

We were under the impression that they all had adequate inspection authority.

I would like to take this opportunity to say that the NARD has a fine record of cooperation with FDA officials.

We like them very much.

We just think that they are wrong in this particular instance.

Mr. Cohen, do you know that?

Mr. YOUNGER. My recollection may be wrong, but I thought that he mentioned that all the States except one—we were discussing that time the question of intrastate, where they were asking permission to go in to investigate and control the sale of these pep pills that they sell to the truckdrivers, and that that trade was out of hand, and while it is intrastate, they want authority to go in.

I asked him specifically how many States did not have adequate inspection, and he said all except one.

I forgot to ask him which one.

Mr. ROBERTS. Is it California?

Mr. YOUNGER. No, sir.

California has one of the most far reaching and adequate inspection laws of any State.

Mr. COHEN. Mr. Chairman, with your permission, we have a list of all the States and how the laws are enforced and who supervises them.

We would be glad to furnish this information for the committee.

The CHAIRMAN. You may supply the information, and we will find out what single State does not have adequate laws.

Mr. COHEN. According to this information, they all have it, Mr. Younger.

Mr. YOUNGER. That is all.

(The information to be supplied is as follows:)

STATE STATUTES HAVING INSPECTION PROVISION FOR DRUGS

1. Alabama: Amphetamines, and/or Other Stimulating Drugs Law Act 189, 1961 Special Session Laws of Alabama. Section 6—Inspection Provision.
2. Alaska: Food, Drug, and Cosmetic Act, chapter 129, Laws of Alaska, 1949. Section 22—Inspections—Examinations.
3. Arizona: Pharmacy, Dangerous Drug & Poison Law, title 32, chapter 18, Arizona Revised Statutes, Annotated. Section 32-1904 (7)—Power and Duties of Board of Pharmacy—Inspection.
4. Arkansas: Food, Drug, and Cosmetic Act, title 82, chapter 11, Arkansas Statutes 1947, Annotated. Section 82-1120—Inspection of Establishments—Examination of Specimens.
5. California:
 - Pure Drugs Act, Division 21, chapter 2, Health and Safety Code, 1947, Deering's California Codes, Annotated:
 - Section 26294—Prevention of Free Access of Agent to Establishment Manufacturing, etc. or to Vehicle Transporting, Drugs Unlawful.
 - Section 26330—Inspection of Factories and Vehicles.
 - Pharmacy Law, Article 8—Dangerous Drugs:
 - Section 4231—Stocks To Be Open to Inspection.
 - Section 4232—Records To Be Open to Inspection.
6. Colorado:
 - Food and Drug Act, chapter 66, article 22, Colorado Revised Statutes, 1953. Section 66-22-20—Inspections.
 - Pharmacy and Poison Law, chapter 48, article 1, Colorado Revised Statutes, 1953. Section 48-1-2—Power and Duties, (g) Inspection.
7. Connecticut: Food, Drug, and Cosmetic Act, title 19, chapter 342, General Statutes of Connecticut, 1958. Section 19-237—Establishing Inspection.

8. Delaware: Pharmacy Law, title 24, chapter 25, Delaware Code Annotated. Section 2562—Inspections.

9. Florida:

Food, Drug, and Cosmetic Act, chapter 500, Florida Statutes, 1959. Section 500.21—Inspection of Factories, Warehouses, etc., by Commissioner and Board. Pharmacy Law, chapter 465, Florida Statutes, 1959. Section 465.131—Authority To Inspect.

10. Georgia: Drug and Cosmetic Act, chapter 42-15, Georgia Code Annotated. Section 42-1515—Access to Factories, etc. by State Board of Pharmacy; Inspections; Examinations of Samples.

11. Hawaii:

Food, Drug and Cosmetic Act, title 7, chapter 51, Revised Laws of Hawaii, 1955:

Section 51-24—Inspection powers of Commissioner.

Section 51-25—Furnishing of Samples to Commissioner Required.

Section 51-26—Commissioner's Right of Inspection and Seizure.

Sale of Poisons law, title 7, chapter 53, Revised Laws of Hawaii, 1955, Section 53-5—Record of Prescriptions. The books and prescriptions shall be subject at all times to the inspection of the department of health or its agent.

12. Idaho:

Food, Drug and Cosmetic Act, title 37, chapter 1, Idaho Code, 1949. Section 37-133—Inspection of Establishments, etc.

Drug, and Medical Supplies Law, title 37, chapter 22, Idaho Code, 1949. Section 37-2209—Inspection.

13. Illinois:

Drug, Device and Cosmetic Act, chapter 38, Illinois Revised Statutes 1959:

Section 186.31—Carriers and Persons Engaged in Holding or Receiving

Drugs, etc., in Commerce—Access to Records by Division.

Section 186.32—Factory, etc., of Vehicle—Entry and Inspection—Power of Superintendent.

14. Indiana:

Food, Drug, and Cosmetic Act, title 35, chapter 31, Burns Indiana Statutes, Annotated:

Sec. 35-3111. Availability of State Records.

Sec. 35-3113. Establishment Inspection.

Dangerous Drug Act, chapter 45—Acts of Indiana, 1961. Section 5. Records—Maintenance of.

15. Iowa:

Drug and Cosmetic Act, chapter 203A, Code of Iowa, 1958. Section 203A.16—Authority of Board—Inspection.

Pharmacists and Wholesale Druggists, chapter 155, Code of Iowa, 1958. Section 155.24—Inspection.

16. Kansas:

Food, Drug and Cosmetic Act, chapter 65, article 6, 1959 Supplement to General Statutes of Kansas, 1949. Section 65-674—Free Access to Establishments and Vehicles for Inspections and Samples.

Pharmacy Law, chapter 65, article 16, 1959 Supplement to General Statutes of Kansas, 1949. Section 65-1629—Inspection of drugs by board.

17. Kentucky: Food, Drug and Cosmetic Act, title XVIII, chapter 217, Kentucky Revised Statutes, 1960. Section 217.155—Department's Rights of Inspection; Requirement That Drug Inspector Be a Pharmacist.

18. Louisiana:

Food, Drug and Cosmetic Act, title 40, chapter 4, part 1, Louisiana Revised Statutes 1970. Section 631—Factory Inspection.

Pharmacy Law, title 37, chapter 14, Louisiana Revised Statutes 1950. Section 1178—Powers and Duties of the Board—Inspection.

19. Maine: Pharmacy and Poison Law, chapter 68, Revised Statutes of Maine, 1954. Section 1—Commissioners of the Profession of Pharmacy: Powers—Inspection.

20. Maryland: Pharmacy Law, article 43, Annotated Code of Maryland, 1957. Section 235—Inspection of Medicines, Drugs, or Domestic Remedies.

21. Massachusetts:

Food, Drug, Cosmetic, and Device Law, chapter 94, Annotated Laws of Massachusetts. Section 189A—Proceedings When Food, Drugs, Cosmetics, or Devices Suspected of Being Adulterated or Misbranded.

- Narcotic Drug Law, chapter 94, Annotated Laws of Massachusetts:
 Section 199. Sales by Pharmacists Upon Written Prescription; Requirements as to Prescriptions.
 Section 203. Prescriptions, Orders, and Records Open Only to Certain Persons; Knowledge Not To Be Divulged; Exception.
- Pharmacy Law, chapter 112, Annotated Laws of Massachusetts. Section 36C—"Wholesale Druggists" etc., Use of Term Restricted; Inspections; Reports of Violations.
22. Michigan: Pharmacy Law, Act 151, Public Acts of Michigan, 1962:
 Section 18. All Prescriptions shall be preserved for a period of 5 years, subject to inspection by the board or its agents.
 Section 5. The board shall appoint, inspectors who shall be registered pharmacists and who shall act as agents of the board within the provisions of this act and such rules and regulations as the board shall promulgate. Inspectors shall be hired from the eligible civil service roster of qualified persons.
 Section 6. The board shall (b) regulate, control, and inspect the sale, character and standard of drugs, devices, and new drugs compounded, possessed or dispensed in this State, etc.
23. Minnesota: Pharmacy and Poison Law, chapter 151, Minnesota Statutes, 1957. Section 151.06—Powers and Duties—Inspection.
24. Mississippi: Pharmacy Law, title 32, chapter 9, Mississippi Code 1942, Annotated. Section 8852—Power of Board of Pharmacy, (d) Inspection.
25. Missouri: Food, Drug, and Cosmetic Act, chapter 196, Missouri Revised Statutes, 1959:
 Section 196.055—Access to Places in Which Food, Drugs, Devices, or Cosmetics Are Manufactured.
 Section 196.060—Carriers in Interstate Commerce Shall Permit Access to Records of Shipments.
26. Montana:
 Food and Drug Law, title 27, chapter 1, Revised Codes of Montana, 1947. Section 27-112—(2591) Duties and Powers of State Board of Health—Regulations. (1) The board shall make all necessary investigations and inspections in reference to all food and drugs, etc.
 Pharmacy, Regulation of Sale of Drugs and Medicines, title 66, chapter 15, Revised Codes of Montana, 1947. Section 66-1504—(3174) Montana State Board of Pharmacy—Powers of Board. (5) To enter and inspect by its duly authorized representative at any reasonable times any and all places where drugs, medicines, chemicals, or poisons are sold, vended, given away, compounded, dispensed, or manufactured.
27. Nebraska: Poisons Law, chapter 71, article 25, Revised Statutes of Nebraska, 1943. Section 71-2503—Poisons: Sale; Duty of Vendor to Record in Poison Register (Register Open for Inspection by Proper Authorities).
28. Nevada: Food, Drug, and Cosmetic Act, title 51, chapter 585, Nevada Revised Statutes. Section 585.240—Inspection of Factories and Vehicles.
29. New Hampshire: Food, Drug, and Cosmetic Act, chapter 146, New Hampshire Revised Statutes, 1955. Section 146:11—Enforcement; Rules; Inspections.
30. New Jersey:
 Food, Drug, and Cosmetic Law, title 24, subtitle 1, New Jersey Statutes, Annotated. Section 24:3-1—Right of Entry: Opening Packages; Inspection.
 Drugs, Manufacturers and Wholesalers, title 24, subtitle 1, chapter 6B, New Jersey Statutes Annotated. Sec. 24:6B-9—Right To Examine and Copy Records Listing Ingredients Used in Manufacture of Such Drug—If Believed Adulterated or Misbranded.
31. New Mexico:
 Drug and Cosmetic Act, chapter 54, article 6, New Mexico Statutes Annotated, 1953. Section 54-6-16—Power To Make Inspections and Secure Samples.
 Drug Store—Wholesaler—Manufacturer Registration Law, chapter 67, article 9, New Mexico Statutes, Annotated 1953. Section 67-9-24—Board Authorized To Hire Inspector.
32. New York: Pharmacy, Drugs, Devices, and Cosmetic Law, article 137, Education Law, McKinney's Consolidated Laws of New York. Section 6819—Factory Inspection.

33. North Carolina: Food, Drug, and Cosmetic Act, chapter 106, article 12, General Statutes of North Carolina, 1943. Section 106-140—Further Powers of Commissioner—Inspection.

34. North Dakota: Poison Law, title 19, chapter 19-04, North Dakota Century Code. Section 19-0403—Record To Be Kept of Poisons Dispensed; Examination of Record.

35. Ohio: Food, Drug, and Cosmetic Law, title 37, chapter 3715, Ohio Revised Code. Section 3715.70—Powers of the Director or Board of Pharmacy—Inspection.

36. Oklahoma:

Drug, Device, and Cosmetic Act, title 63, Oklahoma Statutes 1961. Section 266.15—Right of Access and Entry.

Pharmacy and Poison Law, title 59, Oklahoma Statutes 1961. Section 353.7—Powers and Duties of Board—Inspection (d).

37. Oregon: Poison Law, title 36, chapter 453, Oregon Revised Statutes. Section 453.020—Manufacture and Sale of Drugs To Conform to Standards; Substitutions Prohibited; File of Prescriptions (5) Original Prescriptions Received and Filled—Filed in Manner as Will Readily Be Accessible for Inspection by the Board of Its Duly Authorized Agent.

38. Pennsylvania:

Drug, Device and Cosmetic Act, title 35, chapter 6, Purdon's Pennsylvania Statutes Annotated. Section 780.17—Inspections.

Pharmacy Act, title 63, chapter 9, Purdon's Pennsylvania Statutes, Annotated. Section 390-6—Board of Pharmacy (h) (6) Inspection.

39. Rhode Island: Food, Drugs and Cosmetics Act, title 21, chapter 31, General Laws of Rhode Island, 1956. Section 21-31-21—Inspection of Establishments.

40. South Carolina: Pharmacy and Poison Law, title 56, chapter 22, Code of Laws of South Carolina. Section 56-1311.1. Additional Regulatory Powers of the Board.—The Board shall also regulate the practice of pharmacy, the operation of drug stores and pharmacies * * * and, in so doing, shall make, publish, supervise * * * The inspection of weights and measures used in the prescription department of drug stores and pharmacies and the compounding, dispensing and sale of drugs, medicines, poisons and physicians' prescriptions * * *.

41. South Dakota:

1960 Supplement to South Dakota Code of 1939; Title 22—Foods, Drugs, Oils and Compounds. Part I—General Administrative Provisions. Chapter 22.01—Department of Agriculture. Section 22.104—Assistance of public officers may be required (1) the Secretary of Agriculture, his agents or assistants by written or oral notice may require any police officer to inspect any place or product subject to the supervision of such Secretary under the provisions of this title, to determine whether its provisions are being complied with and to report the result of such inspection in accordance with the rules and regulations of the Department of Agriculture.

Barbiturates: Handling, Sale and Distribution, chapter 22, 12 A, South Dakota Code of 1939 (1960 supplement). Section 22, 13A07—Records: Availability to State Board of Health.

42. Tennessee:

Food, Drug and Cosmetic Act, title 52, chapter 1, Tennessee Code Annotated. Section 52-122—Inspection of Establishments.

Pharmacy and Poison Law, title 63, chapter 10, Tennessee Code Annotated. Section 63-1007—Inspection powers.

43. Texas:

Food, Drug and Cosmetic Act, Senate Bill 43, 1961 Acts of Texas. Section 21—Inspection Powers.

Dangerous Drug Law, title 12, chapter 3, article 726d, Penal Code, Vernon's Texas Statutes, 1960 Supplement. Section 6—Files or Records; Inspection, Inventory of Drugs.

44. Utah: Food, Drug and Cosmetic Act, title 4, chapter 26, Utah Code Annotated, 1953. Section 4-26-21—Power of Board To Have Access to Buildings, Vehicles, and Places—Inspection.

45. Vermont:

Food, Drug, Cosmetic and Hazardous Substance Labeling Act, title 18, chapter 82, Vermont Statutes Annotated. Section 4070—Inspection.

Poisonous Drugs Law, title 18, chapter 81, Vermont Statutes Annotated. Section 4026—Sale of Drugs; Record.

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46. Virginia: Pharmacists and Drugs, title 54, chapter 15, Code of Virginia, 1950. Section 54-417—Power of Inspection.

47. Washington: Food, Drug, and Cosmetic Act, title 69, chapter 69.04, Revised Code of Washington. Section 69.04.370—Right of Access for Inspection.

48. West Virginia: Food and Drug Law, chapter 16, article 7, West Virginia Code of 1955. Section 1371—(3) Inspection of Analysis of Food and Drugs.

49. Wisconsin:

Pharmacy, chapter 151, Wisconsin Statutes, 1959. Section 151.01—Board. (3) The board (pharmacy) shall have the right to employ inspectors, special investigators, chemists, agents and clerical help for the purpose of carrying on the work of the board * * *.

Dairy, Foods and Drugs, chapter 97, Wisconsin Statutes, 1959. Section 97.34—Access to Buildings; Samples; Holding Order.—(1) The department (agriculture) or any of its authorized agents * * * may enter any place or building in which there is reason to believe that any food, drink or drug is made, prepared, sold or offered for sale, and may open any package or receptacle of any kind containing, or which is supposed to contain, any article of food, drink or drugs, and examine or analyze the contents thereof.

50. Wyoming: Pharmacy Act, title 33, chapter 22, Wyoming Statutes, 1957. Section 33-307—Powers of Board Pharmacy (4) To Inspect, etc.

The CHAIRMAN. Mr. Dingell?

Mr. DINGELL. Mr. Chairman, I am glad to see my old friend, Mr. Jehle, before the committee.

He said a number of things with regard to Food and Drug. He said at one point that he did not think it would be appropriate for Food and Drug to conduct vague, rambling, fishing expeditions.

Do you have any indication or any evidence that would indicate to you or to this committee that Food and Drug has been engaged in that kind of practice over the years?

Mr. JEHL. Mr. Dingell, I would say that, based upon information supplied us by certain of our members, that sometimes an inexperienced, less-qualified FDA inspector might be guilty of such an investigation.

But the point we are trying to make here, sir—

Mr. DINGELL. This is a very serious charge you make.

Mr. JEHL. There is no charge being made here. I am saying that—

Mr. DINGELL. You are telling us this morning that less-qualified, inefficient, and inexperienced food and drug investigators have occasionally gone in and meddled in your plants and constituent members' affairs.

Now, is this true or false?

Mr. JEHL. I would like to have the point made exceedingly clear that the provisions of the bill would give an FDA agent the right to make that type of inspection.

Mr. DINGELL. I am not belaboring that point.

Mr. JEHL. That is the only point I wish to make, Mr. Dingell.

Mr. DINGELL. At this time I wish to know: Do you have any evidence that would indicate that the Food and Drug Administration has in the past engaged in any activity that would meet your description of vague, rambling, fishing expeditions?

Mr. JEHL. The statement that I made was not that such investigations have been made as a matter of course or routinely, but potentially they may be made. It is possible under the language of the bill.

Mr. DINGELL. Would you tell the committee this morning whether the Food and Drug has in the past engaged in this kind of practice?

Mr. JEHL. No, sir; because they do not—

Mr. DINGELL. I beg your pardon?

Mr. JEHLE. Let me make it quite clear that FDA agents at present do not have the right to make such inspections without the consent—without the permission of the retail pharmacies.

Mr. DINGELL. I see.

So have you any evidence of Food and Drug agents having engaged in, or any information that would lead you to think that Food and Drug agents have at any point engaged in, vague, rambling, fishing expeditions into the affairs of retail pharmacies?

Mr. JEHLE. I said earlier that we have received complaints from members that FDA agents, even where granted permission by retail pharmacies, have made this type of rambling, vague—

Mr. DINGELL. You have received this kind of information?

Mr. JEHLE. Oh, yes.

I say it is not common. It is not a routine practice.

Mr. DINGELL. You would not object to presenting evidence before this committee on these vague rambling expeditions by Food and Drug?

You would not have any objection to documenting that they have conducted themselves in this manner?

Mr. JEHLE. The complaints that have been received—is that the type of evidence that you would require, Mr. Dingell?

Mr. DINGELL. I would just like to see some evidence that Food and Drug has behaved in this manner.

You have made the statement now that they have done this in the past.

I would like to see it documented.

Mr. JEHLE. I thought I made quite clear, sir, that these instances were sporadic. They are not a matter of routine, a matter of course, at all.

Mr. DINGELL. As a matter of fact, they are very few and far between, are they not?

Mr. JEHLE. Yes.

Mr. DINGELL. Practically nonexistent and not well documented at all, is this not true?

Mr. JEHLE. If this bill should pass, we might have a great many more.

Mr. DINGELL. We are taking this step by step, and I hope you will cooperate with me because we do not have unlimited time.

Mr. JEHLE. Yes, sir.

Mr. DINGELL. As a matter of fact, these inferences that you suggest this morning are not well documented, and they are rather few and far between, are they not?

Mr. JEHLE. I will not say that they are well documented. I can present the evidence, if it should become necessary.

Mr. DINGELL. What I am saying is that your statement is based on hearsay.

Mr. JEHLE. No, sir; absolutely not.

Mr. DINGELL. And not on sound knowledge of FDA practice.

Mr. JEHLE. I wish, sir, that my statement would be considered in the context in which it appears.

The point made is that the language is extremely broad, and I think that under that type of language, vague, rambling, fishing expeditions could be conducted by the FDA inspectors.

Mr. DINGELL. Now, let us get right down to this business.

You say that they can go in right now and can get information where they need to have it for law enforcement purposes through the use of a search warrant?

Mr. JEHL. Yes, sir.

Mr. DINGELL. Is that correct?

Mr. JEHL. Oh, yes.

Mr. DINGELL. The use of a search warrant is permitted only in one instance, is that not so, under traditional Anglo-Saxon law, and that is that it can be had only where the court is satisfied that there is probable cause to believe there has been commission of a crime, and that the warrant is needed for the purposes of gathering evidence useful in the prosecution of that crime?

Is this not a fact?

Mr. JEHL. Probable cause; yes, sir.

Mr. DINGELL. This is the only time, probable cause that a crime has been committed and that the evidence is on the premises?

Mr. JEHL. And this is a criminal statute with which we are dealing.

Mr. DINGELL. In the case of the Food and Drug Administration in the protection of the American public, they are not going to always have evidence that a crime has been committed, but, rather, they are going to very frequently be looking to make a check to discern whether or not good manufacturing practices are being used, whether dangerous and harmful drugs like amphetamines and barbiturates are being released upon the market through sundry channels. Is this not a fact?

Mr. JEHL. Not that retail pharmacists manufacture.

Mr. DINGELL. I am not engaging in any fencing match.

Mr. JEHL. That is what you just said. You referred to the manufacturing processes of the retail pharmacist.

Mr. DINGELL. No; I said this: I said, is it not a fact that this situation will not apply in many instances where the Food and Drug is involved because Food and Drug's function is not basically the prosecution of crimes?

Mr. JEHL. Yes, sir.

Mr. DINGELL. But it is to assure that commodities are manufactured in a wholesome and safe way; that they are not adulterated, filthy or dangerous, is this not a fact?

Mr. JEHL. Yes.

Mr. DINGELL. And so also it is a fact that Food and Drug will very frequently in its operations not have evidence of crime, but will simply be seeking to determine whether or not manufacturing processes are sound, safe, sanitary, and whether or not commodities of various kinds are safe, unadulterated and are fit for public use and not dangerous.

Is this not a fact?

Mr. JEHL. That is correct; yes.

Mr. DINGELL. So, very frequently, where they need to perform their basic function, they will not have an opportunity to satisfy the re-

quirements of the law with regard to search warrants, and, yet, they must have certain information to carry out their basic function.

Is this not also true?

In other words, they must have the opportunity to gather information which will enable them to discern whether or not these commodities which they have responsibility over are actually safe and fit for public use; is this not true?

Mr. JEHLER. At the manufacturing level, yes.

Mr. DINGELL. At the manufacturing level, and I assume that in the course of their check, they are going to have to discern whether or not these commodities are on the shelves and in the stores of the retail pharmacies.

Mr. JEHLER. Let me say right now, Mr. Dingell, that the relationship between the NARD members and the FDA have been very fine for many years.

I think, as I told you, almost all of our members will cooperate with the FDA agents.

Mr. DINGELL. As a matter of fact, it has been so good over the years that you really have no cause to be fearful of any provisions of this bill, on the basis of your past experience, because your membership has been able to have a fine and wholesome relation with Food and Drug?

Mr. JEHLER. Why do we not just leave it on a voluntary basis, then? Why turn it into a compulsory process?

Mr. DINGELL. You have no reason to fear, on the basis of your past experience.

Mr. JEHLER. We do not want the compulsion, sir. We think that the State authorities are doing an excellent job of inspecting our files, our business records, and we would like to keep it that way.

Mr. DINGELL. Let us talk about the amphetamines. It is a fact, is it not, that there are large quantities of amphetamines that are getting into the marketplace, that are having a very dangerous effect upon the populace? This is true, is it not?

Mr. JEHLER. I think so; yes, sir.

All the evidence would indicate that that is true, sir.

Mr. DINGELL. And the Food and Drug indicates to us that controls under existing laws are not sufficient to protect interstate commerce and the people of this country from the large flow of both barbiturates and amphetamines; is this not correct?

Mr. JEHLER. That is correct.

Mr. DINGELL. And they are, of course, expert in the enforcement of law, and they have a good understanding of basic needs with regard to amphetamines, which I think perhaps is superior to the knowledge of the National Association of Retail Druggists, do they not?

Mr. JEHLER. I am not going to debate that, sir.

Mr. DINGELL. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Jehle, did I understand you to say that there is a voluntary understanding and cooperation between the pharmacists of the country and the Food and Drug inspectors?

Mr. JEHLER. That is correct.

I would like to have Mr. Cohen elaborate somewhat upon that in view of his experience.

Mr. COHEN. Mr. Chairman, in almost every instance where an FDA inspector comes into a retail pharmacy and identifies himself properly, he is treated very courteously and given the opportunity to get the information that he seeks.

Also, on the State level the FDA has had excellent cooperation with the State enforcement agencies. Where they have not been able to go into some isolated drugstores, they work through the State agencies.

I know of no instance where an FDA agent has had any problem getting the information that he seeks.

The CHAIRMAN. I have had some reports in my own district where on at least two occasions inspectors have gone into a drugstore and obtained the cooperation of the druggist, and, during the course of their inspection they came across certain things out of which came some charges. In one instance this caused some very serious problems for the druggist.

Have you had any similar reports?

Mr. COHEN. Yes.

There have been some reports to that effect.

The CHAIRMAN. I suppose they are not widespread. In my district, which is a rather large district, with a good many communities, and a lot of drugstores, there have been very few such instances reported to me. I can think of only one in which they did give the druggist a great deal of trouble and caused him a lot of concern.

But your great worry or fear is that if the authority of the agency is expanded, there will be a great many more such instances?

Is that your fear?

Mr. COHEN. Yes, sir.

It is very possible that that could happen.

The CHAIRMAN. Or is your objection based on the confidentiality of information between the doctor, the druggist, and the patient?

Mr. COHEN. That is a very important point, sir, because there has always been the feeling that the pharmacist should not disclose any information about a prescription unless the physician desires it or orders it.

He is very careful, in fact, to disclose information to the patient when such information is sought.

He usually, and in almost every instance, will refer the inquiry back to the physician.

Mr. JEHLE. And we might point out, Mr. Chairman, that those professional considerations apparently have moved the Federal Food and Drug Administration to exempt licensed medical practitioners from the provisions of this bill. I am referring to the patient-physician relationship.

The CHAIRMAN. Thank you very much.

Mr. SCHENCK. Mr. Chairman, may I ask one question?

The CHAIRMAN. Mr. Schenck?

Mr. SCHENCK. Thank you.

It was suggested during the testimony of one of the witnesses that information on the prescription or a duplicate copy of the prescription could be given to the patient by the pharmacist in the event that the

patient felt he might need that information, at a time when he was away from his home community and his own physician.

Is that possible or is that unethical or is it illegal for a pharmacist to do that?

Mr. COHEN. Mr. Schenck, the Durham-Humphrey law is very explicit in what the pharmacist may do in filling, refilling, or giving information on a prescription. He is not allowed to give a prescription out for the purpose of having it filled in another pharmacy, whether it is in the same State or another State.

However, he has the professional authority to write across the face of the prescription "for information purposes only."

In other words, if the patient will take this prescription to another pharmacy and try to get it filled, the pharmacist will respect that legend written across the face of the prescription and will not fill it because it is what we refer to as a legend drug and nonrefillable.

Also, if another physician or the physician would like to see the prescription or he does not have record of the prescription and he asks the patient to bring it in, this is the proper way to furnish that information.

That is the only way the pharmacist writes a copy of a prescription that comes under the regulation of the Durham-Humphrey law.

Of course, all prescriptions are not necessarily nonrefillable.

There are some that may be refilled, but this applies entirely to those prescriptions that are not allowed to be refilled unless you get the authorization of the physician either orally or by written prescription to refill the prescription.

