.

Mr. YOUNGER. Mr. Chairman, I wonder if he would prepare a suggested section to the bill and send it to us for our study?

Mr. BRUNER. We would be happy to, Mr. Younger. That is going to take a little time, but we will start working on it, I assure you.

Mr. YOUNGER. Thank you.

(The requested information was not available at the time of printing.)

The CHAIRMAN. Of course, there is some overlapping in your presentation here and in the consideration of the other bill H.R. 12437, on which hearings were held a few days ago.

Mr. BRUNER. That is right.

The CHAIRMAN. The committee will have to take that into consideration, too.

Mr. BRUNER. Mr. Chairman, we did not complete our testimony on August 7 before the committee, and, as I understand it, that Committee on Health and Safety was adjourned upon call of the chairman.

So, while our statement is in the transcript of proceedings, it has not and might not be printed, and we would like very much to have our entire presentation, with the exhibits that were attached, included in the record, in this record.

The CHAIRMAN. Very well.

(The statement referred to, together with the attachments, is as follows:)

TESTIMONY OF D. L. BRUNER, EXECUTIVE SECRETARY, ANIMAL HEALTH INSTITUTE

My name is D. L. Bruner, and I am appearing today on behalf of the Animal Health Institute, of which I am executive secretary, to express the views of AHI on H.R. 12437.

AHI is an association of more than 80 firms engaged in the manufacture and distribution of animal drugs—animal health and nutrition products. Our membership accounts for the major share of the production of these products in the United States, the sales value of which approximate \$300 million annually. The health and productivity of our livestock and poultry populations are dependent, in great measure, on the flow of our industry's products to the farm. Research has made that flow of effective animal health and nutritional products possible. Continued research will provide even better products for the future, and help to lessen the tremendous annual livestock losses which, in 1959, were \$2.5 billion.

This, Mr. Chairman, is the credo of AHI—that through the advances and breakthroughs made in the research laboratories of our member firms, we will be able to do an increasingly better job of protecting the Nation's livestock

from disease and nutritional deficiency. Great strides have been made toward these goals in recent years, particularly through preventive therapy by means of incorporation of animal health and nutritional products in animal feeds. The bulk of manufactured feed, in fact, now contains such drugs in minute amounts for disease prevention and growth promotion.

These drugs have been a major factor in revolutionizing feed technology. They have improved the efficiency of feed conversion and affected the organization of production on the farm, with a resulting higher production of meat, milk, and eggs than would otherwise be possible. At a symposium held in 1956, representatives of the National Institutes of Health stated that the main direct benefit to mankind from the use of medicated feeds is the present availability of more and better foods at relatively less cost to the producer and to the consumer.

However, much remains to be done—new and improved animal health and nutritional agents must continue to flow from the research laboratory, through development and ultimately to commercial production and to the farm. These agents are needed—indeed, they are indispensable if we are to have an adequate food supply for our expanding population. The research and development effort required to find them make them available must be encouraged.

Before dealing with the specific provisions of H.R. 12437, I wish to summarize as clearly and as briefly as possible the effect of the Federal Food, Drug, and Cosmetic Act as currently in force on the incentive for research and development of animal drug products. We believe that the proposed legislation should be viewed in that context, because in our opinion the act as presently administered is curtailing such incentive.

Furthermore, we wish to invite the subcommittee's attention to two measures now pending before the full committee and amounting to a major revision of the Federal Food, Drug, and Cosmetic Act. These are H.R. 11581 and H.R. 11582. These proposed bills, we believe, would in several respects result in further curtailment of research incentive.

H.R. 12437 addresses itself to the food additives amendment of 1958, as do H.R. 12420 and sections 302(a) and 303 of H.R. 11582. In fact, it is limited in its application to ingredients in animal feeds. Therefore, we must assume that the broad problems arising from the application of existing law to animal drugs and the need for legislative remedy therefor have been assigned to this subcommittee.

#### TRIPPLICATION OF CONTROLS

The Federal Food, Drug, and Cosmetic Act as presently interpreted and administered is narrowing down and, we fear, consigning to oblivion the incentive to research and develop new animal drugs—through a triplication of controls. This is a major problem which is shared by drug manufacturers, feed manufacturers, livestock and poultry producers, and ultimately, the consumer. The protection of the public health does not, in our opinion, require such a top heavy superstructure of regulatory clearances as presently exists.

The premarketing clearance of new drugs for safety was first incorporated into our basic food and drug law with the enactment in 1938 of the Federal Food, Drug, and Cosmetic Act. The new drug section of this statute, section 505, was written primarily to require the pretesting of drugs for use in humans. While many such drugs were known to be useful in the field of animal health, subsequent research established the usefulness of incorporating drugs as ingredients in animal feeds for promotion of growth and prevention and treatment of animal diseases. The FDA found it necessary to interpret the then existing law so as to make it apply to these new uses of drugs for which the law had not been specifically designed. This was accomplished by applying fundamentally the same criteria to those drugs as had been established for drugs for use in humans.

One of the basic criteria for the clearance of a new drug application is the control commitments which will insure that the marketable finished dosage form would be identical to that which was tested clinically. This is justified in the case of human pharmaceuticals. However, this concept was carried over into drugs incorporated into animal feeds by requiring that each feed manufacturer submit and obtain an effective new drug application for his medicated feed. This over and above the requirement that the basic drug manufacturer establish the safety of the drug in the first instance. Thus, the FDA saw fit to exercise controls going beyond the establishment of safety of drugs for use in animal feeds, a result which was never contemplated by Congress.

Following World War II, Congress added to the act section 507, requiring the batch certification of penicillin and subsequently four other antibiotics and their derivatives. As in the case of the new drug section, the antibiotic section of the law was primarily designed to provide that such drugs would be safe and efficacious when used in humans. Subsequently, these antibiotic drugs were discovered to be useful when incorporated as ingredients in animal feeds. However, it was obviously impractical to require the certification of each batch of an animal feed containing a certifiable antibiotic. The law authorized FDA to exempt any drug or class of drugs from the requirements of the antibiotic section when such requirements are not necessary to insure safety and efficacy of use. Therefore, once the safety and efficacy of an antibiotic drug intended for use in animal feeds have been established it would have been appropriate for FDA to have exempted such a use of these drugs from any further requirement of the antibiotic section.

However, following a line of reasoning similar to that adopted under the new drug section, the FDA actually proceeded to promulgate regulations, which on the one hand exempted these drugs from batch certification and on the other hand established conditions which served to control the ultimate use of such drugs in animal feeds, reaching as far as individual feed formulations.

The approach the FDA took has produced a paradoxical situation. Any finished feed which contains any amount of a certifiable antibiotic is regulated as though the feed itself were an antibiotic drug. This enables FDA to subject drugs other than antibiotic drugs to the antibiotic regulations, since a preponderance of feeds currently marketed contain other drugs, and such drugs must be cleared in combination with the antibiotics. A vast superstructure of regulations was thus produced by the necessity to apply for so-called exemptions under the antibiotic section covering each individual feed formulation.

In 1958 Congress enacted the food additives amendment, section 409, of the act. This law was primarily designed to require the pretesting of chemicals used as direct or indirect additives in food for human consumption. There is no convincing evidence that Congress intended that this section should be applicable to articles such as drugs for use in animal feeds, which were also subject to the preclearance requirements of other sections of the law. However, following enactment of the food additives amendment, the FDA determined that such drugs fell within the meaning of the term "food additive". This was based upon the interpretation that an animal feed is a food within the meaning of the law, and therefore a drug incorporated into an animal feed is a food additive. The foregoing also applies to animal health products administered orally (other than in feed) and by injection when there is a residue of the drug in the tissues of food byproducts of the animal.

The existence and administration of these provisions of the Food, Drug, and Cosmetic Act, which were written without special consideration for animal drugs, have produced a regulatory system adverse to their development and efficient use. We know of no other type of product which must face a similar regulatory hurdle. This situation does not exist in the case of drugs for human use and cannot be justified in the case of drugs for animal use.

Furthermore, animal drugs are subject to three separate statutory procedures for the same uses, involving three separate regulatory divisions of FDA.

The situation is further complicated by the fact that these sections of the law have differing provisions, are subject to differing interpretations, and the actions taken under one are not always consistent with the actions taken under the others. As a result of this situation, there has developed an unreasonable distortion of regulatory effort which is totally unjustified and which may seriously retard further progress in agricultural technology.

This distortion of regulatory effort, stemming from triplicate statutory procedures applicable to animal drugs, is manifested by a proliferation of regulations—some duplicating others, and some in conflict with others—which must be observed prior to the marketing of these products. These regulations go beyond the establishment of the safety of drugs in animal feed and actually undertake the policing of feed manufacturing industry practices. They constitute substantial overregulation, and they have also produced unreasonable delays, overlapping jurisdiction, and extreme confusion within the drug and feed industries. While they were made possible in part by unusually restrictive interpretations of the law, these interpretations were made possible, in turn, by the application of laws intended primarily for human products to products for animal use.

The regulatory effort of FDA in this field, being split among three separate divisions of the agency, necessarily lacks positive and effective direction. Regulations are issued almost on a production line basis without regard for their necessity to establish the safety of animal health products, or even to their consistency with other regulations by other divisions of the FDA.

To illustrate, let us assume that a drug manufacturer develops a new drug for the prevention of transmissible gastroenteritis (T.G.E.) in swine, a disease for which no satisfactory treatment is presently available. Such a drug would be proposed for use in swine feeds in order to insure a steady and effective level of the drug in the animal.

The first step which the drug manufacturer must take is the preparation and submission of a new drug application under section 505 of the act. This application is filed with the Division of Veterinary Medicine in FDA. It would contain data establishing the safety of the drug to swine, safety of edible products of the swine to humans, controls guaranteeing potency and purity of the drug, and labeling providing adequate directions for use of the drug.

Since the drug is to be incorporated in an animal feed, it is a food additive and therefore must also be cleared under section 409 of the act. Accordingly, the new drug application must be considered in addition as a petition for a food additive regulation. As such, it must also be assigned to staff personnel of FDA having the responsibility for issuing food additive regulations. In order to satisfy the technical requirements of section 409, additional data not related to the safe use of the drug must also be included in the new drug application.

Let us assume that in due course the new drug application becomes effective and the food additive regulation issues, establishing the safe use in swine feed of our new drug for the prevention of transmissible gastroenteritis. Nevertheless this drug cannot yet be incorporated in swine feed, nor can a veterinarian even prescribe this drug for any herd of swine which may need the drug. In order to incorporate this drug in his swine feed, each feed manufacturer must obtain a separate new drug application, since any feed containing this drug is itself construed as a new drug product. Therefore, for each feed manufacturer the time period for the consideration of a new drug application must be further extended before ultimate use of the drug is permissible.

In order to obtain an effective new drug application, however, the feed manufacturer must submit to manufacturing and marketing controls prescribed by FDA. Thus, a law designed primarily to require pretesting to establish the safe use of drugs in humans has been distorted so as to enable FDA to establish licensing controls over feed manufacturers.

Even after all the above steps have been taken, our new drug for the prevention of transmissible gastroenteritis will still be unavailable for use in the great bulk of manufactured swine feeds. This is because such feeds ordinarily contain drugs for other diseases of swine as well as drugs for the purpose of growth promotion. Therefore, the whole process discussed above must be repeated for each combination of drugs which will appear in swine feed, in which our hypothetical new drug is incorporated, and in addition, for each feed formulation containing this drug. Thus, we could anticipate that a substantial number of separate feed formulations would require clearance before extensive use of this new drug could be achieved.

However, we still have not established clearance for the optimum use of our hypothetical new drug for the prevention of transmissible gastroenteritis. In order to do this, it is necessary to obtain clearance, under section 507 of the act, for the use of the drug in feed formulations which also contain one or more of the certifiable antibiotics. In order to obtain such clearance, an application must be prepared and submitted to the Division of Antibiotics in FDA. It will contain essentially the same basic information as originally presented in the new drug application, even though in form the application is a request for an exemption from the requirements of section 507.

Subsequently, a regulation will issue establishing the necessary "exemption" and also prescribing the conditions of use of the drug in antibiotic-containing swine feeds. No feed formulation containing our drug in combination with a certifiable antibiotic drug will be permissible in the absence of a regulation establishing an "exemption" for that particular formulation.