Mr. SCHENCK. Thank you very much.

Mr. YOUNGER. Mr. Chairman, I would like to correct the record because I find now that Mr. Larrick did furnish that information.

The one State was Florida.

The CHAIRMAN. Mr. Rogers, of Florida, may have permission to extend his remarks at this point.

Mr. Jehle, thank you very much.

Mr. JEHL. Thank you, sir.

The CHAIRMAN. Mr. Fuller Holloway?

STATEMENT OF FULLER HOLLOWAY, GENERAL COUNSEL, TOILET GOODS ASSOCIATION; ACCOMPANIED BY DR. EMIL S. KLARMANN, VICE PRESIDENT AND MANAGER OF THE TECHNICAL SERVICES OF LEHN & FINK

Mr. HOLLOWAY. My name is Fuller Holloway. I am an attorney admitted to the bar of the State of North Carolina and the District of Columbia and a member of the firm of Hamel, Morgan, Park & Saunders, of Washington, D.C. I appear here today on behalf of the Toilet Goods Association, for which trade association I am general counsel. The members of the Toilet Goods Association manufacture in excess of 90 percent of all toilet preparations sold in America.

I have with me, Mr. Chairman, Dr. Klarmann, who is the vice president and manager of the technical services of Lehn & Fink.

He holds the degrees of chemical engineer and a doctor of science.

He has published many papers and is renowned in his field and is

very knowledgeable in the manufacturing phase of this business, as well.

Mr. Chairman, bearing in mind your admonition of the limitations of the time of this committee, and, with your permission, I will refrain from reading the 10 pages of my prepared statement, but, rather, summarize it in my own words.

I think it will take much less time.

The CHAIRMAN. Your statement will be included in the record.

(The complete prepared statement of Mr. Fuller Holloway is as follows:)

STATEMENT OF FULLER HOLLOWAY ON BEHALF OF THE TOILET GOODS ASSOCIATION

One may inquire why an association of cosmetic manufacturers is interested in the terms of H.R. 11581, which is directed primarily at the drug industry. The reason is very simple. The definition of drugs in the Food, Drug, and Cosmetic Act requires that many products of the cosmetic industry are classified as drugs. It may surprise some members of the committee to know that products which they have regarded as cosmetics are in fact drugs by this definition. Some examples may be helpful. They include antidandruff shampoos and hair dressings, certain toothpastes, antiperspirants, some sunburn preventatives, depilatories, and so forth.

H.R. 11581 makes no change in the definition of drugs in the basic Food, Drug, and Cosmetic Act. All the provisions of the bill, therefore, with the exception of a few that name specific classes of drugs (such as barbiturates and amphetamines) apply equally to antiperspirants and antihypertensives, to dandruff remedies and diabetes injectables. It is a far cry from a prescription drug taken internally to affect a major body process to a product used topically for a strictly local effect. We believe that H.R. 11581 was drafted with prescription drugs in mind and without due consideration of proprietary drugs.

I would like to take a few minutes of the committee's time to point out how the bill would affect some cosmetic drugs.

PROVISIONS RELATING TO EFFICACY OF DRUGS

Part A of H.R. 11581 includes provisions relating to efficacy of drugs. Dr. Theodore Klumpp, testifying in behalf of the Pharmaceutical Manufacturers Association on Monday, August 20, 1962, presented a comprehensive review of the problems related to proof of efficacy, as this pertains both to the definition of new drugs and to the new drug clearance procedures. As Dr. Klumpp emphasized, medical opinion is not always unanimous with respect to the therapeutic effectiveness of drugs in the treatment even of well-characterized disease entities. We submit that the division of opinion may become even more marked when the problem deals with a condition like dandruff, the level of sweating, or the control of body odor. The evidences of these natural body functions are largely subjective in nature, and the effectiveness of a given product may perhaps best be judged by the user himself. The well-trained investigator, experienced in the art of "armpit sniffing" or in the exact measurement of sweat production, can predict no more than a probable response of users of products of these kinds. The submission of "substantial evidence" of the effectiveness of products developed to combat the personal problems of dandruff, sweating, and body odor should certainly be adequate to support a new drug application for such products. Even assuming that a given product is not effective for a certain percentage of users, these individuals can have lost at the most the price of a single package of the product. (Obviously, these statements are based on the assumption that the product has been demonstrated to be entirely safe for the purpose, to the satisfaction of both the manufacturer and the Food and Drug Administration.) And if, indeed, the product does not offer, to a sufficient number of consumers, the benefits that are claimed, the greatest loser will be the manufacturer, for he depends on consumer acceptance to recover the costs of research and development, and to show a profit to his shareholders. Certainly, products of this kind must comply with the statutory requirements that prohibit false and misleading labeling, but it seems unrealistic to require more

than substantial evidence of effectiveness to permit marketing of such products, when the ultimate judgment of effectiveness is made by the consumer himself.

One provision of the bill, section 102(a), materially amends the definition of "new drug" to include drugs which are not generally recognized as efficacious. Dr. Klumpp in his testimony last Monday discussed the subject at considerable length. I want to conserve the committee's time and am mindful of the chairman's injunction to avoid duplicating testimony. Let me say, therefore, that the Toilet Goods Association supports the views expressed by Dr. Klumpp as they appear on pages 18 to 20 of his prepared statement. We urge strongly that the criterion of effectiveness not to be added to the definition of new drugs, since this provision could result in a requirement that many products that have been on the market for long periods, with an excellent record of safety and acceptability, would needlessly go through the new-drug procedures again.

STANDARDIZATION OF DRUG NAMES

Part B of the bill covers the standardization of drug names. Section 111(a) adds a new section (508) to the Food, Drug and Cosmetic Act, giving the Secretary of Health, Education, and Welfare authority to promulgate regulations establishing a single standard name for a drug.

Section 112(a) amends paragraph (e) of section 502 of the Food, Drug and Cosmetic Act by deleting the provision which requires a drug to bear the common or usual name of the active ingredients and substituting provisions which would require that it bear the established name and quantity of each active ingredient. It further provides that the established name, which is either the name selected by the Secretary as mentioned earlier, or the name in an official compendium or the common or usual name, appear on the label preceding the proprietary name in type at least as large and prominent as that used for such proprietary name.

What would this do to the manufacturer of an antiperspirant who markets his product, we'll say, in a 1- or 2-ounce container bearing a label about a square inch in size? I remind the committee that, by present definition, this product is a drug and bears the information presently required under the Food, Drug and Cosmetic Act, including the name or names of the active ingredients. In the first place, the manufacturer would have to scale down the size of his trademark, the name by which his unique product is identified in the drug, or department store, or the supermarket. The buyer of cosmetic drugs usually relies on the trademark to identify the desired product. Any provision which interferes with this free choice seriously handicaps the manufacturer who has established a valuable property right in the trademark and does a disservice to the consumer who would have difficulty in identifying the product of her choice. Further, the manufacturer, after reducing the size of his trademark, would have to find room to list the active ingredients—and there may be several—preceding the trademark in type of equal size and prominence. This morning I examined several antiperspirants. The active ingredients of one product are listed as aluminum sulfate, sodium aluminum lactate, and water-soluble lanolin; of another as zirconyl chloride and aluminum hydroxychloride; and of a third as basic aluminum formate and aluminum chloride. The problem of presenting the names of these ingredients on a small label, in the size and prominence required by the bill, together with other required label information, is self-evident. The identity of the product itself could be lost in a profusion of words.

In addition to listing the active ingredients as I have described, the manufacturer would also have to list the quantity of each. It is not clear whether this is to be an absolute figure or is to be stated as a percentage. In either event he is forced to give away a valuable trade secret for no apparent reason. Furthermore, he may be forced into an ingredient race with his competitor using the same active ingredient on the theory that a product which contains 5 percent of ingredient X is five times as effective as one which contains only 1 percent, whereas in fact that conclusion may be totally incorrect.

I have dwelt on this subject at some length to illustrate some of the difficulties that would confront the members of the cosmetic industry in the labeling of some of their products if part B of the bill is applied across the board to all drugs—proprietary as well as prescription.

The Pharmaceutical Manufacturers Association has fully explained to the committee the consideration with regard to the standardization of drug names

and the labeling of prescription drugs. We of the Toilet Goods Association are addressing ourselves to a completely different area. Regardless of the decision of the committee as to prescription drugs, we respectfully submit that the provisions relating to standardization of drug names would serve no useful purpose with respect to proprietary cosmetic type drugs.

We suggest, therefore, that the committee keep in mind the broad sweep of the drug definition in the act and consider whether it need apply the same legislative standards to the whole spectrum of drugs covered by this definition.

FACTORY INSPECTION

Section 201 of H.R. 11581 (pp. 30-32 of the print) greatly expands the authority of the Food and Drug Inspector into the areas of records, files, papers and, perhaps, secret formulas and processes.

Under section 301(f) and section 303 of the Federal Food, Drug and Cosmetic Act, the refusal to permit inspection of anything authorized by section 704 of the act, including whatever is authorized under the proposed amendment, subjects the person to fines and imprisonment. On pain of criminal prosecution one must make sure that all records, files, papers, processes, controls, and facilities bearing on violations or potential violations of the act are within the scope of the inspector's examination. The proposed amendment would also include consulting laboratories (but restricted to those performing services for a fee or other remuneration), apparently whether or not such consulting laboratory has connection with interstate commerce or the shipment of goods therein.

It is said that inspection of consulting laboratories as well as the manufacturers is necessary because the Food and Drug Administration must be assured of the accuracy of data furnished it from such laboratories.¹

A statutory confirmation of authority to inspect the records of both the manufacturer applicant and consulting laboratory relating to a specific product to validate data furnished the Food and Drug Administration with respect to that product (and to ascertain that the terms of an approval or certificate is carried out), may be in order. This is a very considerably different authority from that proposed in the bill.

Constitutional questions with respect to the application of the proposed provisions in the case of an unincorporated personal business are presented both as to the fourth² and fifth³ amendments (as well as the interstate commerce problem with regard to consulting laboratories). Certainly the proposed language is deficient in that certainty required in criminal statutes.

Research with respect to development of new products ought not be stifled for fear of premature disclosure of discoveries made. Secret formulas must be protected. Consider, for example, a cosmetic product such as a perfume.

¹The Assistant General Counsel for Food and Drugs, Department of Health, Education, and Welfare reported on Aug. 8, 1962, before the American Bar Association, San Francisco, some administrative self-help as follows:

"The list of [inspection] refusals is indeed a long one. It covers all types of business. It covers all kinds of requested information. And it all arises from the uncertain situation that prevails under existing law.

"In addition to asking the Congress to reexamine and to legislate on this problem, we have taken what steps we could by administrative action to improve the situation.

"As the reports of refusal of inspection increased in numbers and in variety of questions involved, we centralized them to be sure exactly what was going on. We found that some firms with a fixed policy against inspection were applying for effective new drug applications, certification of antibiotics, insulin, and coal tar colors, exemptions from certification, food additive regulations, and hazardous substance labeling exemptions. They were presenting data to us to support these requests, asking us to rely on it, but at the same time denying our inspectors the right to inspect to determine the accuracy of the data. So long as the refusals of inspection continue, we will—wherever the refusals are germane to the exercise of our statutory responsibilities—use every administrative means to withhold the new drug applications, the exemptions, the regulations, and the certificates."

²Amendment IV: "The right of the people to be secure in their persons, houses, papers, and effects against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

³Amendment V: "No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation."

Perfume formulas have been devised after years of research by expert perfume chemists and the expenditure of oftentimes very large sums of money. The formula is the most valuable asset of the perfume company. It is what distinguishes its product from all others and makes possible its sales. The secrecy of such formulas is essential to the company. The formula of a popular perfume would be an extremely valuable item for sale by anyone coming into its possession.

It would not be fair to the manufacturers, to the consulting laboratories, or in fact to the inspectors themselves, to require under pain of criminal prosecution that such confidential or secret data and formulas be placed in the hands of any food and drug inspector who may happen to be assigned to the geographic area.

It is respectfully submitted that inspection authority, if extended beyond present limits, ought to be clearly defined and restricted to the coverage of records to substantiate data on which rests the administrative recognition of the product as lawful for its intended use.

Mr. HOLLOWAY. Also, Mr. Chairman, bearing in mind your advice that this hearing is limited to H.R. 11581, I will speak only to that bill and not H.R. 11582.

It is certainly a far cry from the type of products that you have heard mostly about here; that is to say, drugs having the capacity to alter the life processes of the body.

I speak only to those products which are applied, for the most part, topically, to the body's surface, which we will have to call, I believe, a hyphenated name, cosmetic-drugs.

We are only here really—I will change that for fear of making a very bad pun—we have been dragged into this drug bill because of the very broad definition of "drugs." Not only are those things which have the effect upon the life processes, that is, drugs, but those things which can in any way alter or change the structure of the skin surface are classified as drugs, such as antiperspirants.

Now, an antiperspirant inhibits the flow of sweat. It is compounded to have the end result of making one more acceptable among his fellows and perhaps himself lessening assault on the olfactory nerves.

The Pharmaceutical Manufacturers Association and the Proprietary Association representatives have gone into considerable detail with respect to the provisions of this bill regarding efficacy.

Those cosmetic-drugs such as the antiperspirants and the suntan lotions, which may also be devised to prevent sunburning, or such things as shampoos that have a germicide in them, are drugs under the definition, and we believe that in terms of the proof of effectiveness the best judge of the efficacy of these products is the consumer, because such products have a bearing on how that particular person—how he or she looks or smells and that sort of thing.

If I may make a reference to the Senate bill, which, I understand, has now been reported out of committee, the efficacy provisions in that bill have been changed, or at least they vary from the bill, H.R. 11581, and I believe, has terms that are much more acceptable than are in H.R. 11581.

The one thing I would like to emphasize most strongly before this committee is the provisions relating to the standardization of drug names.

This, in the first place, is an economic concept. What its bearing on prescription drugs may be, I am not prepared to cover.

With respect to proprietary drugs particularly, and with respect to cosmetic drugs, we believe that the provisions of H.R. 11581 would be disastrous.

Take, again, the example of the antiperspirant, which usually is in a little jar, perhaps, the top of which is about the size of a silver dollar.

The present law provides that the active ingredients in that preparation must be shown on the label.

Many other things must also be shown on the label: the name and address of the manufacturer, the quantity of the contents, directions for use, the percentage of alcohol, all on this very small label.

The customer coming in to get a toilet preparation 99 times out of 100 chooses that toilet preparation because of its trademark, because of a trusted name, because of past experience.

It is not intended to have anything other than cosmetic application to him or her.

The Senate bill, again, the provisions of the Senate bill, as I read them, would require that the active ingredients be placed, or continue the requirement that the active ingredients be placed on the label.

A statement of the quantity of the active ingredients need not be shown.

As I understand the bill, although it is a little ambiguous, from a hasty reading, that the proprietary name, or, rather, stating it the other way, the active ingredients must be half the size, the print must be half the size of the proprietary name.

This, we believe, is still very bad. While the brand name or the trademark name need not be submerged in the ingredients, the design of the package is such that a consumer going along a supermarket shelf still wants to take a look and find out the brand of product that she wants. The Senate provision requiring a size of type relationship in connection with proprietary drugs cannot create anything but confusion.

Going over to the matter of factory inspection in H.R. 11581, it seems to me that after taking a look at what the Food and Drug Administration has really said that they are concerned with, which is the fact that they sometimes are not getting accurate information when they have to put out a certification or they are requested to clear a new drug or things of that nature, and that they really ought to have the authority to investigate and validate the information that is given them before they, in effect, approve what has been done, in terms of that it seems to me that this is a legitimate request.

That in the event information is supplied by an applicant, that information may come even from a consulting laboratory not within the control of the applicant. Then, as a basis for approval of the request, I would think the Food and Drug Administration ought to be able to go back to get to the original records to support it.

That is to say, the chart which the fellow made when he weighed the rats or the guinea pigs, or what he did back there, so that they can be sure that the basis of the Food and Drug Administration's approval or denial is well founded and can be validated.

But when we go over to the language of the bill that is before us now, it seems to me that the bill is asking that the entire facility of the manufacturer is to be opened up for inspection, and this, to my knowledge, has not been shown to be necessary.

In the area of consulting laboratories, it would seem to me again that there are problems with respect to the commerce clause of the Constitution as to whether actually they should be able to go into these consulting laboratories at all.

On the other hand, if the consulting laboratories file some data with them, then that would be that which would let them there for inspection.

These are the things that bother us, Mr. Chairman, and I respectfully submit that the matter of the standardization of drug names, insofar as proprietary drugs are concerned, should be deleted from this bill, and the matter of the factory inspection ought to be confined to the extension to which I have addressed myself.

Mr. ROBERTS. Thank you very much, Mr. Holloway.

Any questions by the committee?

Thank you very much.

Our next witness will be Mr. F. F. Dittrich, president of the Essential Oil Association of the U.S.A., 2 Lexington Avenue, New York 10, N.Y.

STATEMENT OF FRANK F. DITTRICH, TREASURER OF THE UNGERER CO., AND PRESIDENT, THE ESSENTIAL OIL ASSOCIATION OF U.S.A.; ACCOMPANIED BY R. E. HORSEY, VICE PRESIDENT, GIVAUDAN-DELAWANNA, INC., AND CHAIRMAN OF THE LEGISLATIVE COMMITTEE OF THE ESSENTIAL OIL ASSOCIATION OF U.S.A.

Mr. DITTRICH. I am Frank F. Dittrich, treasurer of Ungerer Co. of New York City, and have been engaged in the essential oil industry for more than 20 years. I am appearing here today in my capacity as president of the Essential Oil Association of U.S.A., and speak in behalf of its members.

Accompanying me here today is Mr. Robert Horsey, chairman of our legislative committee.

We are opposed to section 201 of H.R. 11581, the factory inspection provision, which is the only provision in this bill that directly affects our industry.

The Essential Oil Association comprises 78 companies which manufacture, process, and supply no less than 90 percent of the fragrances used in all the cosmetics, beauty preparations, and related articles of toiletry purchased by the American public. Fragrances also constitute a vital ingredient in soaps and detergents, and in many other commonly used articles. Therefore, we urge you to consider that virtually the entire population—in fact, each one of us—each day, no matter how simple his mode of life may be, buys and uses articles containing these fragrances. Moreover, our choice and enjoyment of them, and even the wish to use such articles at all, whether deliberate or unconscious, is decisively influenced by the fragrance which the article may have.

Thus, while our particular industry may be a comparatively small one, its influence in everyday life is great, and it is important, not

to any special group or class of people, but to all of us in a very personal way.

Another intriguing feature of fragrances is the fact that while their effect on the popularity, desirability, and usability of consumer goods is a vital factor, the amount of perfume oils needed to accomplish this vital effect is indeed very small. This is one reason why, in addition to the many years, and in some cases, centuries of safe experience with these materials, no hazard of any consequence is involved in their use. Amazing as this may seem to the layman, a few examples are cited to illustrate:

A widely used cosmetic, such as a cold cream, contains on the average of one-half of 1 percent of perfume oils. One point of perfume oils is used to impart the pleasant fragrance to 200 pounds of the cream, or 800 four-ounce jars. In terms of consumer use, this would represent 32,000 to 40,000 individual applications.

The ever popular cologne used so widely today contains about 3 percent of perfume oils. One pound of perfume oils prepared 4 gallons of cologne—or 128 four-ounce bottles—a common size unit sold on the retail market. If used lavishly by our charming ladies, this would be sufficient for 8,000 applications.

Thus, the concentration of perfume ingredients in contact with the body under normal usage is very low; and among all the literally millions of occasions on which such contact is made daily, nothing in our many years of experience indicates any adverse effect on the public health. Thus, there is not now, nor has there ever been, a problem which, as far as the perfume and fragrance industry is concerned, calls for the inclusion of our industry in the factory inspection authority of this bill.

The problems of our industry are entirely different from those of the manufacturers of drugs. I should like this committee to know what our problems are, for they have a direct bearing on the provisions to which this statement is directed—those of the factory inspection provision of H.R. 11581 (sec. 201).

The heart of our industry, and our most valuable assets, are the innumerable secret formulas, each of which contains anywhere from 20 to more than 200 ingredients. These formulas are the sophisticated end products of centuries of development—perfume making being as old as civilization itself. The creation of perfume bases is not just a skill or a craft; it is truly an art. All of the magic of a beautiful fragrance springs from the imagination and creative artistry of those few rare individuals whom we call perfumers. Using the vast multitude of ingredients—many from all corners of the earth—and after months and often years of experimentation, they finally produce the formula for that beautiful new scent which may be a perfume or a cologne, or a part of a beauty preparation such as a cream or lotion.

We possess nothing in our business that is more valuable than these formulas. All of our artistry, know-how, and experience repose in them. We must go to great lengths to protect their secrecy, and the inevitable loss which would result from formula disclosure would be a tragic blow to the companies in our field. The patent laws by their very nature do not, as a practical matter afford effective protection for perfume formulas. The only means available to duplicate or suc-

cessfully imitate these exclusive fragrances is to have access to the formula. It cannot be accomplished by analytical means. It is also notoriously difficult to obtain effective redress from the courts in situations where our trade secrets have been appropriated and used by third parties. Indeed, our only security is to take the most elaborate internal precautions against disclosure of the formulas, including the limiting of access to them to the fewest possible people.

The factory inspection provision, section 201 of H.R. 11581, would be tantamount to disclosure of our secret formulas and processes. It is not wholly inconceivable, nor entirely without precedent, that FDA personnel may, at some future time, be employed by competitors. Yet, under this bill, our industry will be under criminal penalty to show these formulas to FDA employees. What problem of national health and safety requires this endangering of our entire industry? We know of none.

Among the very few cases cited by FDA representatives where injuries were caused by cosmetics, not even one incident was given where the products of our industry were blamed as the cause of the injury.

We feel that we must strongly protest these proposed new broad powers as an attempt to grant authority for unreasonable search and seizure. There are well-established legal procedures for acquiring information or evidence where violation of laws is suspected. On the other hand, enactment of the proposed revision would, as a practical matter, open the door to unlimited browsing, fishing, and harassment at will by any one or more officers, any number of times, and of undetermined duration each time, under the cloak of entirely discretionary police powers ostensibly granted to every wearer of an official badge— with or without probable cause or suspicion of violation, or reasonable grounds for same. While the oppressive nature of such procedure is certainly apparent, we believe that its constitutionality is in grave doubt, to say the least.

From all our past experience, and from a careful and considered projection of how these broad new powers of inspection sought to be conferred upon the Food and Drug Administration would operate, we do not see how the inspection of our processes and formulas would confer any additional safety or protection on the consumer; but it would impose oppressive, expensive, and damaging burdens on us. The Essential Oil Association of U.S.A. strongly recommends that this committee take into consideration our industry's unique dependence upon the inviolability of its trade secrets, as well as its unique record of product safety; and exempt perfumes and fragrances used in cosmetics from the factory inspection provision of H.R. 11581.

We, however, suggest that the efforts to obtain drug legislation at this session of Congress should not be impeded by controversy involving other industries, arising solely by reason of this general factory inspection provision in its present form. For the same reason that this committee decided to restrict its hearing to H.R. 11581, and not take up at this time the complexities involved in H.R. 11582, we recommend that the factory inspection provision be revised to conform with those already approved by the Senate Judiciary Committee, which omits reference to foods and cosmetics.

On behalf of the members of the Essential Oil Association of the U.S.A., I express our appreciation for this opportunity to state our views on this bill.

Mr. ROBERTS. Thank you, Mr. Dittrich.

Any questions, gentlemen of the committee?

Mr. YOUNGER. Just one.

I judge from your testimony that one of the things that your industry fears is that some good promoter like Billie Sol Estes might very well get some Government inspector to copy a formula and disclose it.

Is that your feeling?

Mr. DITTRICH. Our feeling is that a man that would look at our formulas, and, necessarily, it is not erased from his mind as far as the disclosure of the formula is concerned, and there are certain ingredients that are specialties of particular houses that would be invaluable information, for example, to my house, which we do not know about, which help us to make a better product to compete with our competitors.

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

Mr. ROBERTS. Anything further, gentlemen?

Mr. Glenn?

Mr. GLENN. Mr. Dittrich, I am curious as to what kind of oil this is that you use as the basic ingredients in these preparations.

Is that a trade secret?

Mr. DITTRICH. No.

I would just say that we use essential oils and aromatic chemicals, and I would say that maybe there are 4,000 to 5,000 of them in common usage.

Mr. GLENN. Is it an olive oil, or what?

Mr. DITTRICH. Oils from plants and trees and from nature itself, most of the oils, citrus oils which come from the peel of the lemon, the orange and the lime. There are oils from wood.

Mr. GLENN. Do you use any petroleum products at all?

Mr. DITTRICH. Not to a great extent.

Mr. GLENN. That is all. Thank you.

(The following self-explanatory letter was subsequently received with accompanying pamphlet:)

THE ESSENTIAL OIL ASSOCIATION OF U.S.A.,
New York, N.Y., August 28, 1962.

Re statement of Mr. Frank F. Dittrich, president, Essential Oil Association of U.S.A.

Chairman OREN HARRIS,
House Committee on Interstate and Foreign Commerce,
New House Office Building, Washington, D.C.

DEAR SIR: During the questioning period following presentation of my statement last Thursday, Representative Glenn inquired as to what were essential oils.

The attached pamphlet published by the association might be helpful to your committee in understanding our members' products and activities. It also lists the member companies.

If possible, we would appreciate if this pamphlet could be made a part of our statement.

Very truly yours,

FRANK F. DITTRICH, *President.*

ESSENTIAL OIL ASSOCIATION OF U.S.A., NEW YORK, N.Y., REPRESENTING THE PRODUCERS AND DISTRIBUTORS OF ESSENTIAL OILS, OTHER NATURAL MATERIALS AND SYNTHETIC AROMATIC CHEMICALS—FOR THE FRAGRANCE AND FLAVOR INDUSTRIES

ENRICHING OUR LIVES

In the simple daily routine of our lives, flavors and fragrances play an important part, subtle, at times almost unnoticed, but always adding enjoyment. In a sense they act as catalysts, helping to sell the profusion of consumer goods produced in the United States and making these goods more pleasing to the user. The refreshing tang of a tasty carbonated beverage, the clean smell of a cake of soap—our lives are enriched many times each day by the pleasures of taste and smell.

THE INDUSTRY—ITS SIZE AND SCOPE

Recorded history does not reveal when essential oils were first sold commercially, although there is evidence of the use of fragrances that goes back to the days of the early Egyptian dynasties. The development of the industry, however, as we recognize it today started over 100 years ago, maturing in terms of technological advancement at the time of World War I. Today, as a result of research and modern production techniques, it serves manufacturers of numerous finished products—foods, beverages, pharmaceuticals, soaps, cosmetics, toiletries, and many others. To give these products either a flavor or a fragrance—the essential oil industry gathers ingredients from all over the world—peppermint from the United States, lemongrass from southern India, rosewood from the rain forests of Brazil, citronella from the island of Formosa, civet from Ethiopia. Importing, collecting, processing, distilling, refining, the essential oil industry prepares these raw materials for use by other industries, whose products are merchandised directly to the consumer.

But the processing of these natural substances is only part of the story. In the last 20 years, the industry has advanced considerably in chemical technology, with the result that manmade materials today account for a large proportion of total tonnage produced. The modern "essential oil" plant now utilizes chemical research and all the complex tools of modern chemistry, including new production techniques used throughout industry. This swing to synthesis has required a much higher capital investment in manufacturing buildings and equipment, but the rewards have been substantial in terms of new materials, lower costs, better quality, and almost unlimited supplies.

In 1957 it is estimated that the essential oil industry produced over \$150 million worth of flavor and fragrance materials, with a healthy outlook of steady and substantial growth in the immediate years ahead.

DEFINING THE PRODUCTS

Aromatic and flavor materials range, in broad terms, from the synthetic chemical compound emerging from a modern research laboratory to the jasmine oil or lemon oil extracted from natural materials. There are several hundred natural materials that are processed into essential oils. They include flowers, grasses, spices, herbs, citrus products, fruits, leaves, roots, wood, gums, and animal products. The processing of these materials by various methods, including distillation, extraction with a volatile solvent, maceration, and enfleurage (cold fat absorption), is done much the same way that it has been for many years, except that processes and equipment have gone through many stages of improvement and advancement.

Research has shown that these natural oils contain a multitude of chemical compounds, such as alcohols, esters, aldehydes, ketones, phenols, lactones, terpenes, and sesquiterpenes. They are reasonably uniform in composition and identifiable by such physical characteristics as specific gravity, refractive index, optical rotation, solubility in alcohol and other solvents.

Identification of these constituents in essential oils has led to the synthesis of many of them by researchers trying to duplicate nature's chemistry. In addition, modern research has produced a number of new synthetic aromatic chemicals similar in structure and odor to the constituents of the natural oils, as well as some that have entirely new odor characteristics. In all, there are perhaps 3,000 or more synthetic materials which have become important ingredients in the development of finished perfume or flavor compounds. With some of these compounds containing as many as 200 ingredients, it can be readily seen that the

synthetic is playing a vital role, not only from the standpoint of cost and quality, but from the standpoint of providing the perfume and flavor creative chemist with the tools that are necessary to produce better products.

SERVICE TO INDUSTRY

It is the aim of each member of the Essential Oil Association (EOA) to serve industry with products of superior and consistent quality, purity, and esthetic value. To maintain such standards, companies have worked together with the EOA, providing the leadership necessary for a growing, changing industry. This organization now has close to 60 active members—companies engaged in the production or sale of essential oils, aromatic chemicals, perfume, or flavor compounds in the United States and its possessions. There are a dozen associate members—U.S. representatives of companies engaged in these activities in other countries.

What is today a vital organization, started as a forum of 30 processors, importers, and dealers. Called together by E. V. Kileen of George Leuders & Co., they met to discuss problems confronting the trade in 1927. The Essential Oil Dealers Association evolved from that meeting. By December 1931, the association adopted a new constitution and a new name, in keeping with the growing scope of the industry—the Essential Oil Association of U.S.A.

As set forth in the constitution, the object of the association is the cultivation of sound relationships among essential oil producers, dealers, and distributors, by providing a meeting ground for the discussion of trade problems which are common to all. Promoting harmony and understanding grows in significance each year because of the international character of the essential oil industry, which brings American goodwill and trade to many countries throughout the world.

Guiding the Essential Oil Association are its three officers—and five members of the executive committee, elected annually. The headquarters of the association, at 2 Lexington Avenue, New York City, are under the direction of the executive director, Ray C. Schlotterer, who, with his staff, administers and coordinates the various functions of the organization. Reflecting the broad range of the association's activities are the standing committees.

COMMITTEES

Scientific.—The work of the Scientific Section, organized in 1937, is aimed to keep pace with the accelerated progress of the essential oil and aromatic chemical manufacturing industry, in their rapid advances in flavor and perfume manufacturing techniques. One of its responsibilities is to accept quality standards and specifications so as to facilitate the buying and selling of various commercial grades of essential oils and aromatics.

As of October 1958, some 150 specifications have been established with 21 test methods to aid in their determination. These have all been incorporated in the internationally accepted booklet "E.O.A. Standards and Specifications." This work, first released in 1946, has received worldwide recognition and has enhanced not only the professional stature of the industry, but has upgraded the increasing number of new products introduced during the years in commerce. This service to large-scale users filled a need which has not been covered previously by the official monographs of the United States Pharmacopoeia (USP) and the National Formulary (NF).

The Instrumental Analysis Committee, a separate section of the Scientific group, evaluates new spectroscopic developments in the analytical techniques of perfume and flavor materials as an aid to research and quality control. The preparation of pure organic compounds, and studying their idiosyncrasies under spectra, has been of considerable service to all interested.

Import.—The Import Committee is primarily concerned with U.S. customs and tariff regulations, ocean freight rates, and marine and war risk insurance on imported shipments. It represents the association before Government groups, and expresses trade opinion before Federal agencies. It contacts freight rate conferences and informs the membership of its activities through periodic bulletins. The committee also advises regarding difficulties with shippers as to weights, quality, etc.

Export.—The complex problems of international trade are reviewed by the Export Committee which keeps the membership informed of regulations and restrictions abroad. The committee takes an active interest in proposed re-

reciprocal trade agreements, export statistics, and legislation affecting shipments of these materials out of the continental United States of America.

Credit.—Members' inquiries concerning credit problems and policies are handled by the Credit Committee. It receives credit information from individual members and reports matters of importance to the membership through a bulletin service.

Trade names.—This committee publishes the "Coined Names and Trademark Catalog," and establishes the rules and principles which guide members in the selection of names for new products. Its list includes those names that have already been registered, and those that are in the coined-name category.

Legislative.—Proposed legislation affecting the essential oil industry is studied by the Legislative Committee for recommendation to the membership. This committee is the official representative of the association at all deliberations in Washington.

Arbitration.—Conflicts of interest between members of the association are submitted to the Arbitration Committee for settlement or advice.

There are many other fields of action of the association, all pointed to the promoting of fraternal relationship and goodwill. The EOA truly provides a common meeting ground for the discussion of trade problems common to all in the essential and natural oils, isolates, and synthetic aromatic chemical industries.

MEMBERSHIP

The members affiliated are as follows:

American Aromatics, Inc., 24 East 21st Street, New York City.
 Aromatic Products, Inc., 235 Fourth Avenue, New York City.
 Belmay, Inc., 116 East 27th Street, New York City.
 Bertrand Freres, Inc., 443 Fourth Avenue, New York City.
 Centflor Mfg. Co., Inc., 500 West 52d Street, New York City.
 Ph. Chaloyer, Inc., 160 East 56th Street, New York City.
 Charabot & Co., Inc., 114 East 25th Street, New York City.
 Antoine Chiris Co., 212 East 23d Street, New York City.
 Citrus & Allied Essential Oils, Inc., 61-63 Sheffield Avenue, Brooklyn, N.Y.
 Dodge & Olcott, Inc., 180 Varick Street, New York City.
 P. R. Dreyer, Inc., 601 West 26th Street, New York City.
 Felton Chemical Co., 599 Johnson Avenue, Brooklyn, N.Y.
 Firmenich & Co., 250 West 18th Street, New York City.
 Fleuroma, Inc., 38 West 21st Street, New York City.
 Florasynth Laboratories, Inc., 900 Van Nest Avenue, New York City.
 Fries Bros. Inc., Post Office Box 8, Carlstadt, N.J.
 Fritzsche Bros. Inc., 76 Ninth Avenue, New York City.
 General Aromatic Products, Inc., 8044 N. Lawndale Avenue, Skokie, Ill.
 Givaudan-Delawanna, Inc., 321 West 44th Street, New York City.
 The Glidden Co., 52 Vanderbilt Avenue, New York City.
 Hercules Powder Co., 350 Madison Avenue, New York City.
 Hoffman-LaRoche, Inc., Roche Park, Nutley, N.J.
 D. W. Hutchinson & Co., 700 S. Columbus Avenue, Mt. Vernon, N.Y.
 Laitier Fils, Inc., 321 Fifth Avenue, New York City.
 George Lueders & Co., 427-9 Washington Street, New York City.
 Magnus, Malce & Reynard, Inc., 16 Desbrosses Street, New York City.
 Mane Fils, Inc., 9 East 19th Street, New York City.
 J. Manheimer, 214 East 21st Street, New York City.
 Maywood Chemical Works, 100 W. Hunter Avenue, Maywood, N.J.
 Neumann, Buslee & Wolf, Inc., 5800 Northwest Highway, Chicago, Ill.
 New York Aromatics Corp., Post Office Box 15, High Bridge, N.J.
 Norda Essential Oil & Chemical Co., 601 West 26th Street, New York City.
 Noville Essential Oil Co., Inc., 1312 Fifth Street, North Bergen, N.J.
 Orbis Products Corp., 601 West 26th Street, New York City.
 Compagnie Parento, Inc., Croton-on-the-Hudson, New York, N.Y.
 S. B. Penick & Co., 50 Church Street, New York City.
 Perry Bros., Inc., 61-12 32d Avenue, Woodside, L.I.
 Polak & Schwarz, Inc., 667 Washington Street, New York City.
 Polak's Frutal Works, Inc., 33 Sprague Avenue, Middletown, N.Y.
 Polarome Manufacturing Co., Inc., 73 Sullivan Street, New York City.
 Reynaud, Ltd., 335 West 52d Street, New York City.
 Rhodia, Inc., 60 East 56th Street, New York City.

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F. Ritter & Co., 4001 Goodwin Avenue, Los Angeles, Calif.
 P. Robertet, Inc., 221 Fourth Avenue, New York City.
 Roubechez, Inc., 8 East 12th Street, New York City.
 Roure-DuPont, Inc., 308 Madison Avenue, New York City.
 Ryland-Johnson Co., Inc., 174 Front Street, New York City.
 Schimmel & Co., 601 West 26th Street, New York City.
 Standard Aromatics, Inc., 88 University Place, New York City.
 Synteur Scientific Labs., Inc., 33 Oakley Avenue, Monticello, N.Y.
 Syntomatic Corp., 114 East 32d Street, New York City.
 A. M. Todd Co., 1717 Douglas Avenue, Kalamazoo, Mich.
 Tombarel Products Corp., 725 Broadway, New York City.
 Trubek Laboratories, State Highway 17, East Rutherford, N.J.
 Ungerer & Company, Inc., 161 Avenue of the Americas, New York City.
 Van Ameringen-Haebler, Inc., 521 West 57th Street, New York City.
 Albert Verley, Inc., 1375 East Linden Avenue, Linden, N.J.
 Verona Pharma Chemical Corp., 26 Verona Avenue, Newark, N.J.
 R. D. Webb & Co., Inc., 137 Boston Post Road, Cos Cob, Conn.

EOA Associate Members

J. Berlage Co., Inc., 11 East 44th Street, New York City.
 L. A. Champon & Co., 303 West 42nd Street, New York City.
 Doran & Schmiedel, 306 Main Street, Fort Lee, N.J.
 Julian W. Lyon, 7 Dey Street, New York City.
 Walter F. Mahneke, 75 Maiden Lane, New York City.
 Calvert Mills Co., 44 Whitehall Street, New York City.
 Ludwig Mueller Co., Inc., 24 State Street, New York City.
 A. K. Peters Co., 501 Fifth Avenue, New York City.
 Schmitz-Schoenwald-Turner Co., 20 Vesey Street, New York City.
 Ufinindo International Corp., 82 Beaver Street, New York City.
 George Uhe Co., Inc., 76 Ninth Avenue, New York City.
 John D. Walsh Co., Inc., 32 Broadway, New York City.

Mr. ROBERTS. Anything further?

Mr. DINGELL. Mr. Chairman, I am rather caught by surprise.

I would like to have permission of the Chair briefly to explore this with the witness, if I may.

Have you ever had any bad experience with the Food and Drug in the course of their factory inspections so far?

Mr. DITTRICH. No, sir.

Mr. DINGELL. None.

They have engaged in some factory inspections of your membership; have they not?

Mr. DITTRICH. Yes, sir.

Mr. DINGELL. And have you had any bad results of their inspections insofar as divulging of trade secrets or engaging in any other practice that might have been harmful to your industry or to your representatives?

Mr. DITTRICH. I do not believe they have had access to our trade secrets up to this point.

Mr. DINGELL. I see.

Now, what language in the bill—and I assume you have studied it—in the factory inspection section specifically authorizes the Food and Drug Administration to go into trade secrets and to engage in practices harmful to your industry?

Mr. DITTRICH. I believe the bill states that processes and formulas will be available for inspection.

Mr. DINGELL. If we put into the bill strict language making it a Federal criminal offense to divulge trade secrets except in cases where it is necessary to effect a criminal prosecution or to effect same action

by Food and Drug necessary to protect the public health and welfare, would this meet your objections to the bill?

Mr. DITTRICH. No, sir.

Mr. DINGELL. It would not.

Why not?

Mr. DITTRICH. Because, as we pointed out in our statement, it is impossible to determine whether or not a formula has been copied or whether somebody has duplicated it. These perfumers that we have, if we want to get into the intricacies of our business, are able to duplicate to a degree.

In other words, if Z company makes a perfume or a perfume base, we might duplicate it to a degree by determining through smell—odor—by determining by odor what is in there.

Therefore, we would not know whether this was divulged or not.

Mr. DINGELL. As a matter of fact, it is in the bill, there is language now that says:

The using by any person to his own advantage of revealing other than to the Secretary or officers or employees of the Department or to the courts when relevant in any judicial proceeding under this Act as authorized by law any information required under authority under sections 404, 409, 505, 506, 507, 706.

Mr. DITTRICH. I am aware this is in the bill, but I do not think this is sufficient protection for us.

Mr. DINGELL. I would like to meet your objections and still have factory inspection of your industry.

Mr. DITTRICH. You have factory inspection at this point.

Mr. DINGELL. But I mean inspection of your books and records, too, and here is the reason.

You use, I assume, or could use benzine derivatives, do you not?

Mr. HORSEY. I do not know what you mean by "derivatives" here.

Mr. DINGELL. Coal tar derivatives.

Mr. HORSEY. Compounds made from coal tar products?

Mr. DINGELL. Yes.

You do use these?

Mr. HORSEY. That is possible.

Mr. DINGELL. And there are instances where some of these from time to time are found to be harmful to human life. Is this not a fact?

Mr. HORSEY. We do not know of any cases of the materials we make.

Mr. DINGELL. Well, for example, coal tar colors have been found from time to time to be extremely harmful. Do you use any coal tar colors?

Mr. HORSEY. No.

We only use colors that are prescribed under the regulations of the Cosmetic Act.

Mr. DINGELL. Have you ever used coal tar colors?

Mr. HORSEY. Yes.

Mr. DINGELL. Did you ever use red 1 and 2; did you ever use butter yellow?

Mr. HORSEY. No.

Mr. DINGELL. You do use aromatic hydrocarbons, though, do you not?

Mr. HORSEY. Not to my knowledge.

Mr. DINGELL. Aromatic hydrocarbons are benzene derivatives. You know what I mean?

Mr. HORSEY. I know what you mean.

Mr. DINGELL. You use these?

Mr. HORSEY. No; we do not.

Mr. DINGELL. Do you mean to say that your industry has never used benzene or benzene derivatives?

You said you used benzene derivatives.

Mr. DITTRICH. Coal tar products, we said.

There might be a different definition, in our opinion.

Mr. DINGELL. Essentially it is the same thing.

Benzene and benzene derivatives are essentially coal tar products, are they not?

Mr. DITTRICH. Mr. Horsey's concern makes aromatic chemicals. My company does not.

Mr. DINGELL. But aromatic chemicals you have used, have you not?

Mr. HORSEY. I did not follow your question.

Mr. DINGELL. Your industry has used aromatic chemicals?

Mr. DITTRICH. We use aromatic chemicals.

Mr. HORSEY. This is not the strict chemistry definition. When we speak of aromatic chemicals, we speak of chemicals that have an odor, an aroma.

Mr. DINGELL. I do not mean that definition of "aromatic." I mean derivatives of benzene, of coal tar.

Mr. HORSEY. There are benzene-derivative chemicals made.

Mr. DINGELL. Which are not found, let us say, in nature, but which are generally produced from coal tar distillates?

Mr. HORSEY. They may not have been found in nature, but whether they are present in nature may not have been ascertained.

Mr. DINGELL. How is Food and Drug going to discern the full safety of the substances used by your industry if they do not have authorization to look at books and records?

Mr. DITTRICH. First of all, you were talking before about some of these things, and I believe you think we are talking about internal or ingestion.

Mr. DINGELL. You are using them on the skin?

Mr. DITTRICH. On the skin, and the percentage, as I pointed out here is a larger percentage than normal usage.

For example, the example I gave on cold cream—a half of 1 percent is much larger than the average usage. Only one-tenth of 1 percent is used in an aerosol shave. It is a minute and miniscule portion.

Mr. DINGELL. But it is found from time to time that in foods and in drugs parts on the order of parts per million are harmful, is this not a fact?

Mr. DITTRICH. That is true.

Mr. DINGELL. So 1 percent is on the order of several thousand or perhaps 10,000 times larger than the level that is sometimes found to be harmful, is this not a fact?

Mr. DITTRICH. That is a fact.

As far as our information is concerned from polling our members, though, we have had no complaints.

In other words, when our finished-goods manufacturers—in other words, the witness before represented our customers, so to speak—

when they get a complaint, we would hear about it, if it came from our product.

We have never, to any great degree, I know of none in my own company, and in checking the industry we have heard of very few complaints that came from the items that we manufacture, that we sell to, say, the toilet goods manufacturers.

Mr. DINGELL. Thank you very much, Mr. Chairman.

Thank you, Mr. Dittrich.

Mr. ROBERTS. Anything further, gentlemen?

Thank you very much, Mr. Dittrich.

Our next witness is Dr. J. A. McCallam, American Veterinary Medical Association, 1507 M Street NW., Washington, D.C.

STATEMENT OF J. A. McCALLAM, V.M.D., WASHINGTON REPRESENTATIVE, AMERICAN VETERINARY MEDICAL ASSOCIATION

Dr. McCALLAM. I am J. A. McCallam, local representative. Unfortunately, due to a chain of circumstances, our witness is not present this morning to testify, Dr. Jones from Chicago, nor did the statement arrive in time.

I talked with him this morning on the telephone. It is on the way, and at this time I request permission that it be included in the record of the hearings.

Mr. ROBERTS. Permission granted.

Dr. McCALLAM. Thank you.

(The statement referred to is as follows:)

AMERICAN VETERINARY MEDICAL ASSOCIATION,
Chicago, Ill., August 24, 1962.

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

DEAR SIR: The following statement of the American Veterinary Medical Association regarding H.R. 11581, 87th Congress, 2d session, is submitted for the consideration of the Committee on Interstate and Foreign Commerce.

The attention of the American Veterinary Medical Association (AVMA) has been called to the statement of D. L. Bruner, executive secretary, Animal Health Institute, given to your committee on August 21, 1962, concerning H.R. 11581.

The AVMA is unalterably opposed to the writing of a separate statute, or category, in the food, drug, and cosmetic (FDC) legislation for animal drug and feed products. Historically, animal drugs and feed additives did not meet their present high standard until controls for these products were included with the present FDC regulations for drugs used on man. Prior to this time the animal health field was commonly an outlet for drugs that were outdated, impure, not entirely safe, and otherwise undesirable. Recent FDA activities, authorized by a single statute applying to both man and animals, have provided the animal health field with effective, safe drugs. The veterinary profession strongly supports this situation.

It is altogether logical that the FDA statute for regulation of human and animal products remain as one, because:

1. Most of the drugs employed in man are in use to a greater or lesser degree in animals. These drugs come off the same production lines and differ only in respect to packaging. Thus, the problems of production, inspection, distribution, and even use are similar, if not the same, in many instances.

2. Many new drugs are now available for injection into, spraying on, or feeding to animals producing food for man. Many of these drugs will leave, for varying lengths of time, tissue residues in animal foods eaten by man.

3. As an agency with consumer protection responsibilities, we are frankly fearful of a backsliding of control over the products going into the animal health field if separate statutes are introduced for human- and animal-line products.

The animal outlet constitutes a massive market for a needed and effective drug; and this need should neither be hindered by excessive regulation, nor so loosely controlled as to constitute a hazard to the livestock industry and the public.

We do sympathize, however, with the current problem of drug manufacturers in getting new drugs approved under the "triplicate" control arrangement existing in the FDA. The necessity for many new drugs having to be cleared by three different sections of FDA (veterinary medicine, antibiotics, and food additives) with three different sets of requirements is unrealistic. Previously, all animal products were cleared by the Division of Veterinary Medicine to the reasonable satisfaction of parties concerned.

When the food additives amendment was passed in 1958, the legalistic interpretations were allowed to prevail over the knowledge and judgment of scientists within the FDA—resulting in the current state of confusion and delay in making desirable products available for use in the animal health field. The AVMA believes that the difficulties responsible for the current problems of manufacturers of animal health products and feed additives—and attributed by them to faulty legislation—can be corrected by returning all responsibility over animal health products to the Division of Veterinary Medicine to operate under current regulations. In this section there are veterinary scientists with knowledge and judgment to advise the Commissioner of the Food and Drug Administration for concise, prompt decisions.

The AVMA opposes any proposals to decrease the supervisory power of the Food and Drug Administration over the manufacture and use of nonprescription drugs and food additives. In fact, we feel that FDA supervision should be greater over food additives and nonprescription drugs than over prescription drugs, because with the latter there are professional practitioners controlling the dispensing and use of prescription products. Although the FDA cannot be expected to duplicate the supervision of prescription drugs provided by the professional man, we believe that increased control of nonprescription drugs and food additives for man and animals is necessary in the interest of greater consumer protection.

The AVMA firmly supports the general goal of consumer protection espoused by H.R. 11581, specifically, the efforts to "assure the safety, efficacy, and reliability of drugs," and to "authorize standardization of drug names." With respect to other items mentioned in H.R. 11581, the AVMA is willing to accept judgment of the Department of Health, Education, and Welfare in requesting the authorities contained in the bill and to support the provisions of H.R. 11581 not discussed above.

The AVMA presumes that it is not the intent of H.R. 11581 in title II, section 704, to regulate and limit the professional freedom of the practitioner to serve his patient. However, the wording of the above section is such as to cause the AVMA to urge that the following paragraph be included in the revised bill. "The provisions of section 201 and 704 shall not apply to practitioners of any profession who are lawfully entitled under a State or territory law to either prescribe, compound, or dispense any food, drug, device or cosmetic for patients within such State or territory, nor shall anything in this Act be construed as enlarging, reducing, or otherwise altering professional rights and privileges conferred by a State or territory law."

The AVMA, in behalf of the members of the veterinary profession in the United States, respectfully requests the committee's consideration of the views expressed herein and would request that this statement be also made a part of the record of the hearings conducted on H.R. 11581.

Respectfully,

L. MEYER JONES, D.V.M., Ph. D.,
Director of Scientific Activities,
American Veterinary Medical Association.

Dr. McCALLAM. I should also like to request, Mr. Roberts, that the statement presented to your subcommittee, I believe on August 7, be included as part of the record of this hearing, if appropriate.

Mr. ROBERTS. Without objection, it will be so ordered.

(The statement referred to is as follows:)

STATEMENT OF THE AMERICAN VETERINARY MEDICAL ASSOCIATION RE H.R. 12420,
H.R. 12437 AND H.R. 12715

Mr. Chairman and members of the committee, the veterinary profession, as represented by the American Veterinary Medical Association (AVMA), has a keen interest in all proposed legislation involving the Food, Drug and Cosmetic Act. We are vitally interested in having a constant supply of safe, efficacious and reliable drugs for treating and preventing animal ailments. We are also concerned that the drugs used in food-producing animals not affect the animal product in any way deleterious to man.

Most of the drugs employed in man are in use to a greater or lesser degree in animals. Some of the drugs used in animal feeds for growth stimulatory purposes and for mass medication are the same drugs used in human medicine, veterinary medicine, and as feed additives. Therefore, the American Veterinary Medical Association feels it should comment on these matters, since they do concern the practice of veterinary medicine.

The AVMA strongly supports the activities of the Food and Drug Administration, Department of HEW, its supervision of consumer foods, drugs and devices for man and animals. In the past, the FDA has extended its jurisdiction for protecting consumer interests over both man and animals. The AVMA will object strongly to any thinking and any effort to dissociate the supervision of foods, drugs and devices for animals from that of man. Newer knowledge about drug residues harmful to man in tissues of food-producing animals makes entirely clear the necessity for consumer protection through FDA supervision of drug usage in animal medicine. In particular, the AVMA commends the Division of Veterinary Medicine within the Bureau of Medicine, FDA, for many improvements in the area of animal drugs and feed additives within recent years. Furthermore, the AVMA urges that the scientists within the Food and Drug Administration be given full opportunity to use their scientific knowledge and judgment in determining a Government decision on problems arising under the Food, Drug and Cosmetic Act. This position is consistent with the White House Report of May 14, 1960, prepared under the chairmanship of Dr. Kistiakowsky, which stated that the supervision of drugs and feed additives for man and animals would not be improved until the scientists in the Food and Drug Administration were given the opportunity of making the decisions on the basis of their scientific knowledge and judgment.

The provisions of H.R. 12420 and 12715, as we interpret the language, provides the Secretary of HEW with authority to restrict a product if there is "substantial doubt as to its safety." We believe this feature is important and should be incorporated into the legislation as approved by this committee.

All three bills (H.R. 12420, H.R. 12437 and H.R. 12715) approach the problem of "prior sanction" as it affects the animal feed industry from an economic standpoint. The AVMA supports early correction and redress of this unfair and discriminatory situation among manufacturers of animal feeds and feed additives. The AVMA prefers the features of H.R. 12420 (Nelsen bill) and H.R. 12715 (Dominick bill) because of the previously mentioned safety clause.

The AVMA opposes any proposals to decrease the supervisory power of the Food and Drug Administration over the manufacture and use of nonprescription drugs and food additives. In fact, the AVMA feels that FDA supervision should be greater over food additives and nonprescription drugs than over prescription drugs, because with the latter there are professional practitioners controlling the dispensing and use of prescription products. Although the FDA cannot be expected to duplicate the supervision of prescription drugs provided by the professional man, we believe that increased control of nonprescription drugs and food additives for man and animals is necessary in the interest of greater consumer protection.

We view the proposed legislation outlined in H.R. 12420 and H.R. 12715 as support for the Food and Drug Administration. We would be opposed to any efforts to decrease FDA supervisory powers over drugs administered to animals, or added to their feed. If any changes are made, these should consist in more careful and extensive scrutiny of the safety, efficacy and reliability of chemicals and drugs distributed by nonscientific, nonprofessional persons for administering or feeding to animals producing food for man. The possibility of tissue residues harmful to man in food products from animals receiving drugs or chemicals is

not to be ignored. The only way such a circumstance can be prevented is to provide the FDA with the authority needed to insure the consumer public and the livestock feeders that drugs for animals are safe, efficacious and reliable.

In behalf of the practitioners of veterinary medicine, we wish to thank the committee for its courtesy and time in hearing this testimony.

Mr. ROBERTS. Mr. Ernest Giddings, National Retired Teachers Association and American Association of Retired Persons, 1346 Connecticut Avenue, Washington, D.C.

STATEMENT OF ERNEST GIDDINGS, DIRECTOR OF LEGISLATION, NATIONAL RETIRED TEACHERS ASSOCIATION AND AMERICAN ASSOCIATION OF RETIRED PERSONS

Mr. GIDDINGS. Mr. Chairman and members of the committee, my name is Ernest Giddings. I am director of legislation for two nonprofit organizations of older persons, the National Retired Teachers Association and the American Association of Retired Persons. I am appearing today on behalf of the 500,000 members of our associations to urge an early favorable report by your committee on H.R. 11581 in order that the bill may be taken to the floor of the House of Representatives for debate and action during the next few weeks before adjournment.

The associations I represent were organized to help older persons help themselves and to encourage them to accept a major share of the responsibility for making their later years meaningful and independent. Membership in the National Retired Teachers Association is open to any retired teacher. Membership dues are \$2 a year. Membership in the American Association of Retired Persons is open to any person 55 years of age or over upon payment of the annual membership fee which is also \$2. Both organizations are nonprofit and nonpartisan. The combined membership of the two organizations is approximately 500,000.