Furthermore, under the rules established by FDA, no such exempting regulation will be issued by the Division of Antibiotics unless and until another regulation has been issued by the personnel administering the food additives section, section 409, of the act. But this is not all. Each feed manufacturer must also submit an application to the Division of Antibiotics to enable him to use the drug

in his antibiotic-containing feeds. Therefore, in order to establish the optimum use of the drug, an additional number of feed formulations would require clearance.

Up to this point, we have assumed that all of these clearances could be obtained without undue delay, and that when obtained they will be consistent with one another. Unfortunately, this has not been the case.

First of all, we have experienced unreasonable delays extending beyond the time specified by the applicable statutes for consideration of applications and/or petitions. We have conducted a survey which, we believe, demonstrates that applications, as a general rule, are taking substantially more time than permitted by law. We are taking the liberty of attaching a tabulation of the results of this survey to this statement.

Furthermore, a number of inconsistencies in regulations have occurred to hinder clearance of drugs in animal feeds.

For example, a food additive regulation recently issued by FDA established specified levels of certifiable antibiotics for growth promotion and feed efficiency in certain animals. Millions of tons of feed containing certifiable antibiotics have been distributed during the past 12 years. They have been sanctioned under an antibiotic feed regulation. The recently issued food additive regulation, however, conflicted with the existing antibiotic regulation which has permitted the use of certifiable antibiotics at lower levels for growth promotion than those established by the foregoing food additive regulation. This discrepancy portrays how present law leads to inconsistent treatment of animal feeds marketed for the same uses.

The existence of triplicate statutory procedures applicable to animal health products can produce serious dislocations for small manufacturers. Because of the cost and time involved to obtain the multiple-type clearances presently required by FDA, animal health products of a demonstrable utility will sometimes die at their inception, particularly if only a limited market potential can be established.

This point is abundantly illustrated by the recent experience of Mattox & Moore as set forth in the letter dated June 27, 1962, from Dr. William H. Feigh of that company to this committee.

We would like to quote a few paragraphs from this letter:

"On October 19, 1961, we submitted a new drug application (NDA) to the FDA as required by law pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act. This application was identified as NDA 13-187 by the FDA. After several months of review by these people during which time numerous scientific questions were raised by them, all of which we answered to their satisfaction, a conditionally effective NDA was granted on January 18, 1962. The conditions required that we follow all procedures as outlined and submit samples of the final printed label, literature, and product to be certain that in all respects our product complied with the specifications as set forth in our NDA.

"On January 24, 1962, Mr. J. K. Kirk, Assistant Commissioner of the FDA wrote us stating that he regarded our product a food additive and that it would not be legal to market until we had an approved food additive petition. We were surprised at this decision since our product is not administered via the feed or water but is injected, and we had proven to the satisfaction of ourselves and the scientific staff of the Food and Drug Administration, who permitted our application to become conditionally effective, that there are no residues in edible meat when the product is used as intended and directed in the labeling.

"Representatives of our company, including myself, visited Mr. Kirk in Washington in regard to his letter. We were told that the technical people had approved the product but that the administrative component of his food additive group, who incidentally are laymen and not scientifically trained, was of the opinion that the product should be classified as a food additive, even though as Mr. Kirk admitted they had no scientific evidence on which to base their opinion and that, therefore, our product would have to be subjected to the further tests and provisions which are required under this section of the law. The questions which Mr. Kirk's group has posed will take another 1 or 2 years to complete plus additional large sums of money. This is something a small company such as ours, which is struggling for its very existence, can ill afford to do. Further, it appears to be absurd to prove the safety of a residue which has been shown to be nonexistent."

Mr. Chairman, we in the Animal Health Institute are convinced there is every reason for the imposition of new drug type controls on products developed by our

members to prevent, control, or cure animal diseases and deficiencies. However, we submit that we are close to being smothered in the triplicate controls and varying interpretations thereof issued in FDA.

A PROPOSED SOLUTION

Accordingly, we urge Congress to enact a new section to the Federal Food, Drug, and Cosmetic Act which would govern the preclearance of new animal drugs. A bill for this purpose could be entitled "Premarketing Clearance of New Animal Drugs." It would amend chapter V of the act by adding thereto a new section 508, and it would contain other conforming amendments to the act, as well as appropriate transitional provisions. Under our proposal, new animal drugs would henceforth be exempt from the preclearance requirements of the food additives, new drug, and antibiotic sections of the act, inasmuch as the preclearance of such drugs would be governed by the newly created section 508 of the act specifically geared for animal drugs.

By such an amendment, Congress can establish a proper basis for the accomplishment of both of the following purposes: (1) To protect the health of consumers by requiring manufacturers of new animal drugs to pretest any potentially unsafe drug for use in animals other than man; and (2) to advance agricultural technology by permitting the use of animal drugs at safe levels. At the present time the second of these purposes is being unreasonably thwarted. This second purpose should be specifically recognized by Congress now, in the same manner that Congress adopted a similar purpose in connection with the food additives amendment in 1958. (See H R. 2284, 85th Cong., 2d sess., July 28, 1958). Under present circumstances, it is imperative for Congress to take positive steps to reestablish its intention to provide for advancement of agricultural technology.

The new section 508 of the act governing the preclearance of animal drugs would be patterned after the new drug law, section 505 of the act, so that the firm intending to market a new animal drug would be required to present evidence of safety for the proposed use or uses of the drug and obtain an effective new animal drug application prior to marketing the drug. Other provisions necessary to fully protect the public health would also be incorporated in the section, which could be suitably identified under a new section of the act.

In addition, we would recommend that the bill we are suggesting for enactment contain provisions which would require the registration of all establishments manufacturing animal drugs or mixing such drugs in animal feeds for sale. Each registered establishment would be subject to inspection and would be required to be inspected at least once in each 2-year period. We would also support a provision in the bill that an animal drug or feed containing such a drug would be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug or animal feed has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Under these provisions, it would no longer be necessary to require the filing of new animal drug applications for individual feed formulations needed by individual feed manufacturers once the safety of the basic drug and combinations of drugs had been established.

As to the agency which would administer an animal drug preclearance section of the law, AHI takes no position.

Alternates that suggest themselves are (1) total responsibility in FDA exercised through a newly created Bureau of Animal Medicine; (2) total responsibility in the U.S. Department of Agriculture exercised through a similar newly created bureau; (3) a divided responsibility between FDA and USDA, with the former passing on the safety of drug residues to humans and with the latter deciding on the use of new animal drugs in agriculture—somewhat in the manner in which pesticides are now processed under the Miller amendment; or (4) any equivalent administrative treatment to insure that reasonable and practical consideration is given to new animal drug applications.

It is the strong feeling of AHI that the assignment of responsibility in this area is the sole prerogative of the Congress. Our prime concern, Mr. Chairman, is with the soundness of the law and not with the controlling administrative agency.

Because of the complexities involved and the shortness of time for preparation of this testimony, we have been unable to prepare detailed statutory language for the proposed new section 508 of the act and the other provisions which would

be incorporated in the proposed bill. We stand ready, however, to assist this subcommittee in the formulation of specific language embodying the recommendations which we have made.

#### IMPACT OF PROPOSED LEGISLATION

Approaching the several bills pending before this subcommittee and the full committee affecting animal drugs, it becomes immediately apparent, Mr. Chairman, that in certain respects these bills would serve to accentuate the triplication of controls and overregulation which we have discussed earlier in my statement. This is an additional reason for the prompt enactment of provisions divorcing the preclearance of animal drugs from human drugs.

I will cite two examples illustrating the unique impact enactment of these proposed bills would have on the animal drug industry.

First, section 105 of H.R. 11581 proposes to extend batch certification procedures under section 507 of the act (now limited to five specified antibiotic drugs) to all antibiotic drugs and to products such as animal feeds containing such drugs. We strongly oppose such a change. Under existing procedures, such extension will only lead to the imposition of more meaningless clearances within FDA for antibiotic-containing feed products, with no concomitant gain to public health. A number of additional feed formulations not now covered by the antibiotic regulations would be brought under these regulations in addition to other regulatory procedures to which they are subject.

There is no justification for the application of batch certification requirements to animal drugs. No batches of antibiotics used in animal feed are actually certified, even today, and none would be certified under extension of batch certification as proposed in H.R. 11581. But, as discussed earlier in my statement, the so-called exempting regulations issued by FDA amount to licensing controls over individual feed formulations.

As has been previously pointed out to this committee, the original law providing for the batch certification of penicillin was adopted as a temporary measure until satisfactory manufacturing methods, tests, and controls to assure uniformity among batches of different manufacturers could be established. The legislative history of section 507 clearly shows that batch testing controls were to be discontinued when no longer necessary to accomplish this objective. Since today antibiotics can be produced with the same assurance of uniformity and quality as other drugs, the entire batch certification procedure has become an anachronism. It has been criticized as wasteful even by a report of the Comptroller General.

Second, section 2 of H.R. 12420, which is identical to section 303 of H.R. 11482, proposes to modify the so-called prior sanction clause of the Food Additives Amendment of 1958. This clause presently appears in section 201(s) of the act. It exempts from the controls of the food additives section of the act, section 409, any additives used in accordance with a sanction or approval granted prior to its enactment. In essence, the modification amounts to this: A prior sanction accorded an additive could be revoked by FDA on the basis of substantial doubt as to its safety. In the case of animal drugs having a prior sanction by virtue of a prior effective new drug application, no hearing of any kind would be required to be given the drug manufacturer prior to the action of FDA.

Mr. Chairman, AHI strongly opposes the enactment of section 2 of H.R. 12420 and section 303 of H.R. 11582. The reasons for our opposition are as follows:

A number of animal drugs became exempt from the food additives section of the act because these drugs had been cleared as safe for use in animal feeds under the new drug section prior to enactment of the food additives section. As to these animal drugs, a measure of dual regulation was thus avoided. Under the new drug section of the act (sec. 505), provision is made for suspension of the effectiveness of new drug applications whenever the evidence shows lack of safety, and there are procedural safeguards to minimize the likelihood of arbitrary action on the part of FDA. We would agree that revocation of an effective new drug application should result in loss of any prior sanction gained by virtue of that application. But we do not think the FDA should be allowed to bypass the new drug procedures entirely and take a drug off the market without resort to the procedural safeguards set forth in the new drug section of the act.

We can see no justification in arming FDA with two separate procedures with two separate legal standards for removing drugs used in animal feed from the market. This would in effect place in the hands of FDA a second power of

revocation. This power would only serve to enhance the duplication and overlapping of regulatory procedures which already bedevil our membership.

We remind this committee again that these products of our industry only became subject to the food additives section of the act at all because residues of them may appear in the tissues or food byproducts of the animal or because they are combined with animal feed for ease of administration and because feed is construed to be food. We do not see on what basis FDA can justify having one remedy under section 505 of the act and a wholly different remedy under section 201(s) whenever it has reason to doubt the safety of a drug which had previously cleared as safe.

With respect to clause (b) of H.R. 12437, however, we note that this clause differs substantially from section 2 of H.R. 12420 and section 303 of H.R. 11582. For example, there is provision for opportunity for hearing and for appeal in accordance with the procedure established by section 505(h) of the act. Accordingly, our objections to the earlier bills on the issue of prior sanctions have in part been met.

On the other hand, clause (b) H.R. 12437 also places in the hands of FDA a second legal standard for removing drugs used in animal feed from the market. Under this bill, the FDA must find, on the basis of substantial evidence of record, that the Delaney clause—section 409(c) (3) (A)—applies to an additive in order to withdraw any sanction or approval available to it. This is in addition to power granted under section 505 to suspend the effectiveness of its new drug application.

We would prefer that FDA be required to avail itself of the remedy set forth under section 505 of the act for suspending the effectiveness of new drug applications. However, in spite of this, we do not oppose enactment of H.R. 12437 as an interim measure pending consideration of our request for basic legislation applicable to animal drugs, provided that H.R. 12437 is amended as recommended by AHI in respect of its Delaney clause provisions.

DELANEY CLAUSE AMENDMENTS

Clause (a) of H.R. 12437 is offered as a relief measure to manufacturers of animal drugs and to feed manufacturers. AHI applauds the purposes of this section.