NRTA and AARP are dedicated to the purpose of serving the needs of their elderly membership. When our campaign for insurance protection was initiated there was no hospitalization or medical program exclusively for retired persons, and most programs designed to serve employed men and women arbitrarily excluded them from participation in the plan the day they reached the age of 65, or the company advanced the premiums with lowered benefits. To break this age barrier the officers of the two organizations worked for 7 years before convincing an insurance company to be daring enough to pioneer with us. The success of this breakthrough is attested by the fact that today more than 350,000 retired men and women are covered by a hospitalization program which was denied them until a few years ago, on no more valid grounds than that of age.

During the years 1958 and 1959 our members by the thousands protested the cost of the drugs. As a final result we established and have conducted for several years a nonprofit drug service for our membership. The major function of our drug service is to fill prescriptions and provide the vitamins ordered by our members. Several registered pharmacists are employed as well as total facilities to meet the regular standards of safety and sanitation.

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Early in our experience with a drug service we invited the Food and Drug Administration to inspect our drug facilities and services as well as our labeling procedures for drug containers. We requested their comments and suggestions and their recommendations were accepted and carried out. We are not in the drug service by choice, but because our members take the position that they have no other way of securing the medicine they need at a price they can afford to pay.

Some organizations resent our entry into the drug field. As associations, we pay the same cost of drugs as they do. We ask no favors or concessions. We pay more than the going wage to our pharmacists. We conduct an ethical pharmacy. We share our potential profits with our members to keep them self-supporting on a limited income. This sharing seems to be the point of contention of those who resent our operation in the drug field. Yet we stand shoulder to shoulder with our critics in the defense of high ethical standards, of the purity of the products and the unquestioned spirit of mission that the dispensing of drugs generates.

Our members are vitally concerned with the subject before your committee for many reasons:

(1) The incomes of our people who were retired from public and private retirement systems were fixed 5, 10, 15 or 20 years ago and cannot readily be adjusted upward as our economy grows and as prices rise.

(2) Their ability to purchase the needed drugs often makes the difference between sickness and health and sometimes between life and death.

(3) When physicians, as is the general practice in writing prescriptions, identify the drug by its trade name instead of by its off name, they leave our aged sick little or no opportunity for reduced costs. The patient must buy the prescribed brand and is left with no opportunity of shopping around to buy at a price he can afford.

(4) Those who exist on a bare subsistence level must often sacrifice on food or some other necessity in order to afford the prescribed drug or else deny themselves or ask for charity.

(5) The opportunity to buy drugs they need at a cost they can afford, will keep them physically fit, able to work part or full time to supplement their retirement incomes, and thus continue to do their part in the productivity of the Nation, and at the same time maintain their self-respect.

(6) When elderly people living on a subsistence income can be saved on drug purchases as much as \$100 to \$300 in 1 year, this saving alone may preserve their sense of self-sufficiency, their feeling of dignity, and keep them from being placed on the relief rolls of their local communities or State.

MONOPOLY

It is certainly to be expected that the work of your committee will result in a bill requiring improvement in the quality of drugs, requiring that physicians be provided with more adequate and complete information about drugs, and restricting the use of advertising matter of the overstated and misleading kind.

However, the bill makes little or no attempt to deal with the factor chiefly responsible for the high drug costs. Most sales of drug prescriptions are of patented drugs. The drug patent, like patents for a door lock or firearm, run for 17 years. This means that the owner of a drug patent is protected for 17 years in his exclusive monopoly, regardless of the fact that this monopoly control may be the single factor which prevents thousands of our members and millions of others of all ages from use of the drug. Cost is an extremely effective deterrent from the benefit of needed drugs in the case of older people with limited incomes. Much as we believe in the principles of free enterprise and protection of the profit motive, it is our position that no person or corporation should be allowed to withhold from public use products which relieve pain and suffering and which may make the difference between life and death. Only two other nations, Belgium and Panama, grant so much protection as we do in the nature of product patent monopolies on drugs without limitations on the drug producer to protect the public welfare.

Drug costs are not fiction; they are very real. Some reasonable part of the high costs can be charged to research. On the other hand, all the evidence indicates that drug industry profits lead all the rest by a wide margin.

Profits after taxes were 19.7 percent of investment in the drug- and medicine-manufacturing industries in 1961, according to reports published by the First National City Bank. This rate is almost double that of all manufacturing which was shown to be 10.1 percent in that year.

Markup on many drugs is appalling. Prednisone widely used in relieving pain from arthritis, has until recently cost the patient about 28 cents a pill or close to \$30 a month. Until recently, the pill cost the druggist 17 cents each. After some investigations into drug costs, McKesson & Robbins commenced manufacture of the prednisone pill and found its costs to be approximately 1 cent per pill.

Our evidence is that tetracycline, an antibiotic, costs about 2 cents a pill to produce; costs the druggist about 30 cents and costs the patient about 50 cents.

We believe the interests of the drug industry can be adequately served and that the welfare of the sick and ailing at any age can be better served if your committee will write legislation to restrict the existing 17-year exclusive patent legislation now protecting the drug manufacturer at the cost of the consumer. We urge your committee to give full consideration to the licensing procedure proposed in S. 1552 in its original form.

Such a provision would require that the owner of a drug patent after a 3-year exclusive monopoly, license for production of the drug any qualified drug manufacturer, that manufacturer being permitted to agree to pay the patent owner up to an 8-percent royalty on all sales for the 14-year period.

Under such a plan competition would to a limited extent replace monopoly and drug costs to the ill and suffering of all ages should gradually become adjusted downward by a competitive marketing of the drug.

REGULATION OF LICENSE AGREEMENTS

A second factor contributing heavily to high drug costs is a practice common in the drug industry which results in price fixing by agreement. Such agreements are frequently entered into during the course of Patent Office hearings between rival applicants for a patent. The contracts thus agreed upon in these proceedings determine who shall receive the patent, who shall be licensed to produce the drug, and the price, usually uniform and identical, which each producer will charge for the drug.

We urge your committee, as it writes up the bill, H.R. 11,881, to include an amendment requiring that all patent interference settlements be filed with the Patent Office. Terms of the agreements would therefore be available to both the Department of Justice and the Federal Trade Commission for use of either in any investigations into possible violations of the Sherman Act. We believe such a requirement would be of immeasurable assistance to these agencies. Since the Pharmaceutical Manufacturers' Association has agreed to the desirability of such a provision, it is our hope that your committee will write this requirement into H.R. 11581 before reporting out the bill. We believe such a requirement would greatly assist in lowering the excessively high prices of many drugs.

PROOF OF EFFICACY

Present law requires only that the Food and Drug Administration be satisfied that a drug is safe before it may be manufactured and sold to the public. Present law does not provide the Food and Drug Administration authority to require proof that the drug is effective in treating the sickness for which it is sold. In fact, and in practice, therefore, a drug may be legally marketed which is safe under current requirements but which is ineffective when taken by the patient for a specific illness. Frequently, the patient may be given the safe drug when he should be given one both safe and effective and in such a case the drug is positively injurious and harmful to the health of the patient. Medicines are too expensive and good health is too precious to receive so little protection from either the drug industry or from our Federal Government. By Federal law we give better protection than this to the products we sell to treat plant or animal diseases. It is our plea, therefore, that your committee insist upon perfecting section 102 of H.R. 11581, not only to require proof with application for a patent that the new drug meet a rigid efficacy test, but also proof of efficacy of every claim made for the drug after the patent has been granted and the drug is on the market.

The drug budget of our members is so limited and the health of all citizens is too vital to themselves and the national welfare to permit any degree of deception, however slight, in advertising a drug for human consumption.

NEW DRUG APPLICATIONS

Our recent experience with the baby-deforming drug thalidomide is ample proof that our Food and Drug Administration needs more protection by Federal statute in its terribly important duty to refuse

any and every new drug application as long as there is a shadow of a doubt about its possible dangerous side effects. A public official with less dedication to his or her tremendous responsibility than Dr. Kelsey might well have yielded to one of the more than 40 contacts from the new-drug applicant, the Merrill Co. In such a case deformed children would have been born by the thousands in our country.

The major impact of the thalidomide catastrophe occurred after the bill was introduced on May 3 of this year. It is to be assumed that you will greatly improve section 104, which, as it stands today, simply extends by a short time the opportunity of the Food and Drug Administration to require proof of safety of the new drug. We believe, the present requirement of automatic approval, whether after 90 days following application or after any other specified number of days, places unnecessary and dangerous pressure on the Food and Drug Administration staff. Some better plan than the automatic approval procedure must be devised.

In this brief statement I have tried to emphasize to your committee the position of our membership that drug prices are excessive. The incomes of older people are static and therefore buying power diminishes with every increase in the cost of living. If drug prices are needlessly high, it is our position that the Congress has a responsibility to the national welfare to seek out and apply the proper remedy. When freight rates became discriminatory decades ago, the Congress provided a partial remedy in enacting the Interstate Commerce Act. When the combinations known as trusts needed regulation in the last century, the U.S. Congress passed the Sherman Antitrust Act.

It seems to us that the Congress has ample evidence of the genuine need for the passing of an effective drug bill before the present Congress adjourns.

Mr. Chairman, I requested the manager of our drug service, Mr. James Browning, to prepare three examples of the difference in costs to our members when their prescriptions call for the drug by its trade name instead of by its generic name.

His reply was as follows:

In our drug service at 1000 Vermont Avenue here in Washington we fill approximately 6,000 prescriptions weekly. If these could all be filled with generic drugs, rather than with the same drugs carrying trade names, the savings to our members would be tremendous. As an illustration, we have many members using a trademarked drug prescribed for heart conditions.

In a 4-month period we dispense some 335,000 tablets of this drug. Sold under the trade name, this would amount to \$13,187. If they were dispensed under the generic name, they would cost only \$7,662, or a savings of \$5,525. I find this is 41 percent below the trade-name price.

To use another illustration: a popular prescription for high blood pressure sells in the amount of 190,000 tablets per month, for a total of \$10,250. This generic could be purchased for \$3,945, or a saving of \$6,301. This is a saving of 61 percent below the trade-name price.

A well-known tranquilizer sells up to 120,000 per month, with a cash value of \$6,840. Purchased under the generic name, they would cost \$3,000, or a saving of \$3,840, or a saving of 56 percent.

These three drugs alone would have saved our members a total of \$15,666 if brought under their generic name.

I want to thank your committee for the opportunity of appearing here before you today.

Mr. ROBERTS. Thank you, Mr. Giddings.

The committee appreciates your appearance and appreciates your support of the bill.

I wonder, though, over on page 7, you talk about the regulation of license agreements.

I wondered if you could give us any examples where that is taking place. You talk about agreements that entered into that go to Patent Office hearings between rival applicants for a patent.

If you do not have any specifically in mind, you could supply some of those for the record.

Mr. GIDDINGS. I would be glad to do that.

(The information requested follows:)

SUPPLEMENTARY STATEMENT TO TESTIMONY PRESENTED AUGUST 23, 1962, BY ERNEST GIDDINGS, FOR THE NATIONAL RETIRED TEACHERS ASSOCIATION AND AMERICAN ASSOCIATION OF RETIRED PERSONS, REQUESTED BY REPRESENTATIVE ROBERTS

The three license agreements named below were submitted by the corporations concerned to the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, during the 2d session of the 86th Congress and printed in 1960, as a part of the hearings before that subcommittee. The specific volume is titled "Part 17: Administered Prices in the Drug Industry."

Example I

Agreement between Rhone-Poulenc and American Home Products Corp., January 1, 1957, relating to Sparine.

The complete text of the license agreement on Sparine between Rhone-Poulenc and American Home Products Corp., executed January 1, 1957, is printed on pages 10075 to 10089, inclusive, in part 17: Administered Prices in the Drug Industry.

Example II

Agreement between CIBA, Ltd., a Swiss corporation, and S. B. Penick & Co., a Delaware corporation, regarding the manufacture of Reserpine.

The license agreement between CIBA and S. B. Penick & Co., regarding the manufacture of Reserpine, was executed January 1, 1956. The text of the agreement is printed on pages 10145 to 10157, inclusive, in part 17 referred to above.

Example III

Agreement between Carter Products, Inc., a Maryland corporation, and American Cyanamid Co., a Maine corporation, regarding the manufacture of Meprobamate.

The agreement between the above-named corporations was entered into July 3, 1957. The text of the agreement appears on pages 9690 to 9701, inclusive, of part 17 mentioned above.

Mr. ROBERTS. Any questions, gentlemen?

Mr. SCHENCK. Mr. Chairman, I have no questions, but I want to commend Mr. Giddings and his association for their splendid statement.

Mr. GIDDINGS. Thank you.

Mr. SCHENCK. I can assure Mr. Giddings and his associates that the committee will give it every consideration.

Mr. ROBERTS. Anything further, gentlemen of the committee?

Mr. DINGELL. I would like to also commend the witness for a very fine statement this morning.

Thank you, sir.

Mr. GIDDINGS. Thank you.

Mr. ROBERTS. Thank you very much.

Our next witness is Mr. Eugene P. Grisanti, general attorney, International Flavors & Fragrances, Inc., 521 West 57th Street, New York.

STATEMENT OF EUGENE P. GRISANTI, GENERAL ATTORNEY AND ASSISTANT SECRETARY OF INTERNATIONAL FLAVORS & FRAGRANCES, INC.

Mr. GRISANTI. My name is Eugene P. Grisanti, and I am general attorney and assistant secretary of International Flavors & Fragrances, Inc. I am appearing today to state our company's opposition to the factory inspection provision, section 201, of H.R. 11581, the only provision of the bill which materially affects our company.

International Flavors & Fragrances, Inc., is a medium-sized American corporation with its principal offices in New York and with manufacturing facilities in New York, New Jersey, Texas, and Oregon. In addition, it has 15 foreign subsidiaries in various countries throughout the world.

In the United States, the major portion of our sales consists of perfume compounds and other fragrance products, all of which, for ease of reference, I shall call "fragrances." Some of these fragrances are sold to manufacturers of perfumes, toilet waters, and colognes. Other fragrances are sold to manufacturers for the purpose of imparting a fragrance to cosmetics, soaps, and detergents and other similar consumer products.

We also manufacture flavors which are used in prepared foods, beverages, baked goods, confections, and ice creams and other dairy products.

We are in agreement with the statement filed with this committee by Mr. McCormick in behalf of the Flavoring Extract Manufacturers' Association concerning the harm which section 201 will cause to the flavor industry. In the time allotted to me, therefore, I should like to address myself to the detrimental effect section 201 will have upon the fragrance business, in the knowledge that the same arguments apply, for the most part, with equal validity to the flavor business.

To begin with, why is our company and industry so particularly vulnerable to irreparable damage from the inspection procedures proposed?

The art of perfumery has for centuries depended upon the secrecy of formulas. Formulas for a single fragrance may contain as many as 200 or more separate ingredients. In some instances, a single formula may be worth many millions of dollars. There is no effective way of protecting these formulas under our present patent laws. As a result, each individual company must still rely on its own security precautions, closely guarding its formulas as the most valuable of its trade secrets. Its stock-in-trade, therefore, literally reposes in its formula files.

Of course, if there was an overriding public need which required the disclosure of these formulas to protect the public health, I am sure that our company, as well as others in our industry, would respond to

that need under proper protective procedures, whereby disclosure to the appropriate governmental authority could be made with a minimum of risk. We are firmly convinced, however, based upon our own experience in the fragrance field, that no such public need exists.

Since the inception of our company in 1909, not a single judgment has ever been entered against us for injury from a fragrance supplied by us, nor has any payment in settlement ever been required to be made by us. One of the reasons for this remarkable record of safety, apart from our own testing programs, is the long experience of safe use of many fragrance ingredients. In addition, it should be noted that our fragrance products always represent only a minor percentage of the finished product in which they are used. A perfume, which traditionally has the highest fragrance content, contains only about 25 percent of fragrance itself, while the cosmetic creams or powders, for example, contain amounts ranging from one-tenth of 1 percent to 1 percent of fragrance. The danger of injury from the individual fragrance ingredients is in such cases, as a practical matter, non-existent.

To illustrate more graphically the safety of fragrances, the experience of one of the largest cosmetic companies in this country shows the remarkably low record of complaints of injury per million units of cosmetics sold. Even these complaints are often due to an unusual allergenicity or hypersensitivity of the individual involved, misuse of the product, or, in some cases, coincidental factors not related to the product at all.

In any event, these figures show the highest number of complaints was for cosmetic creams, and that, at the low level of 5.1 complaints per million units sold. The point I wish to make, however, is this. Cosmetic creams have one of the lowest fragrance contents of any cosmetic, about one-fourth of 1 percent of the finished cream. The same company's statistics show that their perfumes, which have the highest fragrance content of any of their products, I repeat, about 25 percent of the finished perfume, or about 100 times the fragrance content of the creams, had the lowest complaint record, only 0.78 complaints per million units sold.

Similar experience has been had by other cosmetic companies, clearly indicating that no significant safety problem has existed or exists today with respect to the fragrance in a perfume or a cosmetic.

Against this truly unique record of safety, let us contrast the sweeping inspection powers which are sought to be added to the already broad provisions of section 704(a) of the act. Any employees of the FDA can today, simply upon presenting "appropriate credentials and a written notice" inspect one's, and I quote—

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

Section 201(a), of H.R. 11581, would add to this the right to inspect, and again I quote—

all things therein (including records, files, papers, processes, controls and facilities).

An honest analysis of the entire provision leads to the inescapable conclusion that no portion of any office or factory involved will be inviolate from examination by an inspector claiming that his search bears "on violations or potential violations of this act."

This provision, we believe to be unconstitutional. The courts have consistently refused to sanction unlimited access to a company's records and files by a governmental officer or agency. The courts have consistently required the party seeking to examine such files to specify the violation committed and the particular papers relevant to such violation. General browsing to determine whether a crime has been committed has never been countenanced.

There have been implications by proponents of this measure that only those companies which have something questionable to hide, will oppose the proposed factory inspection provision. Nothing could be further from the truth. Americans have always deeply resented the indiscriminate invasion of the privacy of their homes and businesses by officers who demand to search without warrant upon the showing of a badge. It was just this resentment that gave rise to the fourth amendment of our Bill of Rights. It is not un-American to challenge such an invasion. It is un-American not to challenge it.

There are few citizens who do not have a healthy respect for the Food and Drug Administration and the formidable task of protecting the public health which has been entrusted to it. For this very reason, particular vigilance must be exercised to prevent a legislative grant of unconstitutional powers; and it would be difficult to envisage a provision which does greater violence than does section 201 to the safeguards against unreasonable search and seizure, of the fourth amendment. Is it, for example, consistent with the fourth amendment, or for that matter, our traditional concepts of fair play, that a businessman must allow his formula and trade secrets to be examined by any FDA employee during a routine inspection, or be in violation of Federal criminal law, if he does not?

If a formula becomes relevant in an administrative or judicial proceeding under the act, there are existing means for compelling its disclosure, under proper safeguards, enforced and protected by courts of law. The Federal courts can act swiftly to order the production of such records if they are relevant to a suspected violation under the act. Has any sound reason been advanced showing the necessity for imposing upon entire industries such a blanket police power of inspection and surveillance, which bypasses all courts and administrative bodies?

To these urgent constitutional questions, however, must be added the particular plight of companies such as ours which are asked to lay bare the secret formulas and processes upon which their businesses depend, the development of which has cost millions of dollars, and the only protection for which is their own ability to prevent disclosure. This last safeguard is taken from them by the proposed factory inspection provision for the purpose of achieving a solution for a problem which, we believe, as far as the fragrance industry is concerned, to be nonexistent.

This committee has decided to limit the present hearings to H.R. 11581, the drug bill. Hearings on H.R. 11582, the cosmetic bill, have, for the moment, been delayed, for the desirable objective, I believe, of obtaining effective drug legislation during this session of Congress. Consistent with this reasoning, it is respectfully suggested that section 201, which affects the food and cosmetic industries, as well as our own, be modified to conform with the factory inspection

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provision of S. 1552, recently approved by the Senate Judiciary Committee. H.R. 11581 would then truly be a drug bill, and extraneous issues involving other industries would not impede its orderly progress.

I am grateful to the members of this committee for giving me this opportunity to express, on behalf of International Flavors & Fragrances, Inc., why we feel that the proposed section 201 of H.R. 11581 should not be enacted.

Mr. ROBERTS. Thank you, Mr. Grisanti. We appreciate your appearance here.

Any questions?

Mr. Dingell?

Mr. DINGELL. Thank you, Mr. Chairman.

Mr. Grisanti, you have indicated you have never had trouble with the Food and Drug Association in the course of your association and in the course of your company's association with them through the years?

Mr. GRISANTI. I did not so indicate. As a matter of fact, we have not had any.

Mr. DINGELL. You say you have not had?

Mr. GRISANTI. Not to my knowledge.

Mr. DINGELL. I see.

They have had access to your plant through the years, have they not?

Mr. GRISANTI. They have, under the present provisions of the law.

Mr. DINGELL. The present provisions of the law, I am sure you are aware, in the words of the Assistant Secretary of Health, Education, and Welfare and a number of others who have commented on behalf of that Department, constitute authority for the Food and Drug Administration to have nothing more or less than a guided tour of plants subject to the control of the Food and Drug Administration.

This is the situation, then, which you and your company desire to have continued?

Mr. GRISANTI. I do not agree with that characterization at all.

I think that the present law is effective, and I think, if it were utilized, that there would be no need for any additional extension of power.

Mr. DINGELL. But you do have this difference of opinion with regard to the efficacy of the present law, is that correct?

Mr. GRISANTI. Difference of opinion with the Department of Health, Education, and Welfare?

Mr. DINGELL. That is right.

And your difference stems from fear that if this legislation goes through affecting your company, or including your company, that perhaps there will be loss of trade secrets and so forth, is that correct?

Mr. GRISANTI. That is our reason, plus the fact that we believe that this extension of power is quite clearly an example of an unconstitutional grant of power by the legislature.

Mr. DINGELL. Now, let us take, for example, in the case of health inspectors, they have full access, your State health inspectors have full access to your plants, do they not?

Mr. GRISANTI. They have access to the premises and to inspect the premises.

Mr. DINGELL. That is correct.

Mr. GRISANTI. I believe that their access is limited. If they wish to make an inspection, for instance, of our files, and did not specify what they wanted or how it was relevant to their search, we would not allow that inspection to proceed.

Mr. DINGELL. Food and Drug has access to check on narcotics and things of that sort, as does also the Alcohol Tax Unit of the Treasury, which has full access to books and records and so forth, do they not?

Mr. GRISANTI. If they are relevant to the issue, yes.

Mr. DINGELL. Alcohol Tax has full access to books and records, do they not?

Mr. GRISANTI. Relevant to their inquiry, yes.

Mr. DINGELL. Yes.

And this bill authorizes access for nothing more than what is relevant to the inquiry, does it not?

Mr. GRISANTI. No, I disagree there. I think that the difference lies in the broad language at the close of section 201 (a), which states that they can investigate all records and papers and so forth, if they believe that they may bear upon violations or potential violations of the act.

Now, as a practical matter, we know that an inspector under this type of a provision would be able to come into a plant and state that he is investigating a potential violation of the act, and under this broad provision we would be very hard put to deny that he has the right to do so.

Mr. DINGELL. But you have no objection, then, on a constitutional basis to (b) upon violation of the act, is that right?

On a constitutional basis, you have no objection if it goes just as far as to the violation of the act?

Mr. GRISANTI. Mr. Dingell, I think that the act, as it now stands, gives the FDA full authority.

Mr. DINGELL. I recognize that, but that is not responsive to my question.

My question was, if we limit it just to violations of the act, then you would have no constitutional objection to the language of it, is that right?

Mr. GRISANTI. No.

I would have a constitutional objection to the language because the language, as it is written, does not make any qualification of the types of records or papers or controls which are relevant to the violation, and I think that if there were such a qualification and if there were some protection afforded by court review or even administrative review, there would be a better case for its constitutionality.

I think that an inspector who can just walk in without a warrant and want to look at all your files because he claims that there may be a violation of the act is taking constitutional rights away from the person he is investigating.

Mr. DINGELL. The bill here says "to inspect at reasonable times, within reasonable limits, and in a reasonable manner such factory, warehouse," and so forth and so on.

That is a very definite limitation upon the power that the inspector has, is that not right?

Mr. GRISANTI. Of course, this is a question of legislative draftsmanship.

Mr. DINGELL. It is a very definite limitation and it is a very strong limitation.

Mr. GRISANTI. I do not know whether it is or not.

Mr. DINGELL. "Reasonable times," "reasonable manner," "within reasonable limits."

Mr. GRISANTI. I do not know whether you can draft a broad clause, as broad as this is, and simply by inserting the word "reasonable" take away from it all the vagueness in one stroke.

I do not think that that could be done.

Mr. DINGELL. Your basic objection, however, to this bill has to do with possible divulgence of trade secrets, is that not it?

Mr. GRISANTI. As far as our company is concerned, yes, sir.

Mr. DINGELL. For all intents and purposes, your constitutional argument really is thrown in as kind of a catchall to buttress your basic objection, is this not a fact?

Mr. GRISANTI. Well, if you consider a constitutional argument as a catchall, I suppose it is, but I consider it more than that.

Mr. DINGELL. We have gone into this from the standpoint of the fact that traditionally Food and Drug has had factory inspection authority. The Alcohol Tax Unit has had the authority to investigate books and records. The Internal Revenue has authority to investigate books and records. The State income tax, the State sales tax agencies have authority to have full access to books and records.

Mr. GRISANTI. I differ with you.

Mr. DINGELL. And you recognize these as being fully constitutional?

Mr. GRISANTI. I differ with you on that. I think in every case you will find that before they can do that, they have to go to court and get a proper warrant to do it, unless, of course, the party wishes to cooperate and give them such records.

Mr. DINGELL. Not in the State of Michigan, they do not. They just go in and they get access to books and records.

It is also true in the case of Alcohol Tax Unit. They just go in and they have access to books and records.

You know this of your own knowledge from years with the Alcohol Tax Unit.

Mr. GRISANTI. I do not think there is a right there, unless the books and records are relevant. I will say this, however:

I know of no State law, including Maryland, in the case of *Frank v. Maryland*, where the distinction is not made between books and records and inspecting the premises for general hygienic conditions.

I think that books and records and correspondence and confidential files have traditionally been classed under our legal system in a different category than a general health inspection, and where these have been involved, traditionally, there have been the safeguards of subpoena and court warrant.

Mr. DINGELL. Now, let us talk a little bit about your objections.

The committee was told this morning that fragrances can substantially be duplicated.

Is that not true?

Mr. GRISANTI. Of course, I am not in the technical end of the business, but I have been told that a good perfumer can in some cases come close to duplicating a particular fragrance.

Mr. DINGELL. Come very close, and with modern methods, spectrographic analysis, modern chemistry, and perfumers' knowledge, really, a perfumer's secret formula is not too safe, is this not a fact?

Mr. GRISANTI. No, that is not a fact.

Even the most modern methods, including gas chromatography, have not been able to analyze completely the ingredients in a perfume.

Mr. DINGELL. They have been able to come very close, though?

Mr. GRISANTI. Not close enough to duplicate.

Mr. DINGELL. But close enough to substantially duplicate?

Mr. GRISANTI. No, not close enough even to substantially duplicate. It requires a skilled perfumer who uses his nose.

Mr. DINGELL. Who uses his nose?

Mr. GRISANTI. To do it.

Mr. DINGELL. And supplemental information, using modern scientific results to duplicate?

Mr. GRISANTI. He may be able to.