It would amend the food additives section of the act, section 409, by broadening the power of FDA to permit the use of a substance as an ingredient of feed for animals. At the present time such power is arbitrarily limited by overly strict interpretations of various provisions in the law, including the so-called Delaney cancer clause, which appears in section 409(c) (3) (A) of the act.

Existing law operates in the following manner. Assume a substance is thought capable of inducing cancer when administered in massive doses to susceptible laboratory animals. Assume also this substance is a drug proposed for use in animal feeds. By virtue of FDA's interpretation of the Delaney clause, this drug could not receive clearance under the food additives section of the act, even though it could be proven safe under its conditions of intended use.

Now assume further that this drug was proposed for use and was cleared as safe by the FDA prior to enactment of the food additives section of the act in 1958. Let us say that it was on the market and employed extensively in animal feeds pursuant to new drug applications made effective prior to 1958. In our opinion, this drug should be construed as exempt from the food additives section of the act, and thus from the Delaney clause contained therein, on the ground that it was being used in accordance with a sanction or approval granted prior to enactment of the food additives section, and thus falls within the prior sanction clause contained in section 201(a) of the act. Thus, the continued use of the drug should not be affected by the enactment of the food additives section of the Act.

But FDA did not so interpret the law. Using its power to control individual feed formulations of individual feed manufacturers, and narrowly construing the prior sanction clause, FDA held that for certain manufacturers such a drug was a food additive—and its use barred by the Delaney clause—but for others the drug when used in the same feed formulation would be exempt from the food additives section of the act and thus permissible for use. This amounts to economic discrimination, and arbitrary restriction of the safe use of a drug.

Clause (a) deals with this problem. It proposes to exempt from the operation of the Delaney clause a substance used in animal feeds if it will not adversely

affect the animals and if it does not leave a detectable residue in food products. (Clause (c) would similarly amend the Delaney clause contained in section 706 of the act, dealing with color additives.)

If the objectives of clause (a) are to be realized, however, several clarifying amendments are essential.

First, we do not believe the term "no residue," appearing on line 2, page 2, of H.R. 12437, standing alone, is scientifically meaningful. The bill as presently written requires the applicant for a food additive regulation to prove the total absence of residue. This will not be possible in the case of additives which also occur naturally in the tissues of animals. It may not be possible to determine whether a residue is due to the naturally occurring substance in the animal tissues or to the additive. Therefore, we suggest adding the phrase "in excess of background levels thereof naturally present in the animals" following the word "found" on line 2 of page 2.

Second, we suggest deletion of the phrase "reasonably certain to be" on lines 10-11 of page 1 and substituting therefor the phrase "capable of being". The present bill calls for FDA to consider whether the conditions of use and feeding specified in the proposed labeling of an additive are reasonably certain to be followed in practice. Thus, FDA must speculate whether the customers of the drug manufacturer will obey the law prior to the marketing of the drug. We believe any infraction of the law on the part of the customer should be prosecuted without prohibiting the use of the drug for all law-abiding users.

Third, we urge the deletion of the phrase "which regulations shall not be subject to subsections (f) and (g)" on lines 4-5 of page 2. The effect of this phrase is to exempt from any necessity for hearing or review the regulations of the Secretary prescribing methods of examination necessary to determine whether there is a residue of an additive. Such an important issue—which is controlling as to the application of the section—should not be left to the uncontrolled discretion of the Secretary.

While clause (a), if amended as recommended, is unobjectionable, we submit that for the animal drug industry the purposes of this section are much too narrow. Under this section the determining factor in removing a substance from the ban of the Delaney clause is the determination of the existence of residue. The term "no residue" is not scientifically meaningful. Man adjusts to a wide variety of substances in trace amounts, detection of which merely depends upon the sensitivity of the method of assay. We submit that the true test should be more closely related to proof of safety of the additives under actual conditions of use.

The Delaney clause departs from the basic philosophy of the food additive section of the act. The concept of safety used in the statute applies to the capacity of an additive, under the conditions of its use (including the method of its administration and the quantities consumed), to cause harm from any disease. As currently interpreted, the Delaney clause, on the other hand, absolutely precludes the Secretary from finding on the basis of the scientific evidence, that no harm will result from the proposed use of an additive which may be "found" to induce cancer. It does not matter that there may be no agreed-upon definition of the term "cancer" or the term "found," or that the evidence may clearly differentiate the conditions of cancer induction from the conditions of the use of an additive. As Commissioner Larrick of FDA previously testified before this committee, there is no more reason to single out possible carcinogenicity for specific mention in the legislation than to single out production of a host of other disorders.

Among other scientific bodies calling for amendment or repeal of the Delaney clause, the Food and Nutrition Council of the American Medical Association recently issued a policy statement concluding that the Delaney clause contributes nothing to the safe use of food additives, could prohibit the addition of certain essential nutrients and could cause many new food improvements to be postponed or abandoned.

The Animal Health Institute has previously approved a suggested amendment to the Delaney clause which would, we believe, be superior to the "no residue" proposal. This amendment would provide a mechanism through use of the Scientific Advisory Committee whereby an impartial and independent panel of scientists may evaluate scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. A copy of this amendment, and a memorandum in explanation thereof, is enclosed with this statement.

Clause (a) is also narrow in scope in that it fails to deal with the problem of triplication of controls directly. It may, of course, remove a certain amount

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of discrimination produced by multiple controls. But it would leave those controls intact, and thus would not eliminate a major deterrent to the development of new animal drugs. Over the long range, therefore, the Delaney clause amendments to the food additives section of the act would not suffice to solve the problems of our industry in clearing new animal drugs.

ANIMAL HEALTH INSTITUTE,  
Des Moines, Iowa, February 5, 1962.

Mr. J. KENNETH KIRK,  
Assistant Commissioner, Food and Drug Administration, Washington, D.C.

DEAR MR. KIRK: As you know, the Animal Health Institute over a period of years has discussed with the Food and Drug Administration certain mutual problems, and these discussions have resulted in significant advances for both of the groups concerned. Over the past several years we in the Animal Health Institute have been gravely concerned about the length of time it has taken the Food and Drug Administration to process food additive petitions, especially in those areas that simultaneously involve new drugs or certifiable antibiotics.

At the 21st annual meeting of the institute in 1961, Mr. Winton Rankin announced that food additive petitions now were being processed more rapidly, and that following its usual cooperative approach, the Food and Drug Administration would welcome factual information where industry felt that there were undue delays.

With Mr. Rankin's invitation in mind, we have made a survey of member companies of the Animal Health Institute to determine if applications were in fact being processed more rapidly. Unfortunately, our membership has seen no improvement in this connection in the past year. Indeed, our survey indicates that recent applications as a general rule are still taking longer than the 30-day period for filing, and in certain instances longer than 180 days for final approval. Interspaced between these dates may be many requests for additional information which stop the regulatory timeclock. Some of these requests seem quite trivial to us. Of equal concern is the fact that letters asking for additional information are dated the day the letter is written, and not the date the letter is mailed. This has caused delays of 1 to 3 weeks for the company involved.

With a view toward assisting the Food and Drug Administration in determining what steps need to be taken to speed up processing of food additive petitions so that U.S. consumers may benefit from the new discoveries as quickly as foreign countries, we have compiled the attached list of examples of delays which the Animal Health Institute feels are excessive.

After you have had an opportunity to review the attached information, we shall be more than pleased to meet at your convenience to discuss more fully the importance of this problem.

Yours very truly,

D. L. BRUNER,  
Executive Secretary.

## FAP 140

March 9, 1960: Application submitted Food and Drug Administration.  
April 6, 1960: Petition filed by Food and Drug Administration.  
May 6, 1960: Letter from Food and Drug Administration received by company on May 11, 1960 (5 days after mailing), asking for certain samples.  
May 12, 1960: Samples delivered personally by company to Food and Drug Administration.  
October 12, 1960: Food additive regulation signed by the Commissioner.  
October 18, 1960: Final regulation appeared in Federal Register.  
NOTE.—The 180-day extension for this application expired on October 9, 1960, so that it was processed 3 days late.

## FAP 170

June 14, 1960: Submitted petition to Food and Drug Administration.  
July 21, 1960: Food and Drug Administration notified company, application incomplete.  
August 12, 1960: Company submitted additional information.  
August 17, 1960: Food and Drug Administration notified company application incomplete.

September 6, 1960: Food and Drug Administration notified company new drug application withdrawn and resubmitted as of August 15, 1960, but still incomplete.

September 16, 1960: Company submitted additional data.

September 30, 1960: Food and Drug Administration requested further clarification of data by telephone.

October 13, 1960: Food and Drug Administration notified company application still incomplete.

November 9, 1960: Company submitted additional data.

December 13, 1960: Food and Drug Administration notified company that petition had been filed.

January 19, 1961: Company submitted additional data.

March 10, 1961: Food and Drug Administration notified company that a 90-day extension would be necessary to process petition.

May 19, 1961: Petition approved.

## FAP 180

June 22, 1960: Submitted application to the Food and Drug Administration.

July 20, 1960: FDA requested additional data.

September 19, 1960: Company submitted additional data.

November 16, 1960: FDA advised company Food Additives Branch was reviewing petition.

November 30, 1960, December 7, 1960, December 16, 1960, and January 4, 1961: Company told that FDA was in disagreement as to whether or not the product was actually a food additive.

January 12, 1961: FDA advised company that a food additive regulation would be required.

NOTE.—In this case it took FDA 115 days from September 19, 1960, to decide that the product was a food additive.

## FAP 226

October 11, 1960: Submitted petition to the Food and Drug Administration.

October 20, 1960: Food and Drug Administration acknowledged receipt of this application.

November 3, 1960: Gave Food and Drug Administration additional data by telephone.

November 8, 1960: Gave Food and Drug Administration additional data by telephone.

November 10, 1960: Food and Drug Administration notified company application was incomplete.

December 7, 1960: Company submitted additional information.

February 3, 1961: Food and Drug Administration acknowledged receipt of December 7, 1960, data and gave a conditional filing date of December 8, 1960 (New Drug Branch).

February 6, 1961: Food and Drug Administration notified company of food additive petition filing of February 6, 1961.

NOTE.—Filing date is 60 days after application was judged to be complete.

May 17, 1961: Food and Drug Administration notified company that a 90-day extension would be necessary to process petition.

July 21, 1961: Food additive petition approved.

## FAP 252 (CHICKENS)

November 7, 1960: Submitted petition to the Food and Drug Administration covering use in chickens.

December 19, 1960: Petition filed by FDA.

NOTE.—In this instance it took FDA 42 days to file the petition.

March 16, 1961: FDA notified company that a 90-day extension would be necessary to process petition.

July 5, 1961: Petition approved by FDA.

NOTE.—In this case FDA took 263 days from filing date to approval date, or 37 days longer from submittal date to approval date than the maximum provided by law and regulation.

## FAP 252 (SWINE)

December 15, 1960: Submitted petition to the Food and Drug Administration covering use in swine.

DRUG INDUSTRY ACT OF 1962

April 18, 1961: Notification by FDA that petition had been filed on March 20, 1961.

NOTE.—Filing date is 95 days after submission date.

July 5, 1961: Petition approved by Food and Drug Administration.

FAP 446

March 10, 1961: Application submitted to the Food and Drug Administration.  
April 4, 1961: Petition filed by FDA.

October 26, 1961: Food additive regulation signed by the Commissioner.

November 1, 1961: Final regulation appeared in Federal Register.

NOTE.—A total of 198 days elapsed from filing date to approval date. There were no requests for additional information during this time.

FAP 288

November 18, 1960: Supplemental new drug application submitted to Division of Veterinary Medicine, FDA for NDA 11-116.

November 29, 1960: Before FDA had taken any action on the November 18, 1960, submittal, company submitted an application for this product directly to the Food Additives Branch as an amendment to NDA 11-116.

January 11, 1961: Letter from FDA Food Additive Branch acknowledging receipt of application and noting FAP 288 was filed on January 5, 1961.

January 16, 1961: Letter from Division of Veterinary Medicine stating this supplemental application would be considered a separate new drug application and assigned a new number, NDA 12-698. The letter also states that the product was considered a food additive under section 409 of the act. The letter further notes that the food additive petition was filed on January 11, 1961.

NOTE.—The new drug application and food additive petition were not acted upon simultaneously. It took 48 days after receipt of the new drug application for filing, or 37 days after receipt of the food additive petition for filing. Also, it seems strange that two different filing dates were given by FDA for the same petition.

April 7, 1961: Letter dated April 7, 1961, from FDA asking for an additional 90 days to consider the petition.

NOTE.—This letter was dated 92 days after filing date of January 5, 1961.

May 17, 1961: Notice by FDA that they could not recommend favorable action on the petition because there were gaps in (1) the feed assay and (2) residue data.

NOTE.—Thus 132 days from filing date to determine FAP 288 was deficient in two of the fundamental aspects of any petition.

FAP 528

May 24, 1961: Application submitted to the Food and Drug Administration.

June 16, 1961: Letter from FDA indicating application is complete.

July 11, 1961: Letter from FDA stating that application had been filed on July 7, 1961.

NOTE.—In this case 44 days elapsed between submission of application and filing date; actually, the filing date was 21 days after the company was notified that the application was complete.

FAP 558

May 16, 1961: Submitted petition to the Food and Drug Administration.

July 14, 1961: Petition filed by FDA.

NOTE.—In this instance it took FDA 60 days to file the petition.

October 17, 1961: Notification that a 90-day extension would be necessary to process petition.

December 12, 1961: Pending.

FAP 562

July 3, 1961: Submitted petition to the Food and Drug Administration.

August 28, 1961: Petition filed by FDA.

NOTE.—In this instance it took FDA 45 days to file the petition.

November 26, 1961: Notification that a 90-day extension would be necessary to process petition.

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## DRUG INDUSTRY ACT OF 1962

## FAP 564

May 23, 1961: Submitted application to the Food and Drug Administration.  
 August 29, 1961: FDA notified company that petition had been filed.  
 NOTE.—Filing date is 98 days after application had been submitted.

## FAP 565

June 9, 1961: Submitted petition to the Food and Drug Administration.  
 October 3, 1961: Company wrote to FDA inquiring as to status of this petition, since there had been no written reply or acknowledgement of receipt or filing of petition.

October 12, 1961: FDA acknowledged receipt of October 3, 1961, letter and advised that the petition had been given a FAP number of 565. No mention made of filing date.

October 30, 1961: Letter from FDA stating that FAP 565 had been given a filing date of October 25, 1961.

NOTE.—In this instance it took FDA 141 days to file this petition.  
 December 20, 1961: Petition still pending approval.

## FAP 577

August 30, 1961: Submitted application to the Food and Drug Administration.  
 November 20, 1961: FDA advised company that certain additional data were necessary before petition could be filed.

NOTE.—It took 82 days in this case for FDA to determine application was incomplete and could not be filed.

## FAP 583

July 24, 1961: Petition received by the Food and Drug Administration.

October 16, 1961: Letter from FDA stating that petition had been filed on September 20, 1961.

NOTE.—In this instance 53 days were taken to file the petition.

December 12, 1961: Letter from FDA that an additional 90 days would be needed to study the petition.

## ANIMAL HEALTH INSTITUTE

## PROPOSED AMENDMENTS TO FOOD ADDITIVES LAW

## I

Amend Section 409(c)(2):

Add the following sentence at the end of the paragraph:

"If an advisory committee is established as hereinafter provided such order shall be issued within the time specified in paragraph (c)(3)(B)(iii) of this section in lieu of the time specified in this paragraph."

## II

Amend section 409(c)(3) in its entirety so as to read as follows:

"(A) No such regulation shall issue if a fair evaluation of the data before the Secretary (i) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; or (ii) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

"(B) (i) No food additive shall be deemed to be safe, except as provided in this subsection (c)(3)(B), if it is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.

"(ii) In the event that the data before the Secretary suggests that a food additive for which a petition has been filed may induce cancer in man or animal within the meaning of paragraph (i) of this subsection (c)(3)(B), the Secretary shall so notify the petitioner not less than thirty days prior to the issuance of the order required by paragraph (1)(A) or (B) of this subsection (c). If, at any time prior to the issuance of the order required by paragraph (1)(A) or

(B) of this subsection (c), the petitioner so requests, or if the Secretary at any time prior to the issuance of such order deems it necessary, the Secretary shall forthwith refer the petition to an advisory committee for a report with respect to the following questions:

"(a) whether or not the additive induces cancer in man or animal, within the meaning of paragraph (i) of this subsection (c) (3) (B), and if so,

"(b) whether or not the proposed use of the additive, under the conditions of use specified in the petition, is established by a fair evaluation of the data considered by the committee to be safe from the standpoint of the cancer-inducing potential of the additive.

"(iii) As soon as practicable after such referral, but not later than sixty days thereafter, which period may be extended an additional thirty days if the advisory committee deems this necessary, the committee shall certify to the Secretary, with a copy to the petitioner, a report on such matters, together with all underlying data and a statement of the reasons or basis for its conclusions thereon. Within thirty days after such certification, the Secretary shall, after giving due consideration to such report and to all data then before him, issue the order required by paragraph (1) (A) or (B) of this subsection (c). The provisions of paragraph (i) of this subsection (c) (3) (B) shall not be applicable to such order in the event that the Secretary acting upon the advice of the advisory committee has concluded that question (b) set forth in paragraph (ii) therein should be answered in the affirmative.

"(iv) The deliberations of the advisory committee shall be conducted in accordance with regulations promulgated by the Secretary designed to assure impartial consideration of the matters set forth in paragraph (ii) of this subsection (c) (3) (B). The right to consult with the advisory committee shall be afforded to the person who has filed the petition and to the Secretary. All data considered by the advisory committee shall be made part of the record of its proceedings and shall be made available to the petitioner and to the Secretary.

"(v) The advisory committee shall consider, among other factors bearing upon the matters set forth in paragraph (ii) of this subsection (c) (3) (B).

"(a) The appropriateness and reasonableness of the tests for carcinogenicity,

"(b) The reliability of the evidence of carcinogenicity,

"(c) The concentration of the substance above any natural background level resulting from addition of the substance to foods for human consumption, and

"(d) The appropriateness of assay techniques to determine whether the substance is present in food.

"(vi) The advisory committee shall be composed of disinterested experts selected by the Secretary from a panel proposed by the National Academy of Sciences, except that in the event that the National Academy of Sciences fails to act, the Secretary shall determine the membership of the committee. Such experts shall be qualified to consider the matters referred to the committee and shall be of adequately diversified professional background, but representatives of the Department of Health, Education, and Welfare and representatives of persons directly interested in the additive which is the subject of the referral shall be ineligible to serve as members of the committee. The size of the committee shall be determined by the Secretary. Members of the advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary travel and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States."

### III

Amend section 409 (f) :

Add the following new paragraph :

"(4) Any report, underlying data and reasons certified to the Secretary by an advisory committee appointed as provided in subsection (c) (3) (B) of this section shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). The advisory committee shall designate a member to appear and testify at the hearing with respect to the report of such committee

upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing."

MEMORANDUM RE PROPOSED AMENDMENTS TO FOOD ADDITIVES LAW CONCERNING  
DELANEY ANTICANCER CLAUSE

The purpose of this memorandum is to describe, examine, and analyze amendments to the Delaney clause which has been proposed by the Animal Health Institute for consideration in the 87th Congress. A copy of these proposals is enclosed herewith.

By way of background, the Delaney anticancer clause contained in the Food Additives Amendment of 1958 was discussed from time to time in the course of the hearings prior to the enactment of the Color Additive Amendments of 1960. A similar clause was contained in H.R. 7624 which bill, in amended form, became the color additives law. Accordingly, the operation of the Delaney clause under the food additive law was considered pertinent.

H.R. 7624 was amended by the House Committee on Interstate and Foreign Commerce following extensive hearings held between January and May of 1960. As reported, H.R. 7624 contained a provision permitting referral to an advisory committee for a report and recommendations with respect to any matter arising under the Delaney clause if such matter requires the exercise of scientific judgment. While the House committee report indicates that the purpose of this amendment was to provide for a study and report on the question of whether a color additive is a carcinogen, nevertheless, there was considerable confusion as to the scope of the advisory committee amendment. For example, on the floor of the Senate, Senator Hill remarked, in reply to a motion by Senator Javits to reconsider the color additives bill:

"I also wish to state that the report of the group of scientists, under date of May 14, 1960, to which the Senator from New York has referred, did not recommend repeal of the Delaney amendment, as that amendment is now carried in the Food Additives Act of 1958, but did recommend that the Secretary of Health, Education, and Welfare appoint a board, advisory to him, to assist in the evaluation of scientific evidence, on the basis of which decisions have to be made as to prohibiting or permitting the use of certain carcinogenic compounds.

"I may say that the amendment to which we agreed last night not only provides for such an advisory board—they use the term "advisory committee," but an advisory board is the same thing—but gives to anyone who may feel that he needs some redress the right to have such an advisory committee consider the matter."

However, it seems clear that contrary to Senator Hill's impression, the advisory committee as set forth in the color additives legislation is not authorized to evaluate evidence on the basis of which decisions have to be made as to prohibiting or permitting the use of carcinogenic compounds.

The report referred to by Senator Hill, dated May 14, 1960, is commonly known as the report of the Kistiakowsky committee. The panel of experts constituting this committee was convened by the President's Science Advisory Committee. This committee recommended the appointment of an advisory board to assist in the evaluation of scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. It was further recommended that such advisory board consider among other matters:

"(a) Whether or not the tests for carcinogenicity are appropriate and reasonable;

"(b) Whether the substance is or is not in reality carcinogenic as determined histopathologically or by other criterias;

"(c) Whether addition of the substance to agricultural products would result in a concentration of the substance above the natural background level of such substance;

"(d) What assay techniques are appropriate to determine whether a specific carcinogen is present in food."

The report also recommended that appropriate modifications in the law be sought if existing legislation does not permit the exercise of discretion consistent with the recommendations of the committee.

That the exercise of such discretion requires amendment to the Delaney clause is clear from the discussion of scientific issues contained in the Kistiakowsky committee report. For example, the report states:

"From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work such as cited above, the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available."

The report also discusses special problems in the administration of the Delaney clause which might arise when substances useful in trace amount but carcinogenic in large doses are considered, such as selenium, inorganic arsenic compounds, and polyoxyethylene stearate. As to these problems, the committee states: "This list of examples may be expected to lengthen and each case requires scientific judgment to determine the issues involved."

Again, the committee report discussed the problem which arises when carcinogenic substances are permitted to be used under such conditions (as in the feed industry) that they are absent from human food products. As to this problem, the committee states: "Scientific judgment as well as the rule of reason are required to decide what is a proper and adequate assay method."

With respect to each of the foregoing examples, the Delaney clause, even if amended as in the color additives law, does not permit the exercise of scientific judgment recommended by the Kistiakowsky committee.

That the recommendations of the Kistiakowsky committee represent the best thinking of the scientific community is apparent. In the State of Wisconsin, "the Report on Food and Feed Additives and Pesticides of the Governor's Special Committee on Chemicals and Health Hazards," concluded, with respect to the Delaney clause:

"This legislation is extremely rigid and difficult to administer in specific instances, principally because it prohibits the presence of even traces of these compounds, although it is known that the effects of large amounts of a substance may differ profoundly from the effects of small amounts of the same substance and that a material dangerous in considerable quantity may have no measurable effect when present in minute quantities. Experience has shown that this portion of the Federal law should be modified to permit the evaluation of each substance on an individual basis by a competent board of experts."

The report further states:

"A more flexible regulation might provide that no substance with the ability to produce cancer following ingestion by man or animal be used as a food additive unless a safe level of use can be established. In this way the merits of each substance in question could be examined individually by a properly qualified board of experts. This modification of existing legislation is a rational possibility because it is highly probable that for experimental animals there do exist subcritical doses of chemicals known to be carcinogenic; in other words, chemicals known to produce cancers when fed in very large amounts for long periods of time may be completely harmless when given in far smaller amounts."

The majority of the panel of experts which appeared before the House Committee on Interstate and Foreign Commerce on April 5 and 6, 1960, went on record as favoring some modification of the Delaney clause. For example, typical of the majority opinion, Dr. Kensler, Department of Pharmacology, School of Medicine, Boston University stated:

"In my opinion, the Delaney clause, as written prevents the application of proper scientific judgment to this problem. In my opinion, it should be modified in such a way that the current scientific judgment be brought to bear on the problem whenever such judgments are appropriate, and when such information is available, not necessarily having to wait for the passage of another piece of legislation."