Mr. DINGELL. Very close.

Thank you very much.

Mr. ROBERTS. Thank you, Mr. Grisanti.

Our next witness is Mr. P. T. Dalsimer, chairman of Lawyers Advisory Committee of the United States Trademark Association, 420 Lexington Avenue, New York City.

**STATEMENT OF PHILIP T. DALSIMER, CHAIRMAN OF LAWYERS
ADVISORY COMMITTEE OF UNITED STATES TRADEMARK ASSOCIATION**

Mr. DALSIMER. Mr. Chairman, I believe I am the last witness.

Mr. ROBERTS. Yes, sir.

With all due respect to you, may I say we are glad to have you.

Mr. DALSIMER. On behalf of the United States Trademark Association, a statement has previously been filed through its president, Thacher Fisk, and I believe that statement, which is dated June 12, is already of record. I have submitted a brief supplemental statement and ask that it be included.

I just want to make a few brief comments.

The Trademark Association is a relatively old association. It has about 260 members, and among those members perhaps 30 are in the pharmaceutical business. But, essentially, the Trademark Association is not a pharmaceutical association.

I am appearing here to discuss trademarks in principle. I am not appearing here to discuss details of this drug legislation except insofar as they apply to the trademark aspects.

As chairman of the Lawyers Advisory Committee of the United States Trademark Association, I was instructed to do what I could to answer any questions which might be directed either to Mr. Fisk, as president, with reference to his previous statement, or any questions that might be raised by my remarks.

This past year I was chairman of the Federal Trademark Law Revision Committee 201, of the American Bar Association, and so I have had a long and continuing interest in the trademark field.

I am a member of a private law firm, Kane, Dalsimer & Kane, practicing in the field of patents, trademarks, and copyrights.

There are only two provisions of the present bill that we object to in principle.

The first is the one that has a requirement which ties the size and position of the established name directly to the trademark.

The second is the principle under which the Secretary is given permission to determine the established or standard name of a product without, in our opinion, any adequate judicial control.

And so I will direct my remarks only to those two provisions.

First, specifically to the bill, which requires giving the precedence in position to the established name and requiring it to be in type at least as large and prominent as that used for the proprietary name, the association's objection is on basic principle, and our objection applies equally whether the requirement is modified to making the size of the type half as large as the proprietary name, or in any other specified size which ties it directly into the proprietary name.

The association does not object to a requirement for the use of nomenclature which in proper generic terminology states what the product is.

The reference plane for the size of the generic name should, however, not be the trademark. The reference plane should be an independent requirement that the size of the generic name be adequate to accomplish the purpose of the information.

I make reference to the present requirement, which, as you well know, in the Food, Drug, and Cosmetic Act, section 502(c), is that it be—

placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

It appears to us that this provision of the statute is clear and proper and could well be applied in the present situation.

The association believes that Congress must aid in solving problems. However, if Congress needlessly legislates every detail of labeling, such as requiring the precise size and precise position of a generic word with reference to a trademark, Congress may not have solved problems, but may have created them.

All labels are not the same. Products vary greatly. Packaging is of many sizes, shapes, and types.

I would like to interpolate here by referring back to what Mr. Holloway had pointed out:

That, for example, in deodorant packages it would be quite difficult to talk in terms of the size of the type of the word "deodorant" or any other word that might be chosen as the generic name being as large as the name "Mum," for example.

Why subject hundreds of manufacturers and users to a rigid control in a society that believes in and has flourished with flexibility? Rigidity may not be necessary.

Why set up rigid, specific, tied-to-trademark-size, congressional standards, so rigid as to perhaps make them unworkable in operation?

Why not utilize the less rigid, more flexible provisions of the existing Food, Drug, and Cosmetic Act? To put it another way, we believe that a minor problem should not be answered with a drastic remedy that straitjackets and perhaps renders impotent long-estab-

lished trademark values. It is as though all are to be punished for the transgressions of a few.

I am aware of the fact that comment has been made today, while I was sitting here, about the need for a generic name in order to reduce drug prices.

Surely this bill, which applies to so many areas, so many products, should not use the destruction of trademark values, long-established, as the basis for indirectly trying to achieve what perhaps may be justified, I am not sure, but as one who has sought to protect trademarks over a period of many years, it seems to me ill befitting Congress to pass a law that would indirectly seek to lower drug prices by destroying trademark values.

The other basic objection which the association has is to the provision which permits the establishment of an established or standard name for a drug "whenever in the judgment of the Secretary such action is necessary or desirable," and permits this establishment to be, by the Secretary, without, as we see it, any further controls.

There appears to be no provision for preventing the Secretary from taking such action until a proper judicial action has been taken to protect the interest of the trademark owner.

As we read the provision, the Secretary could select as the standard name of the drug an existing trademark.

The association believes that decisions of this type should not rest solely in the judgment of the Secretary. Surely the association is not taking any position of worry over a given Secretary. Government employees do their best, but no person in an administrative tribunal or a Government agency can know all, and persons very closely connected with certain agencies sometimes get a set, warped perspective of value—not warped in the sense that it is totally detrimental, but that they become too close to their work.

And administrative tribunals that both make the decisions and then enforce them are in danger, sometimes, of losing perspective.

We think that proper safeguards should be written into the bill to provide for judicial decision.

The common expression is that "hard cases make bad law."

We urge merely that in this excitement of the moment Congress not enact bad legislation.

We trust that the two suggestions which we have made will be given the fullest consideration, and that their concepts will be embodied in amendments to the bill.

Mr. ROBERTS. Thank you very much.

Your statement is very clear. You take the viewpoint that in the case where the Secretary might select a trademark as the standard or established name, you could force competitors of that trademark to adopt the same name and thereby possibly destroy the competition?

Mr. DALSIMER. I would think that what would happen if the Secretary should choose a trademark as the generic name, that then no competitor could do anything but use that trademark, and, of course, you would have instantly destroyed the trademark for the owner.

This could occur before any further action could be taken, because there are no judicial safeguards in the provisions.

Mr. ROBERTS. And you believe, too, that the Congress, if it undertakes to prescribe size of type and other requirements under this bill,

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it would destroy a great deal of the flexibility that you think the administrator should have in carrying out the provisions of basic law?

Mr. DALSIMER. I think it is important for the administrator to have the flexibility, and I believe it is important for the multitude of manufacturers with the multitude of products they sell to have some flexibility.

Mr. ROBERTS. Thank you very much.

Any questions, Mr. Dingell?

Mr. DINGELL. No questions, Mr. Chairman.

Mr. ROBERTS. This concludes the hearings on H.R. 11581. The record will remain open for 5 legislative days for statements to be filed.

Mr. DINGELL. Mr. Chairman, in order to make sure the record is complete, I would like to ask at this time that the record be kept open for a matter of 7 days, since probably the committee will not be able to meet on this matter before that time.

Mr. ROBERTS. Five legislative days.

Mr. DINGELL. In order to permit Food and Drug Administration to submit, and I would like to have the committee request that Food and Drug submit to this committee any additional statement which they feel would be necessary in view of the comments which have been made by industry witnesses today.

I think that there have been a number of points raised which require either clarification or comment by the Food and Drug Administration, and I hope that the Chair will request of the Food and Drug Administration such additional comment on this as they feel would be necessary or appropriate.

Mr. ROBERTS. The Chair will be glad to comply with the gentleman's request.

Mr. DINGELL. Thank you, Mr. Chairman.

(The additional comments from the Food and Drug Administration follow:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 30, 1962.

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

DEAR MR. CHAIRMAN: In accordance with the desires of the Interstate and Foreign Commerce Committee, we are transmitting the Food and Drug Administration's comments on testimony that has been offered before the committee on H.R. 11581.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

FOOD AND DRUG ADMINISTRATION COMMENTS ON TESTIMONY, H.R. 11581

SECTION 101. REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

Everyone agrees that better quality controls based on good manufacturing practice should be required for drug manufacture. The primary dispute is whether these requirements should be established by regulation or left to litigation on a case-by-case basis.

Some of the industry witnesses who have appeared argued that these regulations not be a rule that must be complied with but rather that they simply be prima facie evidence in case of court contest. The net effect of this latter proposal would be to slow down Government action, forcing us to establish de novo

in each court action whether the individual operations conducted by a firm had or had not conformed to good manufacturing practice. The following example illustrates the dangerous weakness of that position.

In September 1961, we learned that a dicalcium phosphate product used by pregnant women and others was contaminated with diethylstilbestrol, a synthetic sex hormone. Some male patients taking the product were developing enlarged breasts. Some female patients who were using it had abnormal uterine bleeding. We required the manufacturer, Nysco Laboratories, Inc., Long Island City, New York, to recall outstanding shipments of the contaminated product. In April 1962, we learned that another drug, isonicotinic acid hydrazide, manufactured by the same firm, was contaminated with the same synthetic sex hormone. It was causing excessive breast development and other symptoms of precocious feminization of babies in a San Francisco hospital. This product was also recalled. Subsequent investigation of the firm revealed additional products (such as sodamin tablets and a nasal decongestant) contaminated with synthetic sex hormones. The firm was not cleaning out a mill used in the manufacture of tablets unless the color of the second batch differed from that of the first.

When we discovered the cause of the mixups we made an extensive check of the firm's line of products which were both prescription and nonprescription items. We found that a number of products had been contaminated with penicillin left over from earlier manufacturing operations and these were recalled. A number of other products had been contaminated with a poisonous insecticide after the firm had manufactured a stock of lindane tablets. These also were recalled. In each type of contamination both prescription and nonprescription drugs were involved. This manufacturer, although one of the largest private formula firms in the United States, did not follow good manufacturing practice and consequently jeopardized the health of people all over the country.

If the industry proposal prevails we could be forced to establish in court for each of over 1,000 drug manufacturers what constitutes good manufacturing practice. This would detract significantly from the consumer protection intended to be granted by the proposed amendment.

The proposed answer to this problem in H.R. 11581 is to authorize the Secretary to determine and promulgate standards for good manufacturing practice. Appropriate procedures for hearings and appeals would be provided.

We agree with the representative of the Pharmaceutical Manufacturers Association that the standards must not be extreme or so unrealistic or unreasonable that they can be met by no one. The hearing and court review provisions would offer adequate safeguards against our issuing improper standards.

The committee has heard objection also to giving the Government authority to consider whether the manufacturer has followed good manufacturing practice with respect to the qualifications of the personnel employed in manufacturing drugs. No one questions the desirability of determining the competence of a pharmacist before he may fill prescriptions. But it is even more important to have well qualified people manufacturing the drugs the pharmacist dispenses. Yet, under present law, the man who drops out of pharmacy school without completing the course or who fails his pharmacy board examination, and thus is barred from filling an individual prescription, may set up a drug manufacturing establishment and produce potent drugs to be dispensed by pharmacists all over the United States. Clearly, it is desirable and imperative for the Government to be able to look into the qualifications of the key employees in manufacturing plants.

SECTION 102. PREMARKETING SHOWING OF NEW DRUG EFFICACY

Most witnesses agreed that the promoters of new drugs should be required to prove them effective, as well as safe, before they are marketed. The major points in controversy here are over how much evidence is to be required to establish effectiveness and how the new requirements will apply to drugs already on the market.

The committee has heard testimony about the alleged difficulties of establishing whether a drug will or will not accomplish its intended purpose and about the authority that this proposal would vest in one man.

The difficulties have been magnified. Obviously it is necessary to make investigations to determine what a drug will do. The drug companies routinely assert through promotional material in labeling and by other means what they believe their products will accomplish. They do not hesitate to make claims. The only

question is whether they should justify these claims or show the facts upon which they are based.

We have evaluated the effects of drugs for years. Several witnesses have pointed out that we do consider the efficacy of a new drug whenever it is so toxic that we must weigh the disadvantages from its toxicity against its advantages. Additionally, present law requires us to pass on the effectiveness of all insulin-containing products and the five antibiotics and their derivatives which are subject to certification. This evaluation is a true examination of the therapeutic effect that the products will have, not just the "potency" as one witness indicated on August 21, 1962.

Secretary Ribicoff submitted for the record last June some examples of new drug applications that we have had to allow to become effective even though the labelings bore claims that, in our opinion, are not supported by valid evidence. Some of these drugs are offered for very serious conditions. For example, a conjugated estrogen substance is offered for control of various types of hemorrhage such as those associated with surgical procedures and gastrointestinal hemorrhage. Another preparation, edathamil disodium, is offered for removing calcium from pathological deposits such as calcified heart valves and calcified deposits in the kidney. Papain is offered for the treatment of injuries, infections, and inflammations.

These claims are based on something. If they are based on fact there is no reason why the manufacturer should fail to submit to the Government the facts that convince them that the drugs are useful. And if the facts do establish this, there is nothing in the proposed bill to prevent the claims from being made.

If a product is put on the market with claims that are false or misleading, the Government may proceed against the product by seizure action or against the responsible party through injunction or criminal prosecution. No one testified that it is impossible in bringing such actions to determine whether a drug is or is not effective. The only issue is whether the claims of effectiveness are going to be reviewed before a product is put on the market or sometime later when, if the claims are false, the public has wasted its money and has relied on an inadequate product for relief or cure.

The charge that this bill would give one man the authority to determine whether a drug may or may not be marketed is not true. In the case of every new drug that we have held up on safety questions, the manufacturer has a right to insist upon a filing of his application and to force us to a hearing as to the safety of the drug. If he is not then satisfied with the ruling, he can carry the case to the Federal courts. The same safeguards would be available in dealing with questions of efficacy under the proposed bill.

When there are difficult questions of medical fact to be resolved the Food and Drug Administration has routinely called upon the outstanding medical experts for advice and assistance. To mention only a few examples, we have within the past 2 years sought advice as to the labeling of antibiotics to be used for prophylaxis, the labeling of chloramphenicol, the safety of safrole in foods, the safety of quinine for certain uses in beverages, the safety of a vaginal device, the safety of the drug reticulose for sale without prescription, the toxicity of phenacetin, safety of certain iron preparations when sold without prescription, and the safety of an oral contraceptive pill. If this bill becomes law, we will continue to utilize the very finest scientific talent of the Nation in resolving troublesome questions.

The committee has heard it implied that if the efficacy provision were written into the law a drug might be ruled off the market unless it offered a 100-percent cure. This is not true. Where we have dealt with efficacy questions in the past in connection with new drug applications, we have not taken such a position. For example, we have allowed products on the market for the treatment of certain cancers. They may prolong a patient's life by suppressing temporarily the progress of the disease even though the drug will not cure cancer and will not be effective in all of the patients on whom it is used.

Further, the efficacy provision would not allow the Government to specify what drug a doctor shall use in his practice, as one witness suggested. It would merely require the full truth to be told about a drug's effectiveness. The doctor still would choose the particular drug, from the hundreds available, that he wished to use.

The testimony that the medical profession has made mistakes in judging the efficacy of new drugs or treatments has no bearing on this bill. If the medical

profession judges a drug to be effective and it is not, then we will make the same mistake because we must rely upon the profession. And we will make the mistake whether or not H.R. 11581 is enacted. If the medical profession believes that a new drug is ineffective, we will have to abide by that view. But if it is wrong the only thing the manufacturer needs to do is demonstrate effectiveness. And he has authority under the law to have experts conduct tests for this purpose. Certainly it would not be good public policy to allow drugs to be promoted for uses which, on the basis of sound experimental evidence, the profession itself judges to be false.

Much has been said about whether proof of efficacy should rest upon a preponderance of the evidence. In reaching a judgment our scientists would evaluate the total experimental data in an application and otherwise before us. They would evaluate the adequacy of each experiment, the test plan, the controls used, the confirmatory laboratory procedures, and other pertinent factors. If the total evidence showed that a drug would do what the manufacturer claimed for it, the claim would be allowed. Otherwise it would be denied. Of course, there would be occasions in which some tests appeared to discredit a drug but the total evidence clearly showed it to accomplish the benefits claimed. In such event the claim would be approved. There would be other cases where some preliminary testing appeared to support a claim but the total evidence clearly proved it wrong. In such event the claim would not be approved. This is exactly the process employed today in deciding whether a claim being made for a drug already on the market is true or false.

The committee heard much debate about whether the definition of the term "new drug" in the law should be amended to include efficacy. Those who oppose such amendment have ignored the key question, "Why should a product be permitted on the market with unproved claims just because it is recognized as safe?"

The answer is, of course, that it should not. But to leave efficacy out of the definition of "new drug" would permit new unproved claims to be made for safe drugs.

This brings us to the question of a grandfather clause. Some witnesses want a complete grandfather clause. This would mean that the thousands of products that have gone through the new drug safety clearance procedure could continue to be marketed with unproved claims for efficacy while the Government conducted tests or otherwise amassed data bearing on the truthfulness of the claims.

Why should a manufacturer be given a license to continue to promote a drug for conditions in which it has not been shown effective simply because he started doing so before a serious flaw in the act was corrected? On the other hand, we do not propose that these thousands of drugs be summarily taken off the drugstore shelves. We, of course, would suggest a reasonable transition provision.

SECTION 103. RECORDS AND REPORTS AS TO EXPERIENCE ON NEW DRUGS

There seems to be general agreement that drug manufacturers should promptly report to the Food and Drug Administration any clinical experience or other reports casting doubt upon the safety or effectiveness of new drugs or antibiotics (as provided in sec. 106 of the bill).

However, some witnesses would impose a requirement that such reports be made available only to medical officers of the Department. They suggest that medical ethics would demand this. That is not true.

There is no more reason to keep such reports from highly trained and skilled personnel of the Food and Drug Administration who are not M.D.'s than to keep the reports from nurses, pathologists, physical therapists, pharmacists, administrators, and others who properly have access to them in hospitals and clinics.

As the questioning on this point clearly revealed, an expert without an M.D. degree might be the very person best qualified to evaluate a particular report.

SECTION 104. PROCEDURAL CHANGES AS TO NEW DRUGS, AND ADDITIONAL GROUNDS FOR WITHDRAWAL OF SUSPENSION OF APPROVAL OF NEW DRUG APPLICATIONS

Most people recognize that the present time limits for handling new drug applications need improvement.

This brings us to the testimony about whether a new drug application should be "approved." No matter how you describe it, if the Government found that a new drug is safe and effective and allowed it to be marketed under the proposed claims, the drug would have Government approval. We do not understand the objection to saying so. One witness testified that with the concurrence of Secretary Ribicoff, Commissioner Larrick conceded that the law should not be changed to require affirmative approval. A review of the full testimony, to which he referred only in part, will show that the Commissioner made no such concession. We fully support affirmative approval.

H R. 11581 would also establish additional grounds for withdrawal of approval of new drugs and thus significantly strengthen consumer protection.

Under present law a new drug application can be suspended only if we can prove that the applicant made false statements or if new tests show that the drug is unsafe (but while these tests are being run the product may remain on the market).

This situation leaves a serious gap in consumer protection.

H R. 11581 would close this gap by authorizing the Secretary, when he finds that there is substantial doubt as to a new drug's effectiveness or safety, to give the applicant due notice and opportunity for a hearing on the question of withdrawing approval of the application by order. Further, if the Secretary finds that there is an imminent public health hazard, he may suspend the approval of a new drug application immediately upon notice pending the opportunity for a hearing.

Spokesmen for the PMA opposed giving FDA the power immediately to suspend an effective new drug application upon a finding that it poses an imminent hazard to health. They reason that we already have ample powers through publicity and by obtaining a temporary injunction to protect the public in such cases.

The point overlooked by these arguments is that our power to obtain an injunction would depend primarily on the suspension of the approved application. The courts are given jurisdiction to enjoin violations of the act—in this case the introduction into interstate commerce of a new drug for which there is no approved application. So suspension would be a necessary first step in invoking the injunction power of the district courts.

We could, of course, also seek an injunction by proving that the new drug was either misbranded or adulterated. But if we had an outstanding approval of the drug, both from the standpoint of safety and effectiveness, the courts would be reluctant to find that our approval was a mistaken one when we ourselves had not withdrawn it.

And a drug might pose an imminent hazard to the public health, before we were prepared to shoulder the burden of proving that it was adulterated or misbranded. Take a case like thalidomide—had it been approved, the very first notice to us that it was the probable cause of phocomelia would establish an imminent hazard to public health calling for immediate withdrawal of the drug, even though all the facts had not yet developed to pin down the cause and effect.

An imminent hazard to the public health is one that allows no delay. It may arise from the certainty of injury to the public or from the grave consequences that would follow if the suspected dangers actually proved out to be attributable to the drug. In both situations, we think we should have the power immediately to suspend the new drug from the market while the hearing, on an expedited basis, was held to determine whether the suspension should be finalized.

SECTION 105. CERTIFICATION OF ALL ANTIBIOTICS

Batch-by-batch certification of all antibiotic drugs is needed primarily because antibiotics more than any other drugs are the first choice in treating life-threatening infectious conditions; use of a subpotent, ineffective or otherwise unfit antibiotic can deprive the victim of the narrow margin of time that means the difference between life and death.

Some industry representatives believe that the antibiotic manufacturers are now able to do an acceptable job without the added controls afforded by certification. This is not true for all manufacturers.

Within the past 3 years we have had to withhold for varying periods of time, certification services with respect to all certifiable antibiotics distributed by six firms until their operations were brought into compliance with the regulations which are designed to insure safety and efficacy of certified lots.

The firms and dates of withholding are:

(1) Allied Bio Chemical Co., San Francisco, Calif.: Withheld in August 1959; resumed in March 1960. Withheld in September 1961, not yet resumed as of August 23, 1962.

(2) Philadelphia Laboratories, Philadelphia, Pa. Withheld in January 1961; resumed in February 1961. (Recently this firm, along with its president and vice president, was convicted of shipping illegal antibiotics. These included one lot of uncertified, subpotent bacitracin which was refused certification by FDA but which later turned up in New York City hospitals, and a batch of uncertified, low-potency penicillin tablets.)

(3) Success Chemical Co., Brooklyn, N.Y. Withheld in November 1961; resumed in March 1962.

(4) Difco Laboratories, Detroit, Mich. (manufacturer of certifiable antibiotic sensitivity disks). Withheld in April 1962; resumed as of June 1962.

(5) Bio Ramo Drug Co., Baltimore, Md. Withheld in May 1962; resumed as of June 1962.

(6) Jamieson and McKames Pharmaceuticals, St. Louis, Mo. Withheld June 1962; not yet resumed as of August 23, 1962.

In addition there have been a number of suspensions of certification for individual products of antibiotic firms because of unsatisfactory conditions with respect to their production.

Despite the manufacturers' check of each batch of antibiotics before submitting it for certification, in fiscal year 1961 samples from over 100 batches, and in fiscal year 1962 samples from over 120 batches of antibiotics offered for certification failed to meet the standards set forth in the regulations. We attach a listing of these rejections.

Several witnesses have testified to the great strides which have been made in manufacturing techniques relating to antibiotics. Penicillin has been discussed particularly and a statement was made that current techniques make it possible to produce penicillin which is "indefinitely stable."

In the past 19 months, there have been 83 recalls of drugs for human use. Sixteen of these recalls or almost 20 percent have involved penicillin-containing products and have been due to either a material variation from declared potency or because the penicillin was contaminated with excessive moisture (a condition that may speed up deterioration). These products met the potency and moisture requirements of the regulations when manufactured; they were not "indefinitely stable."

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It is not true as one witness suggested, that we want certification of all antibiotics for the additional fees which would be involved. The fees for the certification of antibiotics are paid into the Treasury and are subject to annual appropriation by the Congress.

In our opinion, certification of all antibiotic drugs would be in the public interest.

SECTION 106. RECORDS AND REPORTS AS TO EXPERIENCE ON ANTIBIOTICS

This was covered under section 103 above.

SECTION 107. BIOLOGICAL DRUGS

H.R. 11581 proposes to place biological drugs that are subject to licensing under the Public Health Service Act on the same footing as other drugs, that is, to require them to be proved efficacious before marketing and to deem them adulterated or misbranded under the Food, Drug, and Cosmetic Act if they fail to meet licensing requirements. The Department believes the desirability of this improvement is self-evident.

SECTION 111. AUTHORITY TO STANDARDIZE NAMES

We believe there is general agreement regarding the need to standardize common names for drugs. The Secretary of Health, Education, and Welfare should have a standby authority to establish the official name for a drug if voluntary procedures are not effective in doing so.

It is not the intent of the bill, nor our intent, to make established names of trademarked names.

SECTION 112. NAME TO BE USED ON DRUG LABEL

One witness indicated that he believed the bill could be interpreted as requiring each of the ingredients of a proprietary drug to be listed ahead of the brand name of the proprietary. This is not what the bill says. Using the example the witness employed, the bill would not require any change in declaration of brand name or ingredients for Mentholatum.

PART C. SPECIAL CONTROL FOR BARBITURATE AND STIMULANT DRUGS

The primary objection raised in connection with this section of the bill was that it does not exempt retail druggists from the recordkeeping and inspection provisions relating to barbiturates and amphetamines, while exempting medical practitioners from these provisions. The witness expressed an inability "to understand why such unjust discrimination against the profession of pharmacy should exist in this bill."

The retail druggist has historically been the main source of illegal diversion of prescription drugs. From July 1, 1949, through April 1962, over 1,100 prosecution cases involving illegal sales of prescription drugs (a substantial portion of which were barbiturates or amphetamines) were terminated. Almost 1,900 defendants were convicted in these cases. In almost 88 percent of these cases, the defendants convicted were druggists or their employees. During the same period there have been only 17 cases against a total of 20 medical practitioners.

We do not believe there is a demonstrated need to require the same type of controls over the dispensing of barbiturates and amphetamines by physicians as are needed with respect to pharmacists.

PART D. AMENDMENTS AS TO ADVERTISING

The amendments relating to informative prescription drug advertisements are designed to require truthful statements in drug advertisements delivered to doctors and to require advertisements to give physicians information designed to enable them to do a better job of selecting drugs for use in their practice.

TITLE II. CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY

The committee has heard testimony indicating that food and cosmetic factories, pharmacies, and consulting laboratories should be exempt from the complete inspection requirement and that proprietary drugs should be partially exempt.

In the case of proprietary drugs, such an exemption would create a situation in which we would be empowered to make a complete inspection of that part of a manufacturing operation that yielded prescription drugs but could be barred from inspection of essential data governing nonprescription items.

The representative who spoke for the Proprietary Association acknowledged the need for more complete inspection of proprietary drug manufacturers by recommending substitute language which specifies what records are subject to inspection. However, the suggested language is not satisfactory since it leaves gaps which would make it impossible to obtain the evidence needed to offer adequate consumer protection.

The following are examples of nonprescription drugs recalled from the market within the past 2 years because they were adulterated or misbranded:

C-F Solution, manufactured by Carbo-Fung Laboratories, Inc., Los Angeles, Calif., contained 4 percent phenol but the label of the product declared only 2 percent phenol.

Vi-Jon multiple vitamin tablets from the K. V. Pharmacal Co., St. Louis, Mo., were 50 percent deficient in vitamin B₁₂.

Elixir terpin hydrate and codeine was labeled by the Purepac Corp. of Elizabeth, N.J., as "paregoric."

Turpentine from Dunwoody & Sons, Atlanta, Ga., was labeled as "castor oil."

"Elevens" vitamins and mineral capsules of the Fuller Pharmaceutical Co., Minneapolis, Minn., contained excessive folic acid.

In investigating such incidents the Government should be allowed to make a thorough inspection of all records pertaining to the adulteration or misbranding whether the drugs are intended for sale with or without a prescription.

Lax manufacturing procedures can have just as important a bearing on health with respect to nonprescription drugs as they can with respect to the prescription drugs.

During the Senate debate on S. 1552 on August 23, 1962, Senator Estes Kefauver said:

"Nonetheless, the factory inspection provision, in my opinion, should apply to proprietary drugs, but since whatever the reason, they did not have a hearing, I agreed to their exclusion from this bill, but I have filed a separate and companion bill applying the factory inspection provision to proprietary drugs. If they are included in the House bill, of course, that provision will go into conference." (Congressional Record, vol. 108, Thursday, Aug. 23, 1962, p. 16306.)

The potentiality for serious harm from food is significant and is increasing as food technology becomes more complex and more chemicals are used in food processing. We have just sent to the Department of Justice a case for legal action because of the shipment of a compound for bleaching peeled potatoes which had a deadly poison, a fluoride-containing compound, accidentally mixed into it. We were able to pinpoint the error by checking records in possession of

the manufacturer. Yet some witnesses do not want us to have authority to check records covering receipt for handling of raw materials in food plants.

The pesticide chemicals and food additives amendments allow poisons to be present in the food supply in small amounts that have been proved safe by adequate scientific procedures. This permits the public to receive the benefits of modern technology. But a necessary precaution is authority for the Government to make complete inspections in factories to determine that the poisonous materials are being added in safe amounts.

In past years we have had to take actions against food containing nonpermitted poisons. For example, a number of foods contained monochloroacetic acid; oranges and frozen peaches contained thiourea. The first evidence that these poisons were being used came from factory inspection and then our chemists developed analytical procedures enabling us to detect the poisons without factory inspection evidence. But without the initial evidence we would not have known what chemicals to develop analytical methods for. Further the development of analytical method suitable for enforcement purposes may be a separate research job for each food in which the chemical is found. It is not possible to obtain adequate protection solely on the basis of the examination of interstate shipments.

The cosmetic industry is also reluctant to give us access to records needed to make complete inspections. It is the rule rather than the exception for cosmetic firms to refuse our inspectors access to complaint files. Yet frequently the first indication that a dangerous product is on the market comes through complaints from injured women to the cosmetic manufacturer.

When a dangerous prescription drug gets out on the market and we have to make a complete recall, even down to the ultimate consumer, it is imperative that our inspectors have the authority to inspect prescription files to determine what customers have received the product. In the case of thalidomide we have located a number of pharmacies that had stocks of the drug. Clearly, the Federal agent should be able to check prescription files to determine whether all stocks of this product have been removed from the home medicine cabinets.

Further, when we receive reports of serious abuses arising from the sale without prescription of potent drugs that should be restricted to sale on prescription, it is imperative that our inspectors have the authority to check on the prescription files in the suspect drugstore to determine whether the prescription drugs being received are in fact going out on bona fide prescriptions.

A consulting laboratory is merely an extension of a firm's own operations—an extension which does laboratory work which the firm itself either cannot or does not wish to do. It was said that a consulting laboratory might be criminally liable for guarding too zealously its clients' interests. If he refused to permit complete inspection as authorized by law, and this placed his clients' interests above the public interest, the bill would permit criminal action. It was intended to do so.

Some witnesses would have the committee believe that safety is seldom a factor in inspection actions being brought by Food and Drug Administration against food products. However, many of our more important food actions are because a food is a hazard to health; the value of the preventive enforcement that we are able to achieve through complete factory inspections is great.

The following examples show the need for complete inspection of food firms:

(1) During the spring and summer of 1958, independent investigations of vegetable farmers in the Walla Walla, Wash., area revealed that Birds-Eye Division of General Foods Corp. recommended pesticide uses to their contract spinach growers which were in excess of USDA recommendations. During inspections of the firm's plants in Walla Walla and Nampa (a distribution point), company officials refused to provide information about their spray program, coding system, production, and distribution. Refusals were received from the plant superintendent; local field department manager; manager of the quality control department of Birds-Eye Division, White Plains, N.Y.; local plant manager, and a

local fieldman. All of these supervisory personnel indicated that refusal to provide us with information in these categories was in accordance with company policy from the White Plains, N.Y., office. Company officials would not discuss the possibilities of excessive pesticide residues being in their finished frozen spinach products.

Field and factory samples collected by our inspectors showed many lots of frozen spinach to contain excessive amounts of DDT. Because the firm had refused to provide shipping information, extensive investigations were made at commercial shipping firms. Here it was found that many shipments were billed only as "frozen food," thus complicating the investigation. Finally, some interstate lots of spinach were located, sampled, and seized because of excessive DDT residues. As the number of seizure action increased, the firm's top management conferred with us and instituted a voluntary recall of the entire fall 1958 pack. All in all, over 700,000 pounds of frozen spinach were recalled and destroyed.

(2) Inspections of Tender-Rise Co. of America, Philadelphia, Pa., led us to believe the firm was using undeclared ingredients in some of its products. However, the firm's owners refused to allow inspection of formulas, shipping records, or pertinent information regarding raw materials.

During an inspection on September 25, 1961, the inspector observed the manufacturing of a meat-flavoring product, Adsfavor, which contained nicotinic acid, a food additive not permitted on meat. We attempted unsuccessfully to locate interstate shipments of the product. Within a week, use of Adsfavor by a Philadelphia meat market caused 6 persons to become ill because of the nicotinic acid. When inspected later, the firm said Adsfavor had been discontinued and all outstanding stocks recalled, but it again refused to permit examination of formulas and shipping information. The inspector suspected the firm was still manufacturing Adsfavor, and we did find a shipment of the adulterated product at a meat market in New Orleans in December 1961.

(3) In many other respects full inspection of food factories and pertinent records in them are essential to consumer protection. For example, within the past decade:

(a) Canned spray-dried egg yolk, which contained harmful bacteria, had to be recalled from the market when it caused salmonella poisoning in many babies.

(b) A canned spray-dried soya product used as a substitute for mother's milk had to be recalled when it made babies sick. It also contained harmful salmonella bacteria.

(c) Another canned product for infant feeding was recalled from the market when it produced convulsions in over 130 infants. In this case the manufacturer furnished complete information about manufacturing processes, formulas, and other pertinent data, and one of our scientists was able to pinpoint the difficulty. A change in the formula and processing operation gave a baby food too low in vitamin B₆. When this vitamin was added to the formula there was no more trouble.

(d) Inadequately processed canned mushrooms and canned goats milk have had to be taken off the market because of active spoilage. Our inspectors need to examine control records in canneries to determine whether the proper cooking temperature has been employed for the proper time to destroy all harmful bacteria.

(e) A child died and many other persons were made ill when they ate fish containing toxic amounts of preservative. The fishhouse—Universal Sea Food Co., Inc., Philadelphia, Pa.—denied ever having used the preservative, but we were able to prove through extensive investigation that it had added the chemical to a batch of fillets that was undergoing decomposition. The firm was prosecuted.

The need for clear authority to make complete inspections is growing because there is a trend among some of the regulated industries to discontinue the cooperation under which many firms have permitted complete inspections vol-

unfairly. For example, after inspecting the Athens Canning Co., Athens, Tex., only July 6, 1962, our inspectors reported:

"Mr. Frank Dorsey, the president of the firm, was absent during the above discussions. After he returned, we discussed the FD-483—report of observations as provided for in section 704(b) of the act—and as has already been mentioned, and we then requested interstate shipments of this product. He stated, 'Is that a request?' We replied that if he put it that way, Yes, it was a request. He then stated that he would prefer not to give us such information. He stated that in the past he had been giving us that type of information and that he did not have anything to hide. However, he had just returned from a meeting of the National Canners Association and had been elected to the board of directors. At this meeting the National Canners Association decided not to give the Food and Drug Administration any information that was not required by law. He stated that this included such information as interstate shipments and formulas. He stated that since he was on the board of directors, he would have to go along with their decision not to give FDA this information. The National Canners Association is unfavorable of the bill now before Congress concerning FDA factory inspections.

"We asked Mr. Dorsey if this was going to be a policy of all members of the National Canners Association. He stated that all members would be requested to follow along with their suggestions; however, this is not binding on the individual canner.

"Mr. Dorsey showed us an information letter from the National Canners Association No. 1881 dated June 30, 1962. He referred us to an article on page 15 under the heading 'Statement of Policy on FDA Factory Inspection Bill.' He referred us to this article when he stated that he could not give us information concerning interstate shipments."

There is also need for authority to make complete inspections of cosmetic firms.

(1) FDA scientists believe that many if not most of the numerous injuries attributed to cosmetics each year may be caused by relatively few cosmetic ingredients. However, the facts needed to establish this, and to identify the offending chemicals have never been assembled in one place. The individual firm which knows the composition of its own products does not get the reports of injuries caused by competitive products and may not know the detailed composition of such products. FDA does not have either full reports of injuries or full information on ingredients used in cosmetics. Thus there is no way to determine whether it would be possible to eliminate hundreds or even thousands of injuries per year by the simple measure of ruling out of cosmetic formulations a few chemicals primarily responsible for the trouble. Complete factory inspection authority could well lead to the detection and elimination of primary offenders, and thus to a material gain in consumer protection.

(2) Early this year when we received a report that a shampoo manufactured by Andrew Jergens Co., Belleville, N.J., had caused a severe eye injury, we attempted to make an appropriate investigation at the factory. The firm refused to permit inspection. Seven weeks later, after the firm had been called to a hearing to show why it should not be prosecuted, the manufacturer furnished some of the information needed. It still declined to supply the quantitative formula for the product. However, the quantities of the ingredients in cosmetics frequently determine whether the products are safe. While our chemists do a marvelous job of determining what materials are present in cosmetics, analyses of these complex mixtures are time consuming and sometimes impossible to make completely without formula information.

(3) John H. Breck, Inc., Springfield, Mass., a manufacturer of shampoo and other hair preparations removes the labels from its raw materials and identifies the containers by code numbers. For the past 3 years the firm has refused to let our inspectors know what the raw materials are, thus nullifying any public protection which might be afforded by the examination of raw material labels.

We attach a list of refusals to permit inspection covering the period January 1 through June 15, 1962.

A number of witnesses have stated that any change in the factory inspection authority will make our inspections unconstitutional. On the other hand some of these same witnesses concede that complete inspections can be authorized for drug firms and can even be conducted in food plants by local health authorities. So it appears the problem of constitutionality clearly depends on the reasonableness of the inspection. And what is reasonable depends on the facts in each particular case. In our opinion the constitutional argument was met in 1953 by the extensive report of this committee.

Food and cosmetic firms argue for exemption from the inspection authority provided in the Senate bill on the ground that the same degree of inspection is not needed for food and cosmetic firms as for drug firms. Actually the scope of authorized inspection is limited to matters that bear upon actual or potential violations of the Act. Since the definitions of misbrandings and adulterations for foods and cosmetics differ materially from the definitions for drugs, the inspections also would differ in scope, and would be limited to matters reasonably related to compliance with the law. The Supreme Court noted this in another connection in the *Sullivan* case. But inspection powers at least as comprehensive as the substantive provisions of the law are needed for all articles subject to the act, whether food, drug, device, or cosmetic.

The concern over loss of trade secrets has been expressed by many, yet in almost every instance the witness has admitted that they have no knowledge of any trade secrets being divulged by our employees in the past. We are keenly aware of our responsibility to maintain trade secrets and the bill re-emphasizes the penalties (provided in the general criminal code) for the unauthorized disclosure of any information obtained during a factory inspection.

The bill proposes to tighten the confidentiality requirement by forbidding disclosure not only of trade secrets but also of any other information except a disclosure is authorized by law. The PMA recommends that this be restricted so as to permit disclosure only when required by law. We feel constrained to object to this as too restrictive but would not object to changing that quoted phrase to read "required in the administration or enforcement of this Act."

Antibiotic rejections, fiscal years 1961 and 1962

Date	Product	Company	Batch size	Violation
July 8, 1960	Potassium Penicillin-G tablets.....	Success Chemical Co.....	98,400 tablets.....	Moisture.
July 13, 1960	Penicillin-dihydrostreptomycin-neomycin ointment.....	Strong Cobb Arner, Inc.....	7,142 (24-cubic-centimeter) syringes	Penicillin and dihydrostreptomycin potencies
July 19, 1960	Tetracycline novoboloin capsules.....	The Upjohn Co.....	136,500 capsules.....	Moisture.
July 26, 1960	Procaine penicillin-dihydrostreptomycin-neomycin ointment with sulfas (veterinary).....	G. C. Hanford Manufacturing Co.....	28,298 (24-cubic-centimeter) syringes	Nonhomogeneous, potency.
Aug. 2, 1960	Bacitracin bulk.....	B. B. Penick & Co.....	29,837 grams.....	Moisture
Aug. 11, 1960	Streptomycin sulfate bulk.....	E. R. Squibb & Sons.....	149,020 grams.....	Do.
Aug. 18, 1960	Chloramphenicol for aqueous injection.....	Parke, Davis & Co.....	33,537 (1-gram vials).....	Potency. Material thickens after standing 1 hour and all material cannot be withdrawn. That withdrawn is low in potency.
Do.....	do.....	do.....	33,958 (1-gram vials).....	Do.
Do.....	do.....	do.....	34,170 (1-gram vials).....	Potency. High streptomycin content.
Aug. 24, 1960	Dihydrostreptomycin streptomycin sulfate bulk.....	Chas. Pfizer & Co., Inc.....	100,000 grams.....	Penicillin potency.
Aug. 26, 1960	Penicillin polymyxin neomycin ointment with hydrocortisone and chlorbutanol.....	Jensen-Salsbery Laboratories, Inc.....	48,400 tubes.....	Neomycin potency.
Aug. 30, 1960	Do.....	Vet Products Corp.....	3,804 (10-cubic-centimeter) tubes.....	Do.
Do.....	Dimethylchlorotetracycline bulk.....	Lederle Laboratories.....	341,600 grams.....	Moisture.
Aug. 31, 1960	Streptomycin sulfate bulk.....	Chas. Pfizer & Co., Inc.....	230,000 grams.....	Sterility.
Sept. 1, 1960	Sterile bacitracin.....	Philadelphia Laboratories, Inc.....	2,700 vials (50,000 units each).....	Potency
Do.....	Nystatin bulk (to be used in manufacture of certifiable product).....	E. R. Squibb & Sons.....	63.5 kilograms.....	pH (check test).
Sept. 6, 1960	Streptomycin sulfate.....	Bio-Rumo Drug Co., Inc.....	130,000 vials (1-gram).....	Potency and pyrogens.
Sept. 15, 1960	Buffered penicillin powder.....	Success Chemical Co., Inc.....	3,000 bottles (35 grams each).....	Potency.
Do.....	Buffered Penicillin G with sulfas.....	do.....	1,950 bottles (25 grams each).....	Do.
Sept. 16, 1960	Chloramphenicol palmitate.....	Parke, Davis & Co.....	380.80 kilograms.....	Melting point.
Do.....	do.....	do.....	387.05 kilograms.....	Do.
Sept. 19, 1960	Bacitracin-polymyxin ointment with proteolytic enzymes.....	Armour Pharmaceutical Co.....	16,340 tubes (1/2-ounce).....	Bacitracin potency.
Do.....	do.....	do.....	1,712 tubes (2-ounce).....	Do.
Oct. 6, 1960	Buffered potassium penicillin tablets.....	Chas. Pfizer & Co., Inc.....	1,140,000 tablets (200,000-unit tablet).....	Moisture.
Do.....	do.....	do.....	1,227,000 tablets (200,000-unit tablet).....	Do.
Oct. 7, 1960	Buffered potassium penicillin powder.....	Success Chemical Co., Inc.....	3,337 (5-cubic-centimeter) bottles (1,200,000-unit bottle).....	Potency.
Oct. 18, 1960	Procaine Penicillin G aqueous suspension.....	Chas. Pfizer & Co., Inc.....	50,000 vials (10-dose).....	Sterility.
Oct. 25, 1960	Potassium Penicillin-G tablets (post seizure sample).....	Morse Laboratories, Inc.....	566 bottles (100 tablets each, 200,000 units).....	Moisture.
Oct. 24, 1960	Bacitracin-polymyxin B ointment with proteolytic enzymes.....	Armour Pharmaceutical Co.....	(1,014 tubes (2-ounce tubes).....	Bacitracin potency.
Do.....	do.....	do.....	(7,300 tubes (1/2-ounce tubes).....	Do.
Oct. 26, 1960	Dihydrostreptomycin tablets with carob flour and Vitamin A.....	Vet Products Corp.....	31,600 tablets.....	Potency.
Nov. 3, 1960	Buffered Penicillin potassium, 152 tablets.....	Sons.....	1,137,800 tablets.....	Moisture.
Nov. 4, 1960	Crystalline potassium Penicillin-G with probenecid.....	Dohme.....	76,300 tablets (100,000-unit tablets).....	Do.

Nov. 16, 1960	Trecaine Penicillin G for aqueous injection.....	Promo Pharmaceutical Laboratories, Delta Laboratories.	25,000 vials (1 cubic centimeter, 300,000 units).	Potency (poor draining).
Nov. 22, 1960	Procaine G dihydrostreptomycin ointment with sulfa (veterinary).....	Delta Laboratories.	18,636 syringes (28 cubic centimeters)	Potency (air bubbles)
Nov. 23, 1960	Bacitracin nonsterile bulk.....	Chas. Pfizer & Co., Inc.....	14,700 grams	Potency (submitted for check after results OK).
Nov. 17, 1960	Amphotericin B bulk.....	F. B. Squibb & Sons, Inc.....	71.6 kilograms	Moisture
Jan. 9, 1961	Penicillin dihydrostreptomycin ointment (veterinary).....	Delta Laboratories	9,720 syringes (6 cubic centimeters)	Potency (check test).
Jan. 5, 1961	Buffered potassium Penicillin G tablets.....	Kee Corp.	1,000,000 tablets	Moisture
Jan. 12, 1961	Potassium Penicillin-G ophthalmic ointment.....	Pharmach Laboratories.....	1,872 tubes (1/8 ounce)	Potency (extension of expiration date).
Jan. 14, 1961	Potassium Penicillin ointment.....	The Upjohn Co.	5,441 tubes (1 ounce)	Potency.
Do	Dihydrostreptomycin-streptomycin sulfate solution (veterinary).....	Philadelphia Laboratories, Inc.....	1,281 bottles (290 cubic centimeters); 685 bottles (500 cubic centimeters)	Do.
Jan. 5, 1961	Bacitracin ointment with enzyme.....	Armour Pharmaceutical Co.	24,000 vials (50,000 units each)	Potency (check test).
Jan. 27, 1961	Bacitracin topical powder.....	Chas. Pfizer & Co., Inc.	90.0 kilograms	Pill (check test)
Jan. 23, 1961	Amphotericin B bulk.....	F. B. Squibb & Sons.	90.0 kilograms	Bacitracin potency (extension of expiration date).
Do	Penicillin-dihydrostreptomycin-bacitracin ointment with sulfa (veterinary).....	Rebe Laboratories, Inc.....	19,362 tubes (10 grams)	Potency.
Feb. 2, 1961	Chlortetracycline hydrochloride steel (veterinary).....	Insta Mountain Products Co.....	25,400 bottles (6.25 ounces each)	Real-time streptomycin
Feb. 8, 1961	Dihydrostreptomycin sulfate bulk.....	F. B. Squibb & Sons	315,440 grams	Do.
Do	Do	Do	14,670 grams	Do.
Feb. 7, 1961	Streptomycin sensitivity disks (10 units).....	National Bio Test, Inc.	151 vials (100 each)	Potency.
Do	Tetracycline sensitivity disks (6 mcg).....	Do	231 vials (100 each)	Do.
Do	Penicillin sensitivity disks (2 units each).....	Do	124 vials (100 each)	Do.
Do	Chlortetracycline sensitivity disks (30 mcg).....	Do	244 vials (100 each)	Do.
Do	Chlortetracycline sensitivity disks (6 mcg).....	Do	230 vials (100 each)	Do.
Do	Bacitracin sensitivity disks (2 units).....	Do	128 vials (100 each)	Uniformity
Feb. 28, 1961	Chlortetracycline disks (6 mcg).....	Case Laboratories, Inc.	55,800 disks	Potency and uniformity.
Do	Bacitracin disks (2 units).....	Do	30,240 disks	Do.
Do	Bacitracin disks (10 units).....	Do	10,300 disks	Do.
Do	Tetracycline disks (6 mcg).....	Do	19,500 disks	Do.
Do	Chloramphenicol disks (6 mcg).....	Do	25,500 disks	Potency
Do	Chloramphenicol disks (30 mcg).....	Do	39,000 disks	Do.
Mar. 1, 1961	Chlortetracycline disks (6 mcg).....	Baltimore Biological Laboratories Inc.	25,000 disks	Potency.
Do	Tetracycline disks (6 mcg).....	Do	15,000 disks	Do.
Mar. 3, 1961	Buffered penicillin powder, 250,000 units per 6 cubic centimeters.....	Bryant Pharmaceutical Corp.....	1,000 vials (60 millie centimeters)	Do.
Mar. 6, 1961	Bacitracin polyvinylpyrrolidone ointment.....	Kasco Laboratories, Inc.	7,392 tubes (1/4 ounce)	Do.
Do	Chlortetracycline disks (6 mcg).....	National Bio Test, Inc.	1,000 disks	Do.
Do	Chlortetracycline disks (6 mcg).....	Do	24,300 disks	Do.
Do	Tetracycline disks (6 mcg).....	Do	25,600 disks	Do.
Do	Chlortetracycline disks (30 mcg).....	Baltimore Biological Laboratories	116,000 disks	Uniformity.
Do	Bacitracin disks (10 units).....	Do	100,000 disks	Potency.
Do	Bacitracin disks (2 units).....	Do	137,500 disks	Do.
Mar. 10, 1961	Chloramphenicol disks (6 mcg).....	Do	140,000 disks	Uniformity.
Do	Tetracycline disks (6 mcg).....	Case Laboratories, Inc.	23,100 disks	Potency.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Mar. 13, 1961	Chlortetracycline disks (30 mcg.)	Case Laboratories, Inc.	73,400 disks	Potency, uniformity.
Do	Chlortetracycline disks (5 mg.)	do	24,100 disks	Potency.
Mar. 21, 1961	Procaine Penicillin-G in aqueous suspension (600,000 unit syringe)	The Upjohn Co.	13,885 syringes	Potency due to syringibility.
Mar. 22, 1961	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	304,760 grams	Residual streptomycin.
Do	do	do	307,240 grams	Do
Mar. 21, 1961	Penicillin-dihydrostreptomycin-neomycin ointment	Vet Products Corp.	3,768 syringes (24 cubic centimeters each)	Dihydrostreptomycin potency.
Mar. 24, 1961	Tetracycline disks (5 mcg.)	Case Laboratories, Inc.	62,640 disks	Potency.
Mar. 29, 1961	Procaine and buffered penicillin streptomycin sulfate bulk	Chas. Pfizer & Co., Inc.	32,000 terms streptomycin; 81,000,000 units penicillin	Moisture.
Apr. 3, 1961	Chlortetracycline disks (5 mcg.)	Case Laboratories, Inc.	54,000 disks	Potency.
Apr. 7, 1961	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories	132,500 disks	Do.
Apr. 11, 1961	Dihydrostreptomycin sulfate bulk	E. R. Squibb & Sons	257,300 grams	Do.
Apr. 26, 1961	Bacitracin-neomycin ointment with hydrocortisone	Walck Laboratories, Inc.	12,650 tubes (3/4-ounce)	Bacitracin potency.
Apr. 17, 1961	Dihydrostreptomycin disks (2 mcg.)	Case Laboratories, Inc.	72,350 disks	Potency and uniformity.
May 3, 1961	Penicillin-bacitracin-streptomycin dental paste	Procosal Chemical Co., Inc.	Few hundred tubes	Request for extension of expiration date. Low bacitracin and streptomycin potency.
May 5, 1961	Procaine Penicillin-G-dihydrostreptomycin-neomycin ointment (veterinary)	United Co-operatives, Inc.	10,650 syringes (24 cubic centimeters each)	Neomycin potency.
May 16, 1961	Bacitracin bulk	Commercial Solvents Corp.	7,717 grams	Pyrogens.
May 11, 1961	Penicillin-dihydrostreptomycin-sulfate uterine boluses (veterinary)	Stevenson-Turner & Boyce Guelph, Canada	864 boluses	Import detention; not certified.
May 22, 1961	Bacitracin-neomycin ointment	Eli Lilly & Co.	14,288 tubes (1/4-ounce)	Bacitracin potency.
Do	do	do	14,340 tubes (1/4-ounce)	Do.
May 23, 1961	Potassium Penicillin G tablets	Allied Biochemical Laboratories, Inc.	300,000 tablets (50,000 units)	Potency and moisture.
Do	do	do	220,000 tablets (50,000 units each)	Do.
Do	do	do	301,000 tablets (100,000 units each)	Moisture.
Do	do	do	275,000 tablets (200,000 units each)	Do.
Do	do	do	do	Do.
Do	do	do	120,000 tablets (100,000 units each)	Do.
Do	do	do	120,000 tablets (200,000 units each)	Do.
Apr. 14, 1961	Tetracycline disks (30 mcg.)	Baltimore Biological Laboratories, Inc.	200,000 disks	Uniformity.
May 21, 1961	Bacitracin disks (2 units)	Case Laboratories, Inc.	75,600 disks	Do.
May 25, 1961	Potassium Penicillin-G tablets	Chas. Pfizer & Co., Inc.	1,220,000 tablets (200,000 units each)	Moisture.
May 29, 1961	Streptomycin sulfate (1 gram)	Koninklijke Nederlandsche Glas-En Spiritusfabriek	60,000 vials	Do.
Do	do	do	64,500 vials	Do.
Do	Soluble potassium penicillin tablets (200,000 units)	Pure Laboratories, Inc.	401,700 tablets	(1)
Do	Soluble potassium penicillin tablets (100,000 units)	do	221,600 tablets	(1)
Do	Soluble potassium penicillin (250,000 units)	do	320,300 tablets	(1)
Do	Buffered potassium penicillin tablets (50,000 units)	do	600,000 tablets	(1)

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Do.	do	do	853,785 tablets	(1)
Do	Buffered potassium penicillin tablets (200,000 units)	do	699,500 tablets	(1)
Do	Buffered potassium penicillin tablets (100,000 units)	do	480,000 tablets	(1)
Do	Buffered potassium penicillin tablets (200,000 units)	do	600,000 tablets	(1)
Do	do	do	do	(1)
Do	Buffered potassium penicillin tablets (250,000 units)	do	620,000 tablets	(1)
Do	Buffered potassium penicillin tablets (100,000 units)	do	600,000 tablets	(1)
Do	do	do	500,000 tablets	(1)
Do	Buffered potassium penicillin tablets (250,000 units)	do	733,200 tablets	(1)
Do	Buffered potassium penicillin tablets (400,000 units)	do	220,000 tablets	(1)
Do	Buffered potassium penicillin tablets (500,000 units)	do	100,000 tablets	(1)
June 8, 1961	Sodium Penicillin-G disks (10 units)	Baltimore Biological Laboratories	147,500 disks	Potency.
June 16, 1961	Chlortetracycline disks (6 mcg.)	do	142,500 disks	Do.
Do	Chlortetracycline disks (30 mcg.)	do	142,500 disks	Do.
Do	Tetracycline disks (30 mcg.)	do	145,100 disks	Do.
June 19, 1961	Penicillin disks (2 units)	National Bio Test, Inc.	20,000 disks	Do.
Do	do	do	21,400 disks	Do.
Do	Chlortetracycline disks (6 mcg.)	do	23,100 disks	Do.
June 8, 1961	Procaine and buffered sodium penicillin for aqueous injection	Bio Rame Drug Co.	30,000 vials (500,000 units per vial)	Do.
June 14, 1961	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	262,040 grams	Pyrogens.
June 22, 1961	Demethylchlortetracycline disks (30 mcg.)	Baltimore Biological Laboratories	132,500 disks	Potency.
June 27, 1961	Buffered potassium penicillin-G tablets (100,000 units)	Success Chemical Co., Inc.	389,700 tablets	Moisture.
June 29, 1961	Demethylchlortetracycline disks (6 mcg.)	Baltimore Biological Laboratories	82,500 disks	Potency.
July 6, 1961	Zinc bacitracin bulk	Merck Sharp & Dohme	2.3 kilograms	Moisture (recertification).
July 7, 1961	Procain penicillin G in aqueous suspension	Chas Pfizer & Co.	13,000 vials (10 cubic centimeters each)	Potency (extension of expiration date).
July 12, 1961	Bacitracin bulk	do	147,000 grams	Heavy metals.
Do	Bacitracin vials	do	4,204 vials (50,000 units per vial)	Do.
Do	Penicillin disks (10 units)	Baltimore Biological Laboratories	112,500 disks	Potency.
July 13, 1961	Buffered penicillin powder with sulfas	Philadelphia Laboratories	2,342 bottles (60 cubic centimeters)	Do.
July 21, 1961	Penicillin-dihydrostreptomycin-neomycin ointment with sulfas and cobalt (veterinary)	United Co-operatives, Inc.	30,266 syringes (6 cubic centimeters each)	Neomycin potency.
Do	Penicillin disks (2 units)	National Bio Test, Inc.	20,800 disks	Potency.
July 26, 1961	Procaine penicillin-dihydrostreptomycin-polymyxin-neomycin in oil with sulfas and cobalt (veterinary)	Rhinecliff Laboratories	6,292 syringes (30 cubic centimeters each)	Neomycin potency.
Do	Tetracycline phosphate complex-amphotericin B capsules	E. R. Squibb & Sons	1,444,000 capsules (260 mg-T, 60 mg A)	Amphotericin potency.
July 28, 1961	Procaine penicillin and buffered sodium for aqueous injection	Eli Lilly & Co.	23,491 vials (10 cubic centimeters each)	
Do	do	do	110,597 vials (1 dose each)	Contaminated with Tyloain.
Do	do	do	8,096 vials (10-dose)	
Do	do	do	118,629 vials (1-dose)	
July 21, 1961	Bacitracin bulk	Chas Pfizer & Co., Inc.	94,000,000 units	Heavy metals.
July 31, 1961	Potassium Penicillin-G tablets buffered	Burroughs Bros	176,000 tablets (200,000 units each)	Moisture.
Do	Tetracycline-TAG capsules (157 mg.) (83 mg.)	Chas Pfizer & Co., Inc.	768 capsules	Do.
Aug 1, 1961	Buffered potassium Penicillin-G tablets (200,000 units)	American Chemical & Drug Co.	200,000 tablets	Do.
Do	Streptomycin sulfate bulk	Eli Lilly & Co.	141.09 kilograms	Do.
Do	do	do	126,802 kilograms	Do.
Aug 4, 1961	Dimethoxyphenyl penicillin disks (6 mcg.)	Baltimore Biological Laboratories	140,000 disks	Potency.
Do	do	do	82,800 disks	Do.