The reports and testimony offered in the color additive hearings led to the amendment of the Delaney clause to provide for a scientific advisory committee whose deliberations were limited to evaluating the evidence relating to carcinogenicity of a color additive at any level of administration in any species of man or animal. This amendment, of course, appears in the color additives legislation. No effort has been made to include an advisory committee in the food additives law. However, the former Secretary of the Department of Health, Education, and Welfare conceded the need for amending the Delaney clause in the Food Additives Amendment of 1958, at least insofar as animal feed is concerned. Proposed amendments to the food additives law were accordingly trans-

mitted by the Department of Health, Education, and Welfare to the House Committee on Interstate and Foreign Commerce under date of May 13, 1960. One portion of the Secretary's proposal was to amend the Delaney clause, exempting from its application the use of a substance as an ingredient of feed for animals which are raised for food production, if it is found that the additive will not adversely affect the animals for which the feed is intended, and that no residue of the additive will be found in any edible portion of the animals after slaughter or in any food yielded by or derived from the living animal. The Secretary coupled with this proposal another amendment having the effect of destroying the statutory exemption from the food additives law applicable to substances used in accordance with a sanction or approval, on the basis of a finding that there is reasonable doubt as to its safety. This later amendment would make it unnecessary to abide by the procedural safeguards which would otherwise be necessary to revoke such sanction or approval.

The proposal of the former Secretary of the Department of Health, Education, and Welfare with respect to the Delaney clause, while indicating the need for amendment of that clause, was predicated upon an assumption of questionable merit. The assumption is that it is feasible to amend the Delaney clause on a case-by-case basis each time the use of a compound or class of compounds is unnecessarily prohibited by its strict application. Of course, such an assumption is inconsistent with the basic principle of the food additives law to delegate to the administrative agency the power to determine tolerance for food additives.

There is another fault in the so-called no-residue proposal of the former Secretary. The fault is that the proposal is not consistent with the exercise of sound scientific judgment even in the case of drugs used in animal feeds. For example, it depends upon the issuance of regulations prescribing methods of assay in order to determine whether or not there is a residue of the additive in the meat, milk, or eggs produced from animals. The power to cancel an exemption merely because of the discovery of more sensitive methods of assay is inconsistent with the kind of scientific judgment which should be exercised in accordance with the report of the Kistakowsky committee.

To give another example, the no-residue proposal is totally inadequate to deal with problems of scientific judgment arising from the use of an additive where the additive or its components have a natural background level in food consumed by humans. Since this background level may vary from product to product, from animal to animal, and from tissue to tissue in the same animal, in some cases it may not be possible to make a finding that the exemption should apply, even though the exercise of scientific judgment referred to by the Kistakowsky committee would call for exempting the additive from the Delaney clause. Furthermore, it may be impossible to determine, upon examination of the tissue of animals, whether or not the residue of the additive or any of its components contained therein results from the administration of the additive. In that event, the requisite finding could not be made.

With this background, the Animal Health Institute, concerned lest the Delaney clause adversely affect research and technology, searched for an amendment which would, under the circumstances, best serve the public welfare and preserve scientific judgment.

Outright repeal of the Delaney clause was discarded, though substantial support might be adduced for such repeal. The effect of repeal would be to place cancer in the same position under the law as all other diseases which afflict mankind. Prior to the enactment of the food additives law, Commissioner Larrick opposed the concept of the Delaney clause. In 1957, he told the House Committee on Interstate and Foreign Commerce:

"But we see no more reason to single out cancer production for specific mention in the legislation than to single out production of high blood pressure, destruction of the blood-forming elements of the body, or production of nephritis, diabetes, or a host of other disorders. All of these things are of extreme importance. We certainly do not intend to sanction a chemical additive in the food supply unless the evidence rules out any reasonable ground for believing that the proposed use will constitute a hazard to the public health in any respect."

More recently, a number of scientists who are concerned with the protection of the food supply of this Nation, have given similar testimony. For example, Dr. William J. Darby, Chairman of the Food Protection Committee of the National Academy of Science, indicated to the House Committee on Interstate and Foreign Commerce:

"It is my opinion that the legislative action should continue to charge the Secretary with this responsibility for decision as to safety for use of any pro-

posed food additive, regardless of the kind of hazard. If it is deemed useful by the Congress to call especial attention to the potential hazard from cancer, I believe this could, in the best interest of the health and welfare of our people, be accomplished by the simple device of instructing the Secretary that in reaching a decision as to safety he is to consider evidence bearing upon the possible hazard from cancer which might result from the use of a given substance in the manner proposed.

"Such charge would then assure that he take into account all evidence obtained by methods presently available or which might be developed in the future for judging the safety or hazard for use of a given substance, and that he not only could seek but, in fact, exercise the best scientific judgment in the administration of the law."

The Animal Health Institute also discarded the former Secretary's approach of proposing new legislation on a case-by-case basis. Accordingly, the method adopted was to provide a mechanism through use of the scientific advisory committee whereby an impartial and independent panel of scientists may evaluate scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds. This is similar to the approach used in color additives legislation, differing only in two major respects. First, the Secretary should be authorized to issue a regulation acting upon the advice of the advisory committee permitting the use of an additive, the use of which can be demonstrated to be safe in spite of the prima facie application of the Delaney clause. Second, there should be provisions guaranteeing that the advisory committee will truly be impartial.

Considering the first of these principal differences, it does not involve any weakening of the Delaney clause as it applies to the initial consideration of a food additive petition. It merely means that if there is a referral to an advisory committee, this committee will consider the following specific questions: (a) whether or not the additive induces cancer in man or animal, within the meaning of the Delaney clause, and if so, (b) whether or not the proposed use of the additive, under the conditions of use specified in the petition, is safe from the standpoint of the cancer-inducing potentiality of the additive. Thereupon, the advisory committee is to make a report on these questions within 60 days, unless extended an additional 30 days, after the referral. Meanwhile, the Secretary is precluded from issuing an order on the petition until the committee has certified its report. The proposed amendment specifically provides that the Delaney clause shall not be applicable to the order in the event that the Secretary, acting upon the advice of the advisory committee, has concluded either that the additive does not induce cancer within the meaning of the Delaney clause, or that the proposed use of the additive, under the conditions of use specified in the petition, is safe from the standpoint of the cancer-inducing potentiality of the additive. Under this proposal, the advisory committee is required to consider, among others, those factors specifically listed in the Kistiakowsky committee report. The Secretary is required to notify the petitioner, not less than 30 days prior to the issuance of any food additive order, if the data before him suggests that the food additive may induce cancer. The request for an advisory committee may be made by the petitioner at any time prior to the issuance of such an order, but the Secretary within the same period of time may invoke an advisory committee on his own initiative.

It should be noted that the proposal of Animal Health Institute places the burden of proof on the person proposing the use of the additive to demonstrate to the advisory committee that such use is safe from the standpoint of its cancer-inducing potentiality. Accordingly, in the situation adverted to by the former Secretary in his testimony before the House Committee on Interstate and Foreign Commerce, namely, " \* \* \* that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer \* \* \*," where that principle applies to an additive, the advisory committee could not determine that its proposed use is safe. However, the advisory committee would be empowered to consider, on a case-by-case basis, those instances where the application of the Delaney clause has already been shown to be rigid or might in the future be shown to be rigid.

Considering the second principal difference between the color additive advisory committee and the proposal of Animal Health Institute, namely, the impartiality of the advisory committee, we believe that a certain minimum amount of procedural safeguards must be written into the advisory committee provision. There is no provision in the color additives law which sets adequate standards applicable to the deliberations of the advisory committee. As a matter of fact, pro-

posed regulations under the color additives law, to which regulations objections have been made, do not insure that the deliberations of the advisory committee will be impartial. Among other things, persons wishing to consult with the advisory committee need not be provided with copies of material that is furnished the committee. Neither are there sufficient rules with respect to the manner of consultation or the manner in which deliberations are held.

It is evident that, with respect to the pesticide law and the color additives law, Congress conceived great weight would be placed upon the deliberations of the advisory committee. This is indicated by the provisions whereby various parties are given the right of consultation with the committee, whereby the committee is required to certify all data underlying its report and recommendation, whereby the Secretary is required to give due consideration to all these materials, and whereby all of this data shall be made a part of the record of any hearing if relevant and material. Thus, the advisory committee is in the nature of a court of appeals, for it is hardly conceivable that the recommendations of such a committee would be set aside in any judicial proceeding.

Accordingly, the proposal of the Institute specifically provides that the advisory committee shall be composed of impartial experts. Furthermore, it is provided that the deliberations of the advisory committee shall be conducted in accordance with regulations promulgated by the Secretary and that these regulations shall be designed to assure impartial consideration of the matters which are referred to to the advisory committee. It is also provided that all data considered by the advisory committee shall be made part of the record of its proceedings, as well as all interpretations of law upon which the committee relies, and shall be made available to the petitioner and to the Secretary. In the absence of such safeguards, we feel that the decisions of the committee may not always be impartial and scientific, but may on occasion be touched with politics. On the other hand, we do not believe that the legislation should specify the detailed manner in which the advisory committee should operate, but should leave these details to be fashioned by the Secretary in accordance with the standard of impartiality set forth in the proposed amendment.

In conclusion, we suggest that the Department of Health, Education, and Welfare should reevaluate its policy with respect to the food additives law and adhere in the case of possible carcinogens to the basic philosophy of that law, in accordance with the general recommendations outlined herein. The basic principle of that law is well stated in the report of the House Committee on Interstate and Foreign Commerce on the food additives bill:

"The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance."

The two-fold purpose of the legislation justifies the proposed amendment. Thus, the House committee said:

"The purpose of the legislation is twofold: (1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels."

It has been demonstrated that the Delaney clause is not consistent with these principles and objectives, and constitutes a burden to research and food technology. The opinion of the Department of Agriculture expressed in its letter of May 16, 1960, to the House Committee on Interstate and Foreign Commerce is persuasive:

"The anticancer clauses contained in the Food Additives Amendment of 1958 and in H.R. 7624 on page 10, lines 11 through 22, are flat prohibitions against the exercise of scientific and professional judgment in the determination of safety. That such a flat prohibition may present problems is well exemplified in the case of selenium, a known carcinogen. Several amounts (0.1 p.p.m.) in the diet appear to have no measurable effect upon animal health. Sheep on diets with subnormal amounts (0.03 p.p.m. or less) are not thrifty and show abnormalities of the muscular and internal organs. Excessive amounts (5 p.p.m. and above) in the diet produce poisoning. Here we have a chemical, a carcinogen, a toxicant, which in proper amount is essential to animal health. The law should not prevent proper use of such a chemical as an additive or otherwise.

"In view of the above and since we understand that the Secretary of Health, Education, and Welfare has adequate authority to withhold from use any additive that he is unable to find would be safe in regard to cancer as well as in

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regard to toxicity and other factors, it is our opinion that the anticancer provisions in lines 11 through 22 on page 10 of H.R. 7624 are unnecessary. This is equally true of the anticancer provision in the Food Additives Amendment of 1958. We fully agree that the Secretary of Health, Education, and Welfare should withhold from use any additive which in his judgment would be unsafe but we urge that the decision on safety be left to him rather than being determined by law."

The CHAIRMAN. Dr. Robert J. Feeney?

STATEMENT OF DR. ROBERT J. FEENEY, DIRECTOR OF COMMERCIAL DEVELOPMENT OF CHARLES PFIZER & CO., INC.; ACCOMPANIED BY CHARLES F. HAGAN, LEGAL DIVISION

Dr. FEENEY. Mr. Chairman and members of the committee, my name is Robert J. Feeney, and I am the director of commercial development for the Charles Pfizer Co. which has its headquarters in New York.

I am a doctor of philosophy in organic chemistry and have had extensive experience with all aspects of the research and development of new drugs and antibiotics by my company.

We appreciate this opportunity to appear before you, and we will confine our remarks to the provision of H.R. 11581 which would extend to all antibiotics the certification requirements in the Federal Food, Drug, and Cosmetic Act.

I am responsible at Pfizer for the coordination of all activities—research, production, and marketing—leading to the introduction of new products, including dosage forms, for human and animal use. I am accompanied by Mr. Charles Hagan of our legal division.

Our remarks will supplement the testimony on this provision by Mr. John T. Connor, the president of the Merck Co. Let me commence by relating briefly something about our company's long experience in the antibiotic field.

One of Pfizer's most outstanding achievements, of which we are particularly proud, is the part that the company played in the development of practical penicillin production procedures during World War II. Pfizer was a pioneer with two other companies, Merck and Squibb, in the research which made penicillin available in time to save the lives of countless American soldiers. By the end of World War II, Pfizer was producing about 50 percent of the penicillin used by our military forces.

Pfizer was also one of the first companies to produce streptomycin and later dihydrostreptomycin, two antibiotics most important in the treatment of tuberculosis. Some 2 years later, in 1950, we brought Terramycin on the market. This is a broad spectrum antibiotic discovered by Pfizer scientists. It is still a mainstay of the medical profession in the treatment of a host of infectious conditions, and has also been found to be most useful in veterinary practice, as well as in animal feeds for growth promotion and for prevention and treatment of diseases.

It was the first of the important antibiotics which was not made subject to the certification requirement. No antibiotic discovered since Terramycin has been subjected to the certification procedures except those which FDA considered derivatives of the previously certified antibiotics. In 1954, we marketed Tetracyclin, another broad spectrum antibiotic, also discovered by Pfizer scientists.

The company now produces and markets more antibiotic products than any other company in this country. These include the products that I have mentioned and also bacitracin, neomycin, polymyxin, triacetyloleandomycin and Viomycin.

Of the 10 antibiotics which I have just mentioned, 5 are subject to the present certification requirements in the Federal Food, Drug and Cosmetic Act—penicillin, streptomycin, dihydrostreptomycin, Tetracyclin and bacitracin. The other five are not subject to antibiotic certification. All would be covered if H.R. 11581 were enacted in its present form.

In 1945 an amendment to the Food, Drug and Cosmetic Act requiring certification of penicillin was supported by members of the pharmaceutical industry as a temporary measure. This amendment was passed at a time when production and control procedures were in a crude stage of development. Today, antibiotics can be produced and controlled with uniformity comparable to that for other drug products. There is therefore no longer any meaningful reason for singling out antibiotic drugs for special certification treatment.

As a matter of fact, the Terramycin and other noncertifiable antibiotics which we produce are as uniform in purity, potency, and so forth, as any other drug which we produce. The truth of the matter is that the certification requirement has long outlived its usefulness.

Meanwhile, the burden, which the certification provision now imposes needlessly upon the industry, has increased over the years. The annual fees paid by the industry to the Food and Drug Administration are between \$900,000 and \$1,000,000. Proposals are now pending that would increase these fees most substantially and would require the submission of an increased number of samples for the certification of batches of antibiotics.

The 1959 estimate by the Comptroller General<sup>1</sup> that approximately 150 man-years of effort were devoted in that year by FDA to certification would also be substantially increased if these latest proposed regulations by FDA were adopted—and the figure would be at least double if sections 105 and 106 of this bill were enacted in their present form.

However, the certification fees are not the only expense needlessly incurred as a result of certification requirements. The delays presently caused by certification mean that our inventories must be substantially higher than justified for an efficient operation. Moreover, if the new regulations proposed by FDA are adopted our inventories of presently certified antibiotics would increase by an estimated \$3 million. If certification is extended to all antibiotics, the inventories would be increased another \$1,250,000. These figures represent only one of the burdens on only one company in this field.

At this point, we want to emphasize that if there were a significant problem of safety involved, the cost and other burdens would be gladly accepted. We are in favor of any reasonable proposal to advance public health and safety. For instance, we support a number of provisions in this bill which are practical and which would achieve this aim.

<sup>1</sup> Report to Congress by the Comptroller General entitled "Review of Enforcement and Certification Activities of the Food and Drug Administration, Department of Health, Education and Welfare" dated September 1961.

In the case of extension of certification, however, in view of the advanced state of the art of manufacturing and testing antibiotics, there is no need for the continuation of such requirement, much less for its extension to all antibiotics.

## SECRETARY RIBICOFF'S TESTIMONY

Secretary Ribicoff, in his prepared statement delivered to this committee on June 19, 1962, made four points to support extension of certification. We should like to comment briefly on each of these points:

(a) The Secretary said that antibiotics, more than any other drugs, are the first choice in treating life-threatening infections. We agree but the fact that antibiotics are used to treat life-threatening diseases does not distinguish them from the many other drugs which are also used to treat life-threatening diseases (which drugs, incidentally, do not require certification.)

(b) The Secretary indicated that his Department has had to reject numerous batches of the presently certified antibiotics. We would respectfully refer to the above-mentioned report by the Comptroller General, including the fact that during 1960 only 22 batches of antibiotic drugs were rejected by FDA out of 16,601 batches tested.

The rejection of a few batches is not surprising since it is our practice, and we believe the general practice in industry, to furnish samples of production lots of FDA for testing as soon as production is completed and before we conduct our own tests. The manufacturer's own testing of the above-mentioned 22 batches probably also confirmed the deficiencies observed by FDA. No manufacturers would knowingly market a batch of an antibiotic drug which was subpotent or unsafe.

(c) The Secretary indicated that the Department has had to withhold certification services from some manufacturers until their "operations" were brought into compliance with "regulations designed to insure safety and efficacy of certified lots." We are somewhat puzzled by this statement, since we know of no regulations specifying standards for equipment, facilities, et cetera, to be used by manufacturers of certifiable antibiotics. In any event, however, to the extent that the facilities and equipment of a manufacturer of any drug, are not adequate to assure its quality, potency, et cetera, the answer to this problem is not certification, but rather the answer is already contained in section 101 of H.R. 11581 which would deem any drug manufactured under such conditions to be adulterated.

(d) The Secretary indicated that the Department has had to suspend certification of a number of products that became unstable or otherwise unsuitable for use. Many drugs other than antibiotics are subject to deterioration under certain conditions, or merely with the passage of time, and there is ample authority under the present act to proceed to any such situation.

## BURDENSOME EFFECTS OF EXTENSION OF CERTIFICATION

Extension of certification to all antibiotics, at this late date, would produce most serious difficulties and confusion for the manufacturers of those antibiotic products which are not currently subject to certification.

In order to realize why this is so, it is necessary to understand the mechanics involved in obtaining a certification for an antibiotic product.

Under the general regulations for certification of antibiotics (sec. 146.7) a manufacturer desiring to produce a new antibiotic dosage form must submit to the Department a considerable amount of information, including a full description of the methods, controls and facilities used for its manufacture, processing, and packaging, a full statement of the composition of the drug and all reports of investigation made to show whether the drug is safe and efficacious. (This is the same information required for "new drugs" under sec. 505 of the act as it would be amended by secs. 102-104 of H.R. 11581.)

If the Department is satisfied that the data submitted is adequate to demonstrate the safety and efficacy of the dosage form it issues two regulations which must be complied with in order to have batches of that drug certified.

One regulation establishes standards of identity, strength, quality, and purity for the dosage form (including prescribing, packaging, and labeling requirements) and the other regulation sets forth the tests and methods of assay for determining whether the standards in the first regulation are met with respect to each particular batch of the dosage form.

Pfizer currently markets over 60 human and veterinary antibiotic dosage forms which are not subject to certification, and there are many other manufacturers of noncertified antibiotic dosage forms.

If certification is extended to all antibiotics as proposed, presumably Pfizer will have to petition for regulations providing for the certification or exemption from certification of each of these dosage forms. This is so in spite of the fact that virtually all of these 60 or more dosage forms have already been cleared by the Department via the new drug procedures, and in spite of the fact that many of them have been on the market for 5 to 10 years, and are widely accepted by the medical and veterinary professions. Since new drug clearance for most of these products was obtained a number of years ago, and minor changes in manufacturing procedure, control procedures, labeling have occurred for many of them, there appears to be little likelihood that the Department would issue regulations providing for the certification, or exemption from certification, for these products solely on the strength of the fact that at one point they had been cleared through new drug procedures.

It can be anticipated, therefore, that FDA will re-review the data previously submitted for our dosage forms before issuing regulations providing for certification. We submit that this massive reclearance of our products will involve an entirely unnecessary waste of industry and Government manpower and will result in most burdensome delay.

When you consider that there are many companies besides Pfizer which market a wide range of antibiotic dosage forms that are not currently certified, the magnitude of the difficulties and confusion that will result becomes more apparent. There are about 30 noncertified antibiotics, and hundreds of dosage forms containing those antibiotics.

In the case of drugs for use in treating diseases of animals and for use in animal feeds, the effect of extending certification to cover all antibiotics would be particularly severe, and especially needless

from the standpoint of safety. No logical reason has been advanced to extend certification in the case of such products.

The extreme authority already exercised by the Food and Drug Administration over such products was dramatically illustrated in the testimony before the Subcommittee on Health and Safety on August 6 and 7 of this year during hearings on H.R. 12437 and H.R. 12420 which pertain to animal feed additives.

As indicated in those hearings, the extremely stringent controls over veterinary drugs and animals feeds, which are currently exercised by FDA under two separate sections of the act (the new drug section, and the food additive section) have prompted the Animal Health Institute to propose that the act be amended to provide for clearance procedures for such drugs which are separate from the procedures for clearing human drugs. To extend certification to all antibiotics used in veterinary drugs and feeds would further burden and confuse this highly unsatisfactory situation.

The principal veterinary use of antibiotics is in animal feeds and the problems just discussed are particularly acute in this area.

To extend the antibiotic certification provisions to all antibiotics so used would accomplish no worthwhile purpose whatsoever since it is entirely impractical to certify each batch of such feeds. Three of the currently certifiable antibiotics are widely used in feeds, and FDA, so far as we are aware, has certified no batches of such feeds. Instead, it has issued a maze of "exemptions" from certification. This means that the degree of governmental control is no greater than in the case of feeds containing uncertifiable antibiotics.

Because of practical considerations, if the certification procedures are extended to all other antibiotics used in feeds, it is virtually certain that such feeds will also be marketed under exemptions from certification. However, before such exemptions are granted a wholly unnecessary, wasteful and time-consuming reclearance of each of the antibiotic feed uses will presumably be required in spite of the fact that virtually all of such uses were previously cleared under the new drug procedures.

#### DECERTIFICATION

We now turn to our final point, the extreme reluctance of FDA to exempt from certification manufacturers who have proved their competence.

We submit that it is clear that Congress intended the certification requirements to remain in effect only as long as they were needed to protect the public. Indeed, the statute provides for the decertification of antibiotic drugs individually or as a class when such requirements are no longer necessary "to insure safety and efficacy of use."

However, FDA has taken the position that the statute as now worded would not permit them to exempt a manufacturer from the certification requirements as to a particular product but would only authorize the exemption from certification of all manufacturers of that product. That is, that decertification must be accomplished on a product-by-product basis and not on a manufacturer basis. A few antibiotic products have been decertified, but they are very few, and no antibiotics for human use have been decertified within the past 7 years.

We submit that the existing certification provisions of the act should be amended to allow individual manufacturers to receive exemptions from certification, and that specific and mandatory criteria for decertification should be set forth.

## CONCLUSION

In conclusion, we strongly urge that section 105 of H.R. 11581 not be enacted.

The CHAIRMAN. Does that conclude your statement, Doctor?

Dr. FEENEY. Yes, sir.

The CHAIRMAN. Mr. Younger?

Mr. YOUNGER. Yesterday I had a couple of questions in mind for the pharmaceutical manufacturers, and I did not fully develop them.

When you have a drug that is in the stage of testing, do you have a list of physicians to whom you send these drugs?

Dr. FEENEY. This obviously, sir, is something that is not pertinent to my testimony, but I have had a very close association with this problem.

There is no set listing of physicians for evaluating a new drug. Each drug, whether it be an antibiotic or a drug for mental disease, would have its own particular set of experts who are most competent in the field.

We go to the leaders in medicine, the men with the greatest experience, the men with the greatest interest in advancing drug science, and the men whom we believe to be the most competent in discharging this responsibility.

So there is no set listing.

The industry selects and works in concert with the leaders in medicine in this country and throughout the world.

This is the policy.