See footnotes at end of table, p. 588.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Aug. 18, 1961	Procaine penicillin (100,000 units) and dihydrostreptomycin (300 mg.) in oil with sulfas.	Bristol Laboratories	42,500 tubes (7.5 milliliters each)	Dihydrostreptomycin potency.
Aug. 16, 1961	Penicillin disks (2 units)	National Bio Test, Inc.	22,100 disks	Potency.
Aug. 18, 1961	Bacitracin bulk	Commercial Solvents Corp.	2,641 grams	Pyrogens.
Do.	Buffered penicillin tablets	Merck Sharp & Dohme	600 packages (12 each)	Moisture.
Aug. 4, 1961	Penicillin disks (10 units)	Baltimore Biological Laboratories	137,500 disks	Potency (extension of expiration date).
Do.	do.	do.	140,000 disks	Do.
Sept. 8, 1961	Tetracycline hydrochloride capsules with T.A.O.	Chas. Pfizer & Co., Inc.	1,050,000 capsules	Moisture.
Sept. 7, 1961	Streptomycin disks (2 mcg.)	Difco Laboratories	167,000 disks	Potency.
Sept. 8, 1961	Dimethoxyphenyl penicillin disks (5 mcg.)	Baltimore Biological Laboratories	147,500 disks	Potency and uniformity.
Sept. 19, 1961	Procaine Penicillin-G ointment (veterinary)	O. C. Hanford Manufacturing Co.	65,726 tubes (7.5 grams each)	Potency.
Do.	Bacitracin bulk	Chas. Pfizer & Co., Inc.	2,000,000,000 units	Heavy metals.
Oct. 8, 1961	Chloramphenicol for aqueous injection	Parke, Davis & Co.	34,362 vials (1 gram each)	Potency.
Oct. 8, 1961	Nystatin bulk	F. R. Squibb & Sons	149.0 kilograms	pH (check test).
Oct. 18, 1961	Bacitracin-polymyxin-neomycin ointment	American Pharmaceutical Co.	4,948 tubes (1/4 ounce)	Bacitracin and neomycin potency.
Do.	Streptomycin sulfate solution	F. R. Squibb & Sons	124,378 vials (2.5 cubic centimeters each)	Pyrogens.
Oct. 27, 1961	Bacitracin bulk	Chas. Pfizer & Co., Inc.	612,000,000 units	Heavy metals.
Do.	do.	do.	1,000,000,000 units	Do.
Oct. 30, 1961	Potassium phenethicillin tablets foiled, 128 mg.	Bristol Laboratories	60,000 tablets	Moisture.
Do.	Benztamine Penicillin-G bulk	Chas. Pfizer & Co., Inc.	201,000,000,000 units	Sterility.
Nov. 2, 1961	Buffered Penicillin tablets with sulfas (300,000 units penicillin, and 0.5 grams sulfas)	Nysco Laboratories, Inc.	60,000 tablets	Moisture.
Oct. 31, 1961	Streptomycin disks (10 mcg.)	Baltimore Biological Laboratories	70,000 disks	Potency.
Nov. 2, 1962	Dimethylchlorotetracycline disks (30 mcg.)	Caso Laboratories, Inc.	74,600 disks	Do.
Nov. 1, 1961	Multiple antibiotic sensitivity disks	Difco Laboratories	63,600 rings	Tetracycline, streptomycin erythromycin potency.
Nov. 7, 1961	Streptomycin sulfate bulk	Chas. Pfizer & Co., Inc.	65 kilograms	Sterility.
Nov. 13, 1961	Bacitracin bulk	S. B. Penick & Co.	44,772 grams	Ash content (check test).
Nov. 17, 1961	Penicillin-dihydrostreptomycin-neomycin ointment with sulfas, cobalt, and chlorobutanol	Mast-Kum Products Co.	17,392 syringes (14 milliliters each)	Penicillin potency.
Do.	Dimethoxyphenyl Penicillin disks (5 mcg.)	Difco Laboratories	72,500 disks	Uniformity.
Nov. 27, 1961	Penicillin disks (2 units)	National Bio Test, Inc.	15,000 disks	Potency.
Do.	Chloramphenicol for aqueous injection	Parke, Davis & Co.	26,065 vials (1 gram each)	Do.
Nov. 30, 1961	Procaine Penicillin-G in dihydrostreptomycin solution (veterinary)	Chas. Pfizer & Co., Inc.	23,000 vials (10 cubic centimeters each)	Do.
Dec. 1, 1961	Neomycin bulk	do.	67.72 B.U.	Moisture.
Dec. 8, 1961	Dihydrostreptomycin-neomycin-polymyxin aerosol	Phillips Roxane, Inc.	4,982 bottles	pH.
Dec. 12, 1961	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories	60,000 disks	Potency.
Jan. 2, 1962	Sensitivity testing device	Ankh Laboratories, Inc.	8,038 packages	Erythromycin and penicillin potency, penicillin uniformity.
Do.	Procaine G bulk	Chas. Pfizer & Co., Inc.	1,140,000,000,000 units	Contaminated with Arquad.
Do.	Buffered potassium Penicillin powder	Morse Laboratories, Inc.	8,037 vials (60 cubic centimeters)	Potency, short volume.

Jan. 10, 1962	Dihydrostreptomycin disks (2 mcg.)	Difco Laboratories	87,500 disks	High potency.
Jan. 8, 1962	Dihydrostreptomycin disks (10 mcg.)	Baltimore Biological Laboratories	70,000 disks	Low potency.
Jan. 24, 1962	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	354,160 grams	Pyrogens.
Do	do	do	340,380 grams	Do.
Do	do	do	343,120 grams	Do.
Do	do	do	309,960 grams	Do.
Do	do	do	314,060 grams	Do.
Do	do	do	318,400 grams	Do.
Do	do	do	106,600 grams	Do.
Do	do	do	322,440 grams	Do.
Feb. 6, 1962	Potassium penicillin-G with sulfas	do	600,000 tablets	Moisture.
Feb. 19, 1962	Procaine (300,000 units)-sodium (200,000 units) and streptomycin (0.5 gram) for aqueous injection.	Bio Ramo Drug Co.	100,700 vials (1-dose)	Penicillin and streptomycin potencies.
Do	Crystalline dihydrostreptomycin bulk	E. R. Squibb & Sons	200,800 grams	Pyrogens.
Do	Chlortetracycline hydrochloride dressing	Surgical Projects, Division American Cyanamid Co.	4,260 dressings (8 by 12 inches)	Impregnation and potency.
Mar. 8, 1962	Procaine penicillin-G for aqueous suspension	Bio Ramo Drug Co., Inc.	30,250 vials (1-dose)	Potency and syringeability.
Mar. 2, 1962	Bacitracin-neomycin topical ointment	Pharmich Laboratories	1,454 1/2-ounce tubes (900 1/2-ounce tubes)	Extension of expiration date.
Do	Procaine penicillin-G in aqueous suspension	Chas. Pfizer & Co., Inc.	273,000 vials (10 doses each)	Neomycin potency.
Do	Nystatin bulk	E. R. Squibb & Sons	105.4 kilograms	Sterility.
Mar. 15, 1962	Sodium methicillin vials	do	18,400 vials (1-gram)	pH (check test).
Mar. 19, 1962	Sodium penicillin-G bulk	Castillon, S.A.	(1)	Potency.
Do	do	do	(1)	Heat stability.
Do	do	do	(1)	Do.
Do	do	do	(1)	Do.
Mar. 14, 1962	Chlortetracycline disks (6 mcg.)	National Bio Test, Inc.	23,100 disks	Potency.
Do	Penicillin disks (10 units)	do	30,100 disks	Do.
Do	Penicillin disks (2 units)	do	31,000 disks	Do.
Do	Chloramphenicol disks (6 mcg.)	do	23,000 disks	Do.
Do	do	do	22,000 disks	Do.
Mar. 20, 1962	Procaine Penicillin-G-dihydrostreptomycin-neomycin ointment with sulfas and cobalt.	O. C. Hanford Manufacturing Co.	27,064 tubes (7.5 grams each)	Neomycin potency.
Do	Tetracycline-amphotericin strip	E. R. Squibb & Sons	127,296 vials (5 cubic centimeters each)	Tetracycline potency (not uniform).
Mar. 26, 1962	Procaine penicillin-buffered sodium penicillin for aqueous injection.	Castillon, S.A.	66,100 vials (1-dose)	Sterility.
Do	do	do	56,400 vials (1-dose)	Do.
Mar. 23, 1962	Multiple antibiotic sensitivity disks	Difco Laboratories	50,850 disks	Neomycin potency.
Apr. 16, 1962	Streptomycin sulfate solution	Pure Laboratories, Inc.	18,000 vials (5-gram)	Potency.
Apr. 18, 1962	Procaine potassium penicillin for aqueous injection (also streptomycin)	Chas. Pfizer & Co., Inc.	76,000 vials (1-dose)	Do.
Apr. 24, 1962	Procaine Penicillin-G in dihydrostreptomycin solution (veterinary)	Philadelphia Laboratories	Approximately 4,000 vials (100 cubic centimeters each)	Contaminated with streptomycin.
Apr. 26, 1962	Tetracycline base bulk	Chas. Pfizer & Co., Inc.	678,000 grams	Moisture.
May 3, 1962	Potassium Penicillin-V for oral solution	Abbott Laboratories	1,724 bottles (80 cubic centimeters each)	Potency.
Do	Tetracycline hydrochloride intramuscular	Chas. Pfizer & Co., Inc.	90,000 vials (100 milligrams each)	Potency. Extension of expiration date.
Apr. 26, 1962	Oxacillin disks (1 mcg.)	Baltimore Biological Laboratories	130,860 disks	Uniformity.

See footnotes at end of table, p. 588.

Antibiotic rejections, fiscal years 1961 and 1962—Continued

Date	Product	Company	Batch size	Violation
Apr. 30, 1962	Penicillin sensitivity disks (2 units)	National Bio Test, Inc	213,000 disks	Potency.
Do.....	Penicillin sensitivity disks (10 units)	do.....	190,000 disks	Do.
Do.....	Penicillin sensitivity disks (2 units)	do.....	208,000 disks	Do.
Do.....	Penicillin sensitivity disks (10 units)	do.....	203,000 disks	Do.
Do.....	Bacitracin sensitivity disks (2 units)	do.....	200,000 disks	Do.
May 4, 1962	Procaine Penicillin-G and buffered sodium penicillin for aqueous injection	Laboratorios Castillon, S.A.	66,666 vials (1 dose)	pH.
Do.....	Bacitracin bulk	S. B. Penick & Co.		Ash content.
May 22, 1962	Potassium Penicillin-G ophthalmic ointment	Morse Laboratories, Inc.	7,447 tubes	20 times labeled potency.
Do.....	Tetracycline hydrochloride topical spray powder	Davis & Geck	1,300 grams (1,300 cans)	Potency.
May 24, 1962	Procaine Penicillin and buffered sodium penicillin for aqueous injection	Laboratorios Atral	33,000 vials (600,000 units each)	Do.
Do.....	do.....	do.....	50,000 vials (500,000 units each)	Do.
May 8, 1963	Procaine penicillin and buffered sodium penicillin for aqueous injection	Laboratorios Castillon, S.A.	66,666 vials (1-dose)	pH.
June 1, 1962	Procaine Penicillin-G and buffered sodium penicillin for aqueous injection	Laboratorios Atral, Lda	60,000 vials (1-dose)	Potency.
Do.....	do.....	do.....	do.....	Do.
June 4, 1962	Procaine Penicillin-G bulk	Wyeth Laboratories, Inc.	112,940 grams	Sterility.
June 7, 1962	Procaine Penicillin-G-polymyxin-neomycin ointment with hydrocortisone (veterinary)	Hamilton Pharmaceutical Co.	4,271 syringes (10 cubic centimeters each)	Not homogeneous Potency (all above).
Do.....	Tetracycline sensitivity disks (8 mcg.)	National Bio Test, Inc.	38,000 disks	Potency.
Do.....	Methicillin sensitivity disks (8 mcg.)	do.....	20,100 disks	Do.
June 11, 1962	Tetracycline syrup	E. R. Squibb & Sons	3,616 pint bottles	Do.
Do.....	Tetracycline phosphate complex-nystatin capsules	do.....	624 bottles (100 each)	Potency. Extension of expiration date.
June 15, 1962	Buffered Penicillin-G tablets	Bryant Pharmaceutical Co.	64,000 tablets (200,000 units each)	Potency.
June 20, 1962	Procaine Penicillin-G in aqueous suspension	H. E. Maury Biological Co.	1,528 syringes (300,000 units per cubic centimeter.)	Do.
June 26, 1962	Nystatin bulk	E. R. Squibb & Sons	161.7 kilograms	pH (check test).
June 28, 1962	Tetracycline tablets	A. Wassermann, S.p.A.	1,466 bottles (100 each.)	Moisture.

† All or portions of batches distributed before samples submitted for certification.

* Not given.

DRUG INDUSTRY ACT OF 1962

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Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 16, 1962

FOOD FIRMS

Firm name	Address	Date of refusal ¹
Refusal to permit inspection:		
Health Food Distributors, Inc.	Detroit, Mich.	*Apr. 3, 1962
Weiss Noodle Co.	Cleveland, Ohio	*May 3, 1962
Refusal to divulge status or responsibility of individuals:		
Procter & Gamble Manufacturing Co.	Dallas, Tex.	May 1, 1962
Bowman Biscuit Co.	Denver, Colo.	Mar. 8, 1962
Continental Baking Co.	Gary, Ind.	Apr. 17, 1962
Health Food Distributors	Detroit, Mich.	Feb. 19, 1962
San Joaquin Bakeries, Inc.	Modesto, Calif.	Mar. 2, 1962
Refusal to furnish qualitative or quantitative formulas:		
Hall-Omar Bakery	Somerville, Mass.	May 11, 1962
Kraft Foods Division	Portland, Maine	Mar. 28, 1962
Hall Bakery Co.	Buffalo, N.Y.	May 17, 1962
Kraft Foods	Dunkirk, N.Y.	Apr. 20, 1962
The Red Wing Co., Inc.	Fredonia, N.Y.	Mar. 29, 1962
J. W. Allen & Co.	Chicago, Ill.	Mar. 1, 1962
American Chicle Co.	Rockford, Ill.	Mar. 15, 1962
Chippers, Inc.	Chicago, Ill.	May 8, 1962
General Mills, Inc.	West Chicago, Ill.	Apr. 23, 1962
Home Juice Co.	Melrose Park, Ill.	Mar. 29, 1962
Henri's Food Products	Milwaukee, Wis.	Mar. 5, 1962
Instant Whip	Chicago, Ill.	Mar. 27, 1962
Lauritzen & Co., Inc.	Norridge, Ill.	Feb. 1, 1962
L. D. Schreiber & Co.	Green Bay, Wis.	Mar. 29, 1962
American Dairy Co.	Evansville, Ind.	Apr. 11, 1962
E. Berghansen Chemical Co.	Cincinnati, Ohio	Mar. 22, 1962
Brand X Corp.	do.	Mar. 12, 1962
The Continental Baking Co.	Indianapolis, Ind.	Mar. 26, 1962
General Baking Co.	Louisville, Ky.	May 1, 1962
M & R Dietetic Labs, Inc.	Columbus, Ohio	Mar. 16, 1962
The Pillsbury Co.	New Albany, Ind.	Apr. 3, 1962
Procter & Gamble, (Duncan Hines Division)	Cincinnati, Ohio	Apr. 24, 1962
Stokely-Van Camp, Inc.	Indianapolis, Ind.	Apr. 11, 1962
Strietmann Biscuit Co.	Cincinnati, Ohio	Apr. 3, 1962
Adams Extract Co.	Austin, Tex.	Apr. 16, 1962
Best Foods, Inc.	Dallas, Tex.	Mar. 26, 1962
Harrell-Morris Candy Co.	Clinton, Okla.	May 7, 1962
Procter & Gamble Mfg. Co.	Dallas, Tex.	May 1, 1962
Stokely-Van Camp, Inc.	do.	Apr. 5, 1962
Superior Foods (Procter & Gamble)	do.	May 11, 1962
Triple A A Co.	Oklahoma City, Okla.	May 18, 1962
Bowman Biscuit Co.	Denver, Colo.	Mar. 8, 1962
National Biscuit Co.	do.	Mar. 22, 1962
Wolf Cereal Processing Co.	Colorado Springs, Colo.	Mar. 26, 1962
Campbell Soup Co.	Napoleon, Ohio	Mar. 19, 1962
Continental Baking Co.	Gary, Ind.	Apr. 17, 1962
General Foods Corp.	Battle Creek, Mich.	Apr. 19, 1962
Hol'n One Donut Co.	Flint, Mich.	Mar. 5, 1962
Campbell Soup Co.	Omaha, Nebr.	Jan. 17, 1962
Continental Baking Co.	Spout City, Iowa	Apr. 25, 1962
Dr. MacDonald's Vitaminized Feed Co., Inc.	Fort Dodge, Iowa	Apr. 19, 1962
Perk Foods Co.	Kansas City, Kans.	Mar. 26, 1962
Dip 'N Sip, Inc.	Santa Monica, Calif.	Apr. 23, 1962
Smithers Sons, Ltd.	Los Angeles, Calif.	Apr. 6, 1962
Union Sugar Co.	Betteravia, Calif.	Apr. 19, 1962
Emerald Food Inc.	Emerald, Wis.	Apr. 4, 1962
The Pillsbury Co.	Grand Forks, N. Dak.	Mar. 28, 1962
Sanna Dairies Inc.	Menomonie, Wis.	Apr. 4, 1962
A. W. Thompson Co. (Prairie Division)	Chien, Wis.	Apr. 27, 1962
Goodhill Prepared Foods, Inc.	Ponchatoula, La.	Feb. 14, 1962
Wright Root Beer Co.	New Orleans, La.	Jan. 31, 1962
Hollywood Brands, Inc.	Centralia, Ill.	Apr. 20, 1962
Kitchen Craft Foods Corp.	Brooklyn, N.Y.	Apr. 2, 1962
Leeds-Dixon Laboratories	South Hackensack, N.J.	May 17, 1962
Perck & Ford Ltd., Inc.	Pineknayville, Ill.	Apr. 9, 1962
B. M. Reeves Co., Inc.	Brooklyn, N.Y.	Feb. 1, 1962
Scheff Bros Foods	South Hackensack, N.J.	May 17, 1962
Germantown Manufacturing Co.	Philadelphia, Pa.	Mar. 22, 1962
Beatrice Foods Co.	Kankakee, Ill.	Mar. 28, 1962
Continental Baking Co.	St. Louis, Mo.	Jan. 12, 1962
Do.	do.	May 16, 1962
Hollywood Brands, Inc.	Centralia, Ill.	Apr. 20, 1962
Morris Elevator	Bushnell, Ill.	Mar. 6, 1962
Rio Syrup Co.	St. Louis, Mo.	Apr. 26, 1962
Whistle & Vess Beverage Co.	do.	Apr. 24, 1962
Pillsbury Co.	Reedley, Calif.	Mar. 22, 1962

See footnotes at end of table, p. 592.

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 16, 1962—Continued

FOOD FIRMS

Firm name	Address	Date of refusal ¹
Refusal to furnish qualitative or quantitative formulas—Continued		
Planters Peanuts.....	San Francisco, Calif.	May 17, 1962
Priscilla's Viennese Baking Co.....	do.....	Jan. 26, 1962
Riva Distributing Co.....	do.....	Mar. 13, 1962
The Borden Co.....	Albany, Oreg.	Mar. 20, 1962
Tamarin Bros.....	Boston, Mass.	May 16, 1962
The Julep Co.....	Sycamore, Ill.	Apr. 11, 1962
Great A. & P. Tea Co.....	Altoona, Pa.	May 22, 1962
Fresno Milling Co.....	Fresno, Calif.	May 24, 1962
Pure Foods, Inc.....	Chicago, Ill.	May 16, 1962
Golden Crown Products, Inc.....	Los Angeles, Calif.	Apr. 5, 1962
Marie Nut.....	do.....	Mar. 20, 1962
Refusal to disclose or permit observation of manufacturing procedures: American Dairy Co.		
Refusal to permit review of control records:		
Douglas Packing Co., Inc.....	Nassawadox, Va.	Mar. 27, 1962
Kraft Foods.....	Portland, Maine.	Mar. 28, 1962
Hall Bakery.....	Buffalo, N.Y.	May 17, 1962
Kraft Foods.....	Dunkirk, N.Y.	Apr. 20, 1962
The Red Wing Co., Inc.....	Fredonia, N.Y.	Mar. 29, 1962
American Dairy Co.....	Evansville, Ind.	Apr. 11, 1962
Procter & Gamble (Duncan Hines division).....	Cincinnati, Ohio.	Apr. 24, 1962
Drenthe Creamery Co.....	Drenthe, Mich.	May 2, 1962
Procter & Gamble Manufacturing Co.....	Dallas, Tex.	May 1, 1962
Campbell Soup Co.....	Omaha, Nebr.	Jan. 17, 1962
Sarna Dairies, Inc.....	Menomonie, Wis.	Apr. 4, 1962
Leeds-Dixon Laboratories.....	South Hackensack, N.J.	May 17, 1962
Scheff Bros. Foods.....	do.....	Do.
The Kellogg Co.....	Memphis, Tenn.	Apr. 8, 1962
California Packing Corp.....	San Francisco, Calif.	Apr. 19, 1962
Pillsbury Co.....	Reedley, Calif.	Mar. 22, 1962
The Borden Co.....	Albany, Oreg.	Mar. 20, 1962
Consumers Peanut Manufacturing Co.....	Billings, Mont.	Mar. 26, 1962
Kraft Foods.....	Rome, N.Y.	May 24, 1962
Refusal to permit review of complaint files:		
New England Tea Packing Co., Inc.....	Boston, Mass.	Apr. 18, 1962
Hall Bakery.....	Buffalo, N.Y.	May 17, 1962
Kraft Foods.....	Dunkirk, N.Y.	Apr. 30, 1962
The Red Wing Co., Inc.....	Fredonia, N.Y.	Mar. 29, 1962
Continental Baking Co.....	Indianapolis, Ind.	Mar. 26, 1962
The Pillsbury Co.....	New Albany, Ind.	Apr. 3, 1962
Procter & Gamble (Duncan Hines Division).....	Cincinnati, Ohio.	Apr. 24, 1962
Stokely-Van Camp, Inc.....	Indianapolis, Ind.	Apr. 11, 1962
Bowman Biscuit Co.....	Denver, Colo.	Mar. 8, 1962
Continental Baking Co.....	Gary, Ind.	Apr. 17, 1962
Peterson Nut Co.....	Cleveland, Ohio.	May 17, 1962
Modern Aids, Inc.....	New York, N.Y.	Mar. 20, 1962
A. E. Staley Manufacturing Co.....	Decatur, Ill.	Apr. 16, 1962
Planters Peanuts.....	San Francisco, Calif.	Mar. 6, 1962
Refusal to permit taking of photographs:		
Continental Baking Co.....	Gary, Ind.	Apr. 17, 1962
California Packing Co.....	Sacramento, Calif.	Apr. 18, 1962
Refusal to permit review of shipping records:		
Bush Bros. & Co.....	Dandridge, Tenn.	May 22, 1962
Hall Bakery.....	Buffalo, N.Y.	May 17, 1962
J. W. Allen & Co.....	Chicago, Ill.	Mar. 1, 1962
Glacier Groves, Inc.....	Cincinnati, Ohio.	Jan. 30, 1962
Napoleon Creamery.....	Napoleon, Ind.	Mar. 20, 1962
Reiston Purina Co.....	Louisville, Ky.	Apr. 9, 1962
Midland Produce Co.....	Denver, Colo.	Jan. 2, 1962
Continental Baking Co.....	Gary, Ind.	Apr. 17, 1962
O-So-Good Food Products Co.....	Omaha, Nebr.	Mar. 23, 1962
Smithers Sons, Ltd.....	Los Angeles, Calif.	Apr. 6, 1962
The Pillsbury Co.....	Grand Forks, N. Dak.	Mar. 28, 1962
Sarna Dairies, Inc.....	Menomonie, Wis.	Apr. 4, 1962
Goodhill Prepared Foods, Inc.....	Ponchartraine, La.	Feb. 14, 1962
Nutritional Foods, Inc.....	New Orleans, La.	Mar. 16, 1962
Sea Coast Canning, Inc.....	Biloxi, Miss.	Mar. 23, 1962
Balanced Foods, Inc.....	New York, N.Y.	Apr. 5, 1962
Modern Aids, Inc.....	do.....	Mar. 20, 1962
Nutra Food, Inc.....	Valley Stream, N.Y.	Mar. 27, 1962
Scheff Bros. Foods.....	South Hackensack, N.J.	May 17, 1962
Germantown Manufacturing Co.....	Philadelphia, Pa.	Mar. 22, 1962
Bectrice Foods Co.....	Kankakee, Ill.	Mar. 28, 1962
Continental Baking Co.....	St. Louis, Mo.	May 16, 1962
William Davies Co., Inc.....	Danville, Ill.	Feb. 28, 1962
Planters Peanuts.....	San Francisco, Calif.	Mar. 6, 1962
Harbey Packing Co.....	Astoria, Oreg.	May 3, 1962
Consumers Peanut Manufacturing Co.....	Billings, Mont.	Mar. 26, 1962

See footnotes at end of table, p. 592.