Mr. YOUNGER. Do you know of any manufacturer who pays a doctor for conducting the testing?

Dr. FEENEY. In the sense that a manufacturer will supply certain forms of financial support to such programs, this is not unusual.

For example, new drugs are oftentimes evaluated in hospitals, and you and I have read a great deal about the high cost of medical care. Laboratory tests that are required to be certain of the safety of the drug are very expensive. The manufacturer assumes some of the financial burdens that are involved in that aspect of obtaining drug clearance.

But, in the sense that a reputable manufacturer is purchasing a good report or a positive report, this, of course, is unheard of. It is not done.

Mr. YOUNGER. I can understand how it would be natural to assume the expenses of lab tests, X-rays, and so forth, but do you know of any firms that actually pay the doctor personally for what work he does?

Dr. FEENEY. Not in the sense of the word as you mentioned it, Congressman.

The research program of a particular physician might be supported, but, in the sense that his services are purchased, I am not familiar with anything of that type.

Mr. YOUNGER. Also in connection with this experimental work, is there any other emoluments given by the manufacturer in connection with testing that you know of?

Dr. FEENEY. No, sir; none that I know of.

In my experience—and I am certain that much of this has come before the committee from other witnesses—the most satisfying part of my responsibilities, and I think one of the major roles of my company, is the development of new drugs that are going to be of value to humanity.

We embark upon it with that viewpoint: That we are going to do something positive; that we are going to extend the lives of people who are not even born; and there is so much yet to be done—I do not know how firmly the committee grasps that aspect of it—and we try to work with clinicians and with outside researchers.

My company has about 1,200 people involved in research.

Obviously, we cannot do the entire job ourselves. We try to work with men who are of a similar philosophy: That new drugs and the search for useful new drugs is a challenging and an extremely rewarding effort on our part, for me personally, for our company, and the men we work with.

My experience in a dozen years has been that this is actually the way drug development is carried forward.

Mr. YOUNGER. In your experience, have you found any of the physicians who charge for administering a test of drugs that are furnished to them free, where the physician charges the patient?

Dr. FEENEY. I have never heard of that being done, Congressman.

Mr. YOUNGER. That is all, Mr. Chairman.

The CHAIRMAN. Mr. Glenn?

Mr. GLENN. Doctor, on pages 3 and 4 of your statement you refer to some new regulations by the FDA. Do these in any way have anything to do with this bill which we are considering here today?

Dr. FEENEY. I would like Mr. Hagan to answer that, Mr. Glenn, if you do not mind.

Mr. HAGAN. Mr. Glenn, just in that they would increase the cost of certification, sir.

One of the proposals would increase certification fees by a flat 30 percent.

Another would subject the nonantibiotic, active components of drugs which do contain a certifiable antibiotic drug as one of the other components to the certification requirement.

The net effect would be to increase the cost of certification, and I think we can predict that, since the fees of certification are intended to cover all costs of the certification program, that the fees will be a constantly increasing factor.

Mr. GLENN. But these regulations which you speak of are apt to be placed on the industry by FDA, regardless of whether we pass this act, are they not?

Mr. HAGAN. Yes, sir.

They have been pending for some time, however, without being issued, up to now.

Mr. GLENN. Thank you very much.

That is all, Mr. Chairman.

The CHAIRMAN. How extensive are those fees?

Mr. HAGAN. Well, we estimate that they would very nearly double the present cost of certification, Mr. Harris.

The CHAIRMAN. That still gets me a little more confused.

You just now said that they would be 30 percent.

Mr. HAGAN. No.

One of the three pending proposals would be to increase the costs 30 percent.

Another proposal would subject the nonantibiotic components of a drug that contains a certifiable antibiotic component to certification.

A third increases substantially the amount of testing and sample submission that has to be done.

The CHAIRMAN. In other words, the cost of those which must be certified now would be increased 30 percent?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. And to take in others that you do not have to certify now, would add to your cost?

Mr. HAGAN. That is correct.

The CHAIRMAN. Of course, if anything does not cost much, why, 30 percent does not amount to much.

Mr. HAGAN. That is right.

The CHAIRMAN. The question is how extensive is this cost.

Mr. HAGAN. We certainly do not urge the cost factor as the prime reason for objecting to certification, Mr. Harris. We feel that it is unnecessary and that any cost factor added by an unnecessary procedure should not be continued.

Dr. FEENEY. We submit, Mr. Harris, that our scientific people and those of the Food and Drug Administration might be better employed in the search for new agents and for drugs that do not yet exist.

The CHAIRMAN. Do you know Dr. John L. Harvey?

Dr. FEENEY. Yes, sir.

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Are you familiar with the speech that Dr. Harvey made to the American Bar Association meeting?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Do you recall the statement he made with reference to the reasonableness of the costs?

Mr. HAGAN. I do not recall it, Mr. Congressman, precisely.

The CHAIRMAN. He stated:

Last calendar year certification of the antibiotics now subject to this control cost on the average about one-twentieth of a cent per dose.

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Would you say that would be about correct?

Mr. HAGAN. We have no knowledge of the cost per dose, Mr. Harris.

Our point really is that the additional cost is merely one of the reasons why we oppose extension of certification. During 1960 alone 150 man-years of scientific personnel time was taken up by the Food and Drug Administration in this endeavor. We submit that in view of the scarcity of scientific talent, this scientific talent at FDA could be put to better use.

The CHAIRMAN. Do you contend that the five antibiotics that are now required to be certified—I believe that is true, is it not?

Mr. HAGAN. Yes, sir.

The CHAIRMAN. Do you content that they no longer need to be certified?

Mr. FEENEY. Yes, sir; we do. I have attempted today to create a picture for you of the development of antibiotic production. If you

recall, the urgency for penicillin for the Armed Forces during the war meant that every batch of penicillin that was manufactured, if possible, had to be put into a vial for use by the military; that these were totally new agents at that point in time; and the standards and methods for control were evolving during the course of time that penicillin was being actually distributed to the Armed Forces.

We have long gone past that point.

Antibiotics today are chemicals in the strictest sense of the word.

We would no more consider extending, I do not believe, the certification provisions to any of the drugs that are used in this country, nor would we propose to certify chemicals that go into foods, nor would we propose to certify a monomer or polymer that goes into a man's coat.

The antibiotics are chemicals. Their manufacture is thoroughly understood.

Antibiotic production can be readily controlled just as any of the other chemical processes run by a reputable manufacturer.

The CHAIRMAN. Now, what is required with reference to certification of streptomycin, for example?

Dr. FEENEY. We are still required to submit all batches of streptomycin that are manufactured.

The CHAIRMAN. What is a "batch"?

Dr. FEENEY. A batch will vary, sir. It depends upon the size of the reaction vessels and the fermenter. It could be 500 kilos. It could be 1,000 pounds. It could be 10 pounds.

It will depend upon the production operation, but, generally, it is a very substantial amount of antibiotic. A thousand pounds would not be unusual.

The CHAIRMAN. And under present law you have to provide a sample for these five?

Dr. FEENEY. We provide a sample to the Food and Drug Administration.

The CHAIRMAN. What do they do with it?

Dr. FEENEY. They proceed, among other things, to conduct certain tests. They show that the sample is streptomycin and not something else.

They show that it is biologically active; that it is an antibiotic.

They show that it is pure in the sense that it meets certain standards which relate to it as a chemical.

In the case of streptomycin they show that it is sterile; that it does not contain micro-organisms that would make it impossible to inject it.

They show that it does not contain pyrogens, which are things that cause fever in human beings, and they conduct a whole battery of tests.

We deliver a sample of streptomycin to the Food and Drug Administration, for example, within a matter of hours after we manufacture it.

We then hold the batch in quarantine, which means that we do nothing with it pending completion of our own tests and Food and Drug tests.

At the earliest possible date we start a whole battery of tests of our own which include those being run by the Food and Drug Administration, and in the case of Pfizer we go substantially further in making certain that the material lives up to our own internal standards.

At the end—and this bears on our inventory considerations—at the end of a definite point in time the Food and Drug has completed their tests; we have completed ours; and, as in the case of our statement, only 22 times last year out of 16,000-odd batches that were submitted, was there any reason for the Food and Drug not to pass on the lot that was submitted.

I believe I also made the point that since the manufacturer submits the antibiotic well in advance of his own tests, probably in all 22 of those cases, and we are not privy to the information that is involved, all 22 of those cases, or in the great majority of them, the antibiotic would not have been released by the manufacturer.

The manufacturer would have completed his own tests and decided that the antibiotic should be returned for further purification, if that were the issue involved.

The CHAIRMAN. Now, those that you do not have to submit for certification, do you occasionally find a batch that you have to turn down?

Dr. FEENEY. We have our own internal control, and we do, upon occasion, find a batch that does not live up to the standards of our organization.

The CHAIRMAN. And you take it back and redo it?

Dr. FEENEY. We do not let it out of the company. It is reprocessed or destroyed or whatever is done, as is indicated by the deficiency in the lot.

I wanted to convey to you, Mr. Chairman, that the variations in antibiotic manufacture are no different today than the variations in the manufacture of almost any other chemical.

We have heard so much of the miracle drugs and the magic of their production by micro-organisms and the development of this technology in approximately the last 20 years that we tend to think of these agents as something set apart, and the current state of the science and the manufacturing art is such that that is not the case.

We have not, to the best of my knowledge, for example, in the case of Terramycin, an antibiotic which we discovered and which we produce in enormous quantities, we have not had any instance in which a lot or a dosage form of Terramycin has been distributed to the medical profession anywhere in the world in which—and this is to the best of my knowledge and I believe I am correct—in which there has been anything wrong with the antibiotic.

The CHAIRMAN. Terramycin is an antibiotic?

Dr. FEENEY. It is an antibiotic, sir, yes.

The CHAIRMAN. Is it a drug?

Dr. FEENEY. It is a drug in the sense of the law, yes.

The CHAIRMAN. In other words, you have to get—

Dr. FEENEY. Terramycin was cleared under the new drug procedure of the act.

The CHAIRMAN. You have to clear it with the Food and Drug Administration as to its effectiveness and safety?

Dr. FEENEY. Yes, sir. This was done. The drug was cleared in 1949 and 1950.

The CHAIRMAN. And your reasoning is that since you have it cleared as safe, there is wasted motion in getting these certifications on the batch?

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Dr. FEENEY. We can see nothing useful to be gained by reclearance of the antibiotics that have been cleared under the new drug procedure.

The CHAIRMAN. It appears to me that the ones that you are having to obtain certification on ought to be relieved from this procedure or else the rest of the antibiotics should be brought under the law.

Dr. FEENEY. It would appear, Congressman, that there is an inconsistency here.

There is no doubt in my mind that there is no need for certification of antibiotics in this day and age.

The CHAIRMAN. While we are talking about this, we have heard so much on the subject of efficacy, and we have had Webster's definition.

We have had the definition of this one, that one, and the other one.

We have had a lot of argument around here as to using the term and what effect it would have.

Now, you are a highly competent, well-qualified and experienced individual, I assume. I do not say that to pat you on the back, but I say it because you so impress me.

What is your definition of the meaning of "efficacy" and how is it different from the meaning of the word "effectiveness"?

Dr. FEENEY. Mr. HARRIS, you back me into a corner.

The CHAIRMAN. I know what people do when they get in a corner.

Dr. FEENEY. I am impressed with the multiple interpretations of the English language.

In the last several days I have had an opportunity to marvel at the way it is used by lawyers, and I am a scientist.

Although there are some gray areas in science, most things are black and white.

I was most impressed yesterday with Dr. Klumpp's statement, and it is the one that I subscribe to.

He attempted separately to define both terms, and I am in agreement largely with the way he handled the matter. I would say, though, that, in short, it is what the manufacturer claims for the drug.

The CHAIRMAN. I would assume from that, after having listened to these lawyers, that what the industry is disturbed over now, and as it was in 1951 and 1952, is how the agency will construe the meaning of the word "efficacy." Is that the real problem?

Dr. FEENEY. I would say that that is at the heart of the discussion for the last several days.

The CHAIRMAN. The witness this morning, I believe, used the phrase—I have to paraphrase it, I do not know that I could quote it verbatim, but he used the phrase that efficacy was the extent of the effectiveness.

That gave me the impression that the true meaning of the term must be about the same.

Dr. FEENEY. There is another approach to this, Mr. Congressman.

I told you that I was a Ph. D. in organic chemistry, and everything is either black or white in organic chemistry. It is a pretty exact science. I do not think the word "science" in Webster's dictionary allows for inexactness, but if you have been as close as I have been to medicine for the last dozen years, you become enormously impressed with the fact that some aspects of medicine and the practice

of medicine and the effects of drugs upon human beings are so highly variable that you will find a very wide difference of opinion among physicians as to whether drugs act on certain patients under certain circumstances.

One witness here yesterday, as I recall, said that he was concerned as to what kind of drugs were effective in rheumatoid arthritis, and another witness said categorically that steroids did one thing, and phenylbutazone did another thing, and aspirin did something else.

Within my own experience I have seen this. There is a wide difference in medical opinion on this matter. Medicine is not an exact science. If it were, there would be no need to argue about the English language.

The CHAIRMAN. Well, of course, as a layman and one who does not claim to have any knowledge of these subjects except as a layman would have knowledge, it seems to me the answer is that a particular drug or antibiotic would have different effects on individuals.

Now, the makeup of the individual human being is such that I do not think you could expect aspirin, for example, to have identically the same effect on one person as it would have on another person.

Mr. SCHENCK. Will the chairman yield?

The CHAIRMAN. When you can discover the makeup of all 3 billion people in the world, then you will have this thing whipped.

Mr. SCHENCK. Some people are allergic to aspirin and to a lot of other drugs, so it does affect various individuals differently, and even the same people at different times.

The CHAIRMAN. A Member of Congress just told me only yesterday about a person that is very close to his family who developed a ringing in the ears, and, after a rather extensive examination, it was found that he had been taking too many aspirin.

I never heard of it before, but that is what I was told by a Member who seemed to know what he was talking about.

That is not going to keep me from taking aspirin if I think I need it sometime, but it does point up this problem.

In fact, I know the first time that I had penicillin administered to me, I had a violent reaction to it.

I did not know what was wrong with me.

But another doctor, in another town where I happened to be at that time, asked me if I had recently had penicillin, and I told him, yes, 3 days ago.

So he had to go back to find out from the same doctor what to do to treat it. That has been a good many years ago. Since then I have had any number of penicillin shots but no reaction.

Whether I became immune to it, I do not know.

But those are the things that do worry me about submitting to the final decision of any one individual, as was mentioned here yesterday, about the use of these drugs. I am old fashioned enough to believe that a doctor who has administered to a particular patient over the years probably knows more about what to do than anybody else.

Mr. Thomson, I have used all your time, I am afraid.

Mr. THOMSON. It has been very interesting. I have no questions.

The CHAIRMAN. Thank you very much.

Dr. FEENEY. Thank you, sir.

(The following information was submitted by Chas. Pfizer and Co., Inc.):

**EXTENSION OF CERTIFICATION TO ALL ANTIBIOTICS—SUGGESTED MODIFICATIONS**

Extension of certification to include the many hundreds of human and veterinary dosage forms containing presently uncertified antibiotics will be productive of serious difficulties and confusion.

Requests for regulations permitting certification, or exemption from certification for all these dosage forms, will have to be submitted to FDA. This will need to be done even though virtually all of these drugs have previously been cleared by FDA under the new drug procedures.

In effect, FDA will rereview all of the clearances for these products which it has given over the last 13 years, and it will have the power to change its mind as to whether to permit the labeling for such products to bear any or all of the already accepted recommendations for use. If all antibiotics are to be subjected to certification, the following two modifications are proposed in an attempt to minimize the difficulties and inequities which will likely result:

First: Section 105 of H.R. 11581 should be amended to add the following new subsection to section 507 of the Food, Drug, and Cosmetic Act:

"As a requirement for issuance of a regulation providing for certification, or exemption from certification, for any drug as to which a new drug application, or supplement thereto, was in effect at any time prior to enactment of this Act, and has not been withdrawn or suspended pursuant to section 505(e) of the Act, the Secretary shall not require submission of efficacy data with respect to any indications for use contained in labeling which was a part of such new drug application, or supplement thereto."

Second: The extension should be confined to drugs for human use, and should not include veterinary drugs and drugs for use in animal feeds.

**REASONS FOR THE "FIRST" SUGGESTED MODIFICATION**

The vast majority of the hundreds of dosage forms which would become subject to certification as the result of enactment of H.R. 11581 have been, as beforementioned, already cleared by FDA under the new drug procedures. Unless a modification of the type proposed above is adopted, before FDA will issue regulations providing for the certification of each of these dosage forms, it will rereview the efficacy data bearing on each of the indications for use contained in their labeling.

This rereview will be made by a different division at FDA (and hence by different individuals) than the one which reviewed and cleared the new drug applications for these products. Since "efficacy" is a matter upon which equally competent authorities will frequently disagree, there is a real likelihood that, as a result of this rereview, some, or perhaps many previously accepted (by FDA and the medical and veterinary professions) uses for such drugs will be prohibited. At the very least, there will be prolonged delays while the Antibiotics Division rereviews the massive amounts of efficacy data available on these many hundreds of dosage forms, which data has already been reviewed and found acceptable by the New Drug Division.

The Senate has just considered the problems which "reclearance" by FDA would create for "new drugs" as the result of the "efficacy" provisions in S. 1532. Unfortunately, it did not consider the fact that the presently noncertified antibiotics would encounter the same problems as the result of extension of certification. To resolve such problems for "new drugs," the Senate bill (S. 1552) contains in section 8(g)(3) provisions which, in their essence, are the same as the "first" proposed modification set forth above.

The report of the Senate Judiciary Committee (on p. 7) contains the following explanation of section 8(g)(3):

Under the amendment, a drug which is on the market and has gone through the new-drug procedure would not have to be resubmitted for clearance of existing label claims with respect to effectiveness of the drug unless approval of the new drug is withdrawn or suspended under the act or unless an amendment or supplement to the effective new-drug application is filed (in which event only the changed labeling would be reevaluated)."

The "first" proposed modification set forth above seeks to accomplish the same equitable result.

## REASONS FOR THE "SECOND" SUGGESTED MODIFICATION

The main reason which has been advanced by the Government for extension of certification to all antibiotics is that this extreme form of governmental control is justified because these drugs are more often used against life-threatening infections in man than other drugs. While industry disputes the validity of this justification even as to infectious diseases of man, it is submitted that the fact that antibiotics are sometimes used against life-threatening infections of animals clearly is not of sufficient magnitude to justify such control over antibiotics for animal use.

The existing situation with respect to obtaining FDA clearance to market veterinary drugs or drugs for animal feeds is highly unsatisfactory because it is frequently necessary to obtain clearance for such drugs under both the food additives amendment and either the new drug or antibiotic certification procedures. This situation has become so burdensome and confusing that the Animal Health Institute has proposed legislation which would establish separate FDA clearance procedures for drugs for animal use. Extension of certification to all veterinary drugs and animal feeds containing presently uncertified antibiotics would compound the existing problems in this area.

The problems discussed above are particularly acute in the case of drugs used in feeds. To extend the antibiotic certification provisions to all antibiotics so used would accomplish no worthwhile purpose whatsoever since it is entirely impractical to certify each batch of such feeds. Three of the currently certifiable antibiotics are widely used in feeds, and FDA, so far as we are aware, has certified no batches of such feeds. Instead it has issued a maze of "exemptions" from certification. This means that the degree of governmental control over feeds containing certifiable antibiotics is no greater than in the case of feeds containing uncertifiable antibiotics (although in both cases the degree of control is more than adequate).

Because of practical considerations, moreover, if the certification procedures are extended to all other antibiotics used in feeds, it is virtually certain that such feeds will also be marketed under exemptions from certification. However, before such exemptions are granted a wholly unnecessary, wasteful, and time-consuming reclearance of each of the antibiotic feed uses will presumably be required in spite of the fact that virtually all of such uses were previously cleared under the new drug procedures.

No logical reason has been presented by the Government for extension of certification to antibiotics used in veterinary drugs and animal feeds. The degree of governmental control presently provided over such drugs by the Food, Drug, and Cosmetic Act (including the food additive and new drug provisions) exceeds the control provided over any other products subject to that act. Extension of certification to all antibiotics used in such products is totally unnecessary and would create extreme confusion, burdens, and delay.

CHAS. PFIZER & Co., INC.

The CHAIRMAN. Mr. Franklin M. Depew. We are glad to have with us, Mr. Depew, and we will be glad to have your statement.

## STATEMENT OF FRANKLIN M. DEPEW, CHAIRMAN, FOOD, DRUG, COSMETIC SECTION, NEW YORK STATE BAR ASSOCIATION

Mr. DEPEW. Thank you very much.

Mr. Chairman and members of the committee, my name is Franklin M. Depew of 205 East 42d Street, New York City 17, N.Y. I am a member of the bar of the State of New York and chairman of the section of food, drug, and cosmetic law of the New York State Bar Association. This section was the first organization of lawyers practicing throughout the country in the food, drug, and cosmetic field, and its members represent most of the major companies engaged in the manufacture of food, drugs, and cosmetics.

The executive committee of the section has authorized me to appear in support of the view that the inspection provisions of section 704 of the Food, Drug, and Cosmetic Act, should be retained without

change on the ground that no need has been demonstrated for the proposed expansion of authority as contained in section 201 of H.R. 11581.

This committee has approved the statement which I am about to make.

On March 15, 1962, President Kennedy in his special message to Congress on consumer protection stated that an uncooperative small minority can engage in a game of hide-and-seek with the Government in order to avoid inspection. The proposal is, therefore, apparently directed against an uncooperative small minority, yet, these are exactly the businesses that would be least likely to maintain adequate or accurate records. Thus, the privacy of the great majority of respectable businessmen is to be prejudicially invaded because of the misbehavior of a very small minority.

It cannot be too strongly stated that inspection of these factories as provided by this section, by outsiders, can expose to the world trade secrets, know-how, and other confidential information. This technology is, in the truest sense, the property of its owners. Frequently, it constitutes the element of greatest value—in economic and competitive terms in the manufacture of a product. To subject such technology to outside inspection exposes it to possible dedication to the public domain.

Of course, we are aware that FDA inspectors are subject to injunctions of secrecy. But that is no assurance to business corporations who guard their technology under the most elaborate security precautions. Yesterday's government official is tomorrow's private employee. Proof of unlawful disclosure is difficult. Surely these risks are not outweighed by the administrative inconvenience to which FDA may be put absent the powers granted in section 201 of H.R. 11581.

In concluding I would say that we in the section have the very highest regard for this great public agency, the Food and Drug Administration.

We do feel that, rather than a new law, they might possibly have endeavored to work out a better working relationship with industry with regard to these factory inspections.

Their inspectors, after all, are not administrative people or even trained in this field, and they have never attempted to demonstrate why disclosure would further the remedial purposes of the law.

We strongly urge your sympathetic consideration of this viewpoint. Thank you.

The CHAIRMAN. Thank you, Mr. Depew, for your statement which the committee is glad to have.

Mr. Schenck observes from your statement, "yesterday's government official is tomorrow's private employee," that it might have some bearing on the election.

Mr. DEPEW. Well, it could have.

The CHAIRMAN. It is entirely possible.

Mr. DEPEW. That is very true.

The CHAIRMAN. Mr. Roberts, any questions?

Mr. ROBERTS. No questions.

The CHAIRMAN. Mr. Schenck, I will give you your chance.

Mr. SCHENCK. Mr. Chairman, I would like to commend Mr. Depew for his concise and well-developed statement.

Mr. DEFEW. Thank you.

Mr. SCHENCK. Expressing his point of view, and to also note that it may or not be significant, but your first name is Franklin rather than Chauncey.

That is all, Mr. Chairman.

The CHAIRMAN. Thank you very much, sir. We are delighted to have you with us.

Mr. DEFEW. Thank you. I appreciate the opportunity to be here.

The CHAIRMAN. The Chair would like to inquire if there is any other witness here who is scheduled to testify tomorrow, who would like to testify today.

This completes the witnesses scheduled for today. The committee will adjourn until 10 o'clock in the morning.

(Whereupon, at 2:45 p.m., the hearing was adjourned, to reconvene at 10 a.m., Wednesday, August 22, 1962.)