DRUG INDUSTRY ACT OF 1962

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Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962—June 15, 1962—Continued

DRUG AND DEVICE FIRMS

Firm name	Address	Date of refusal ¹
Refusal to permit inspection: Central Surgical Supply Co.	Pitchburg, Mass.	Apr. 24, 1962
Refusal to divulge status or responsibility of individuals:		
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Cyclo Manufacturing Co.	Denver, Colo.	Do.
Refusal to furnish qualitative or quantitative formulas:		
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	Do.
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Basic Formulas, Inc.	Salt Lake City, Utah	May 8, 1962
Halls Remedy Co.	do.	Apr. 16, 1962
Difco Laboratories	Detroit, Mich.	Feb. 13, 1962
Fredenck Laboratory	Oregon, Ohio	Apr. 20, 1962
North American Mogul Products	Chagrin Falls, Ohio	Apr. 10, 1962
Dorsey Laboratories	Lincoln, Neb.	May 15, 1962
Norden Laboratories, Inc.	do.	May 17, 1962
Vare Electronics	Minneapolis, Minn.	Apr. 19, 1962
National Research Corp.	Lafayette, La.	Feb. 15, 1962
Lambert-Hudnut Manufacturing Laboratories, Inc.	St. Louis, Mo.	Apr. 11, 1962
Dr. J. H. McLean Medicine Co.	do.	Apr. 23, 1962
Mantho Kreamo, Inc.	Clinton, Ill.	Mar. 20, 1962
Flough, Inc.	Memphis, Tenn.	Mar. 5, 1962
Schlicksup Drug Co., Inc.	Peoria, Ill.	May 3, 1962
Caladine Laboratories	Oakland, Calif.	Apr. 26, 1962
Octogen Pharnacal Co.	Utica, N.Y.	May 23, 1962
Refusal to disclose or permit observation of manufacturing procedures:		
Chas. Pfizer & Co., Inc.	Groton, Conn.	Apr. 24-25, 1962
Puritron Corp.	New Haven, Conn.	Mar. 29, 1962
Basic Formulas Inc.	Salt Lake City, Utah	May 8, 1962
National Research Corp.	Lafayette, La.	Feb. 15, 1962
Refusal to permit review of control records:		
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Cyclo Manufacturing Co.	Denver, Colo.	May 2, 1962
Difco Laboratories	Detroit, Mich.	Feb. 13, 1962
Parke Davis Co.	do.	Feb. 3, 1962
Dorsey Laboratories	Lincoln, Neb.	May 15, 1962
Norden Laboratories, Inc.	do.	May 17, 1962
Schlicksup Drug Co.	Peoria, Ill.	Feb. 28, 1962
Caladine Laboratories	Oakland, Calif.	Apr. 26, 1962
Refusal to permit review of complaint files:		
Chas. Pfizer & Co., Inc.	Groton, Conn.	Apr. 24-25, 1962
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Wm. S. Merrell Co.	Cincinnati, Ohio	Jan. 17, 1962
Philips-Roxanne, Inc.	Columbus, Ohio	Apr. 18, 1962
Putman-Moore Co.	Indianapolis, Ind.	Mar. 21, 1962
Difco Laboratories	Detroit, Mich.	Feb. 13, 1962
Norwich Pharmaceutical Co.	Norwich, N.Y.	Apr. 10, 1962
Irwin Neisler & Co.	Decatur, Ill.	Apr. 18, 1962
Caladine Laboratories	Oakland, Calif.	Apr. 26, 1962
Jensen Salsbury Laboratories, Inc.	Kansas City, Mo.	May 11, 1962
Winthrop Laboratories	Rensselaer, N.Y.	May 15, 1962
Refusal to permit review of shipping records:		
Dainty Maid, Inc.	Middlefield, Conn.	Mar. 20, 1962
Puritron Corp.	New Haven, Conn.	Mar. 20, 1962
Approved Pharmaceutical Corp.	Syracuse, N.Y.	Apr. 23, 1962
Ayerst Laboratories, Inc.	Rouses Point, N.Y.	May 2, 1962
Blue Ridge Vitamin Co.	Chicago, Ill.	Apr. 2, 1962
Chattanooga Medicine Co.	Chattanooga, Tenn.	Mar. 15, 1962
Basic Formulas, Inc.	Salt Lake City, Utah	May 8, 1962
Difco Laboratories	Detroit, Mich.	Feb. 13, 1962
Coast Chemical Co.	Los Angeles, Calif.	Mar. 26, 1962
Walker Laboratories, Inc.	Mount Vernon, N.Y.	Mar. 14, 1962
Mantho Kreamo, Inc.	Clinton, Ill.	Mar. 20, 1962
Caladine Laboratories	Oakland, Calif.	Apr. 26, 1962
Bolton's Retail Drugs	Berkeley, Calif.	Mar. 14, 1962
Niagara of Fort Wayne	Fort Wayne, Ind.	May 24, 1962
Winthrop Laboratories	Rensselaer, N.Y.	May 15, 1962
Refusal to permit review of prescription files:		
Bolton's Retail Drugs	Berkeley, Calif.	Mar. 14, 1962

See footnotes at end of table, p. 592.

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DRUG INDUSTRY ACT OF 1962

Inspection refusals—Federal Food, Drug, and Cosmetic Act, January 1962–June 15, 1962—Continued

COSMETIC FIRMS

Firm name	Address	Date of refusal ¹
Refusal to permit inspection. Schratz Products, Inc.	Detroit, Mich.	Mar. 22, 1962
Refusal to furnish qualitative or quantitative formulas:		
John H. Breck, Inc.	Springfield, Mass.	Mar. 27, 1962
Chesbrough Pond's, Inc.	Clinton, Conn.	Apr. 10, 1962
Chesbrough Pond's, Inc. (Stamford Division)	Stamford, Conn.	May 1, 1962
Clairol, Inc.	do	Apr. 24, 1962
North American Dye Corp.	Danbury, Conn.	May 7, 1962
Fraund, Inc.	Chicago, Ill.	Feb. 16, 1962
Colgate Palmolive Co.	Clarksville, Ind.	Nov. 29, 1962
Davis Young Soan Co.	Dayton, Ohio	Feb. 20, 1962
Procter & Gamble	St. Bernard, Ohio	Jan. 15, 1962
United Western Laboratories, Inc.	Denver, Colo.	Apr. 23, 1962
Presto Products Co.	Detroit, Mich.	Apr. 9, 1962
Schratz Products, Inc.	do	Apr. 27, 1962
Sanford Laboratories, Inc.	Tuscaloosa, Ala.	Mar. 16, 1962
Andrew Jergens Co.	Belleville, N.J.	Feb. 27, 1962
The Klutch Co.	Elmhurst, N.Y.	Apr. 17, 1962
Rosal Laboratories, Ltd.	Philadelphia, Pa.	Apr. 2, 1962
Golden Peacock, Inc.	Paris, Tenn.	Apr. 5, 1962
Gold Star Beauty Supply Co., Inc.	Los Angeles, Calif.	Apr. 30, 1962
J. H. Lewis, Inc.	St. Paul, Minn.	Apr. 17, 1962
Refusal to disclose or permit observation of manufacturing procedures:		
John H. Breck, Inc.	Springfield, Mass.	Mar. 27, 1962
Clairol, Inc.	Stamford, Conn.	Apr. 24, 1962
Refusal to permit review of control records:		
John H. Breck, Inc.	Springfield, Mass.	Mar. 27, 1962
Procter & Gamble	St. Bernard, Ohio	Mar. 15, 1962
Schratz Products, Inc.	Detroit, Mich.	Mar. 27, 1962
Rosal Laboratories, Ltd.	Philadelphia, Pa.	Apr. 2, 1962
Refusal to permit review of complaint files:		
John H. Breck, Inc.	Springfield, Mass.	Mar. 27, 1962
Chesbrough Pond's (Stamford Division)	Stamford, Conn.	May 1, 1962
Clairol, Inc.	do	Apr. 24, 1962
Procter & Gamble	Cincinnati, Ohio	Jan. 18, 1962
Refusal to permit taking of photographs:		
Clairol, Inc.	Stamford, Conn.	Apr. 24, 1962
Refusal to permit review of shipping records:		
John H. Breck, Inc.	Springfield, Mass.	Mar. 27, 1962
Clairol, Inc.	Stamford, Conn.	Apr. 24, 1962
H. R. Distributing & Advertising Co.	Philadelphia, Pa.	Apr. 19, 1962
Andrew Jergens Co.	Belleville, N.J.	Feb. 27, 1962

¹ Note.—Firms may be listed under more than one category if they refused more than one phase of inspection during a given inspection.

² When visited again on Apr. 24, 1962, the firm permitted inspection.

³ After being cited for refusal to permit inspection, the firm agreed at an informal hearing on June 7, 1962, to permit inspection in the future.

⁴ When visited again on Apr. 25, 1962, the firm permitted inspection.

⁵ When visited again on Mar. 27, 1962, the firm permitted inspection.

Mr. ROBERTS. The committee has received a great deal of material on this legislation. We will try to place as much as possible in the record and keep the rest of the files for reference.
(The following material was received for the record:)

STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION RE H.R. 11581 AND S. 1552,
BY F. J. L. BLASINGAME, M.D.

I am Dr. F. J. L. Blasingame, executive vice president of the American Medical Association. I would like to submit for the record the association's comments on H.R. 11581 and S. 1552, proposing certain amendments to the Federal Food, Drug and Cosmetic Act. The American Medical Association, as the national association of physicians of the United States, has a serious and long-standing interest in drugs and legislation concerning them. These bills will, in our opinion, directly affect the practice of medicine and the public health and are therefore within the area of knowledge and professional competence of physicians and the AMA.

This committee is, of course, aware of the increased public attention now being focused on drugs, drug investigations, drug marketing and drug legislation. The

uneasiness of the public, the newspapers, and, to some extent, the Congress, is precipitated in large measure by the birth in other countries of infants afflicted with congenital malformations (phocomelia) attributed to the ingestion of the drug thalidomide by the child's mother during the first few weeks of pregnancy.

We as physicians, who have dedicated our lives to the preservation of life and to the relief of human suffering, are particularly concerned over the recent increase in other countries of the birth of deformed children afflicted with phocomelia. We deplore the human suffering and heartbreak attending the birth of a deformed child.

In our opinion, however, the fact that should be uppermost in the minds of this committee and the Congress is that the drug was not released for prescription use here due to presently existing laws. These laws, which were supported by the AMA when they were before the Congress, authorize FDA to withhold a drug from the market for safety reasons and are demonstrably adequate to prevent the marketing of "unsafe" drugs.

The thalidomide incident may have affected the legislative climate, but it has not in any way changed the merits of the legislation which you are now considering. As physicians, we are apprehensive that thalidomide might have a serious and irreparable legislative side effect—the adoption of well-intentioned but ill-advised legislation. What is done by this committee and the Congress within the understandable emotional framework of the thalidomide incident may have serious repercussions affecting permanently the timely supply of new drugs for the alleviation of human suffering and the cure of disease.

It is our understanding that it is the intent, in part, of H.R. 11581 and S. 552 to modify the framework within which prescription drugs are developed, marketed and used. It is also our understanding that these bills are being proposed in an effort to protect the American public from unsafe and ineffective drugs.

We believe, however, that there are provisions in these proposals which would have serious undesirable effects on the practice of medicine, on science, and on the availability of safe, efficacious and lifesaving drugs.

A prescription drug is, by definition, "unsafe" in the sense that its use in human beings can and does involve hazards. It is the existence of these hazards inherent in the use of all prescription drugs that leads to the requirement that they never be used except under the supervision of a physician. Only the physician can add the "safety factor" through the knowledge at his command of all of the consequences which may follow the administration of a specific dosage of a specific drug to a specific patient. Thus, clinical trials and, indeed, all drug research, are not intended primarily to determine "safety" or the lack of it. They are intended to discover all of the effects which may result to patients to whom the drug is administered.

When the physician knows all of the effects which will follow from a specific drug prescription, he can use that drug with a high degree of "safety" and bring about a net improvement in the health of his patient. It should be noted that the emphasis is on "net improvement." The vast majority of prescription drugs cause multiple effects in the human body.

Thus, when the physician is aware of all of the consequences, he can prescribe a drug which will cause more desirable changes in his patient than undesirable ones, and thus effect an improvement in the patient's health.

It is the association's sincere belief that if the above facts are kept in mind during the committee's consideration of this legislation, then the provisions of the bills can be judged on their true merit.

The AMA is justly proud of its long history of support and sponsorship of legislation in food and drug matters. In addition to our legislative interest and activity, the AMA has, over the years, had a close and continuing relationship with the Food and Drug Administration on constructive matters in the public interest. A chronicle of our support of Federal food and drug laws and a brief history of the highlights of our cooperation with the Food and Drug Administration is attached to our statement as exhibit A.

With this record of AMA support and cooperation as background information, we would like to cite the aims we, as physicians, are desirous of achieving.

We want all physicians to be well-trained and fully informed on all aspects of the practice of medicine, including a high degree of competency in the selection and proper use of drugs.

We want a continuing and expanding flow of useful drug products placed at the disposal of physicians.

We would now like to comment specifically on those provisions of H.R. 11581 and S. 1552 which cause us the greatest concern as physicians:

Efficacy of drugs.—Section 102 of H.R. 11581 would amend subsections (b), (d), (e) and (f) of section 505, the new drug section, of the Federal Food, Drug and Cosmetic Act so as to authorize the Food and Drug Administration to determine, evaluate and pass on the efficacy of new drugs prior to marketing. Section 8(c) of S. 1552 would require "substantial evidence" of "effectiveness," allowing the Secretary to determine if it is "adequate." Both bills would also amend section 201(p) of the present act to introduce the concept of drug efficacy or effectiveness into the definition of a new drug. Among other things, the bills authorize the suspension of an effective new drug application when doubts arise on the part of the FDA as to the efficacy of a drug which previously has been approved.

These proposals would require that the FDA come to some conclusion regarding a drug's power to produce effects when administered to human beings, a basic problem in medicine, one which physicians have concerned themselves with for centuries and one which for centuries has defied legislative solution. The problem is this: How much and what kind of knowledge must we have regarding a drug's power to produce effects before it can be used with certainty? And how do we go about obtaining such knowledge?

Under ideal conditions, the profession would be aware of all of the effects produced by a drug before it was administered to the first patient. However, even when a drug has been used over an extended period of time, in hundreds of thousands of cases, the physician must remain alert to the possibility of effects which have never been experienced before. He knows that his knowledge of drug therapy is, and must remain, tentative. No group of men, inside or outside of Government, can change this situation.

Over the years, the profession, in cooperation with others involved in the development of new drugs, has worked diligently to increase our knowledge of the power of drugs and to assure that their use in the treatment of disease will be effective.

Today when a prescription drug is made available to physicians, we know what toxic effects the drug has been known to produce under specified conditions and in a specified number of instances. And we are alerted to watch for other toxic effects as our experience with the drug expands. The FDA does not say that such a drug, in the absolute sense, is "safe." It approves even highly toxic drugs for use by physicians, knowing that the physician can be informed regarding their known toxic properties and will consider such properties when prescribing the drugs. When a drug is approved for widespread use, all physicians become part of a continuing "watch" for other toxic effects.

However, drugs are prescribed and used in the treatment of patients, not to produce effects which we have called "toxic," but to cure or alleviate pain and illness, and it is the power to produce these desirable effects that is referred to by the term "efficacy." We point this out because there is an understandable, but nevertheless, extremely important misconception on the part of many of the term "efficacy" as this term is used in medicine. Physicians seek to treat effectively the medical problems of individual patients. A physician does not treat 10 cases of hypertension, he treats 10 individual patients, each of whom has a medical problem he has diagnosed as hypertension. This difference becomes especially important when he elects to use drug therapy in the treatment of these 10 individual patients. He may find that the same dosage of the same form of the same drug will be efficacious in each and all of his 10 patients. Or he may find that one or more of them need different dosages or different forms of this same drug. He may, indeed, find that one, two, or three of them are allergic to the nonactive ingredients used in one brand of the drug and that a different brand, with other nonactive ingredients, is the efficacious answer. Thus, in one patient, a specific dosage of a specific drug might be said to be efficacious, while in another it would be described as totally ineffective.

The point we are making is this. A drug's efficacy varies from patient to patient, sometimes for known reasons such as allergy, and at other times for unknown reasons. Hence, any judgment concerning this factor can only be made by the individual physician who is using the drug to treat an individual patient. A physician can be told many things about a drug, including its chemistry, its mode of action and, to some extent, its toxic properties. But he must judge its efficacy. A drug which is, on the average, less efficacious than another, must still be available to every physician since it may be completely efficacious in treating the medical problems of one of his patients. We do not

practice medicine on the average—we seek to solve or alleviate the problems of each and every patient.

If this precise usage of the word "efficacy" is kept in mind, the consideration of legislation which would request that an administrative agency of Government determine the efficacy of drugs can proceed more fruitfully.

The proposed amendments would prevent some apparently ineffective drugs from reaching the market. They would also, however, tend to stifle the development and distribution of other drugs which are or might later be shown to be highly efficacious. They would deprive the physician of exercising his professional judgment in deciding which drug was most efficacious for his patient, in that they would deny the physician the availability of certain drugs he might wish to prescribe. Also, they would substitute the judgment of governmental officials for the time-proven system of the consensus of the medical profession as to the ultimate usefulness and efficaciousness of a particular drug. It is our considered opinion that these proposed amendments would not, in the final analysis, result in better medical care for the American people, the objective, we are sure, all are seeking.

We are also concerned that, by granting to a governmental agency the statutory authority to pass on the efficacy of a new drug, Congress will be enabling that agency, through administrative interpretation of the law, to decide the relative or comparative efficacy of a new drug in terms of drugs already on the market. We are apprehensive that the Food and Drug Administration would, under these amendments to the act, decide that it had the authority to refuse to allow a drug to be marketed merely because it was, in their opinion, not the most efficacious drug for the purpose intended or was not as efficacious as one might ideally wish.

Virtually all medical scientists agree that the attempted evaluation of the relative merits and uses of different drugs by governmental employees would not only be a most unfortunate undertaking, but an impossible one. Physicians in the Food and Drug Administration, like physicians everywhere, have their own personal opinions as to the relative merits of drugs. This is the nature of medicine and of the medical profession. What concerns us is that the particular views of the physicians in government might well be translated into a denial of the availability of a particular drug which they, in all good faith, do not believe to be as efficacious as a drug already on the market. Subsequent events could well prove them wrong. Medical history is replete with examples of medical "authorities" who were badly mistaken as to the ultimate usefulness of a drug.

We have closely studied the language of the numerous legislative proposals which would purport to grant to FDA the authority to evaluate efficacy, while denying to it the authority to make determinations as to relative efficacy. We cannot conclude that any of these proposals would suffice to guarantee that administrative determinations, under such a statute, would not be made comparing the relative efficacy of various drugs.

Thus, the American Medical Association opposes those sections of H.R. 11581 and S. 1552 which would grant to the Food and Drug Administration the authority to determine, evaluate and pass on a drug's efficacy and thereby determine beforehand that a drug should not be marketed on that basis.

Factory inspection.—On April 21, 1953, the association submitted to the committee a statement urging enactment of a bill which would have authorized inspection of factories without the necessity of first making a request. It was the belief of the association that the principle of the bill was a proper one and the measure should be adopted "provided the proper safeguards are included to protect the physician-pharmacist-patient relationship." It was also pointed out that the association believed that language should be included which would clearly indicate that the bill has no application to confidential business and professional records "which have no specific bearing on the enforcement of the Food, Drug and Cosmetic Act."

The association continues to maintain this policy, although we are of the opinion that the provisions of section 201 of H.R. 11581 appear to be unnecessarily broad for the purposes for which it is intended.

Section 4 of S. 1552 specifically excludes certain data from inspection and therefore would be more acceptable to the profession. However, the provisions of this bill relating to the qualification of personnel, while not intended to establish Federal standards for personnel, could easily be administered to that end. This, we believe, would not be in the public interest.

Both of the provisions would authorize inspection of consulting laboratories. H. R. 11581 leaves the definition to the discretion of the Secretary. S. 1552 defines the term very broadly. While the association is convinced that the provision is intended to apply only to commercial consulting laboratories, we would suggest that appropriate language be added to any such provision to specifically exclude physicians' offices, hospitals and medical schools from its application. Such an amendment would be in accord with other provisions of section 4 of S. 1552 which exempts physicians' records from inspection and would give recognition to the patient-physician relationship and State laws which give statutory protection to it.

Standardization of drug names.—Section 111 of H. R. 11581 would authorize the Secretary of HEW to establish a single standard name for a drug under certain conditions. Section 10 of S. 1552 would grant similar authority, but would also require the Secretary to review all the official compendia to determine the necessity or desirability of revising official names "in the interest of usefulness and simplicity." Before designating such a name, the Secretary would first have to seek a recommendation from the compilers of compendia.

We believe that the powers which would be granted to the Secretary of HEW by these provisions are unnecessary and would tend to interfere with present successful, voluntary efforts and would create and compound confusion in drug nomenclature. In order to clarify for the committee our reasons for believing legislation in this area to be unnecessary, we would like to describe for you how nonproprietary drug names are currently established under improved, voluntary procedures.

For many years the AMA has played a leading role in the adoption of a drug's nonproprietary (standard) name. This procedure is explained in some detail in exhibit B attached to this statement. We will not repeat the full explanation included in the exhibit, but for the benefit of the committee, we will summarize briefly the present procedure.

Simultaneously with the early development of a new drug, consideration of a nonproprietary name is begun. It is the policy of the AMA that the early adoption of a nonproprietary name should be encouraged to facilitate understanding by all concerned of the properties and proper usage of the drug. It is also our policy that the nonproprietary or generic name should be as simple as possible and that chemically related drugs, used within a given therapeutic area, should preserve some relationship in their nonproprietary names.

In order to improve and streamline the naming process, the AMA and the U. S. Pharmacopoeia formulated last year a joint program for the adoption of nonproprietary names. The objectives of this program are to facilitate the selection of suitable nonproprietary names for drugs and to encourage the use of such names wherever indicated in labeling, in advertising, as titles in the official compendia, and in the scientific literature. The new program represents a dovetailing of the nomenclature interests of the AMA and the U. S. Pharmacopoeia. Briefly, it consists of the modification of the Nomenclature Committee of the Council on Drugs. The joint AMA-U. S. P. Nomenclature Committee consists of two members appointed by the AMA and two members by the U. S. P., and is staffed by the AMA. It is the responsibility of the Committee, after working and negotiating with the pharmaceutical manufacturer, to designate the nonproprietary drug name which will then be adopted by both organizations. In the event that a decision cannot be reached between this joint committee and the manufacturer as to the nonproprietary name to be assigned, either the committee or the manufacturer may take the matter to a Nomenclature Review Board appointed jointly by the AMA and U. S. P., which determines the merits of the controversy and makes the final decision as to the name.

In addition to facilitating the adoption of nonproprietary names, the new program results in a faster and much wider dissemination of the newly adopted nonproprietary names of drugs. As in the past, all interested cooperating agencies throughout the world are consulted for their comments.

The U. S. P. will adopt the name so selected as the U. S. P. title, when and if the drug concerned is admitted to the U. S. P. The U. S. P. also undertakes to publish lists of the names at frequent intervals. The Journal of the American Medical Association publishes monthly a list of the names so selected which are denominated United States Adopted Name (USAN). In addition, the AMA and the U. S. P. have organized a concerted campaign to acquaint the editors of all other medical and pharmaceutical journals of the availability of USAN

nonproprietary names for all drugs that are likely to be the subject of published articles.

The American Medical Association believes that this system of adopting nonproprietary or generic names for drugs has been reasonably effective in the past, and that the recent Joint Nomenclature Committee is making it even more effective and expeditious. Further, the close cooperation of the AMA and U.S.P. in this program is greatly increasing the use of such names and eliminating any confusion that may have existed.

In summary on this point, we believe that the problems which remain in the field of drug nomenclature can and should be solved by the profession itself. Physicians and others will adopt and use nonproprietary names for drugs only when they are convinced that the use of such names will facilitate and improve the practice of medicine. We believe that the programs we have described will be most convincing to them.

Special control for barbiturate and stimulant drugs.—We would like next to briefly comment on part C of H.R. 11581 which embodies special control for barbiturates, amphetamines, and any other drug which the Secretary of HEW finds to be habit forming because of its stimulant effect on the nervous system. These provisions would apply to barbiturates and habit-forming stimulant drugs whether or not they enter or are destined for interstate commerce. They have been the exclusive subject matter of four similar bills now pending before the Congress—H.R. 646, H.R. 3967, S. 1939, and S. 3673—but hearings have not been scheduled on any of these proposals.

We can appreciate the concern of the Congress and this committee over the social effects of barbiturates and amphetamines. The AMA joins the Food and Drug Administration in deploring illicit traffic and sales of such drugs.

However, H.R. 11581 is an omnibus bill dealing with the broad spectrum of all drugs. In our opinion, it would be a serious mistake to include in this bill legislation specifically regulating two classifications of drugs—barbiturates and amphetamines. The time allotted to hearings on this proposal does not permit the necessary legislative inquiry as to the necessity for further Federal legislation with respect to these drugs; nor does it provide sufficient time for an inquiry as to the appropriateness of the measures proposed. The Senate Judiciary Committee in its consideration of S. 1552 urged no action on this provision pending the outcome of further study by the Senate Labor and Public Welfare Committee.

We do not believe that the necessity for, or appropriateness of, additional Federal legislation has been adequately demonstrated at this time. Accordingly, we would urge the committee to defer action on this part of H.R. 11581 pending further study of this portion of the bill.

In this connection, the American Medical Association and its Council on Drugs stands ready to cooperate with the Congress and the appropriate department of the executive branch of Government in studying the medical and social problems inherent in the illicit and medically unsupervised use of these drugs and the appropriateness of additional Federal legislation.

Prescription drug advertising.—Section 131 of H.R. 11581 and section 11 of S. 1552 are concerned with the advertising of prescription drugs to physicians. Generally, an advertisement would be deemed to be misleading in a material respect if such advertisement fails to contain (A) a conspicuous, full and accurate statement of the efficacy of the drug, and (B) a conspicuous and truthful disclosure of (i) the quantitative formula of the drug with each active ingredient listed by its common or usual name, (ii) the side effects of the drug, and (iii) the contraindications of the drug.

Advertisements for prescription drugs are directed to physicians in order to keep the name of a given product before the medical profession. Most physicians accept such ads for what they are—reminder information, not educational material. The proposals contained in these bills are quite obviously based on the erroneous, mistaken assumption that the purpose of prescription drug advertising is educational.

In 1914, when the Federal Trade Commission Act was adopted, it contained the exception to the false advertising provisions of the act that "No advertisement of a drug shall be deemed to be false if it is disseminated only to members of the medical profession, contains no false representation of a material fact, and includes, or is accompanied in each instance by truthful disclosure of, the formula showing quantitatively each ingredient of each drug."

The reason for such an exception is obvious to us as physicians. Prescription drug advertising is directed to a sophisticated, trained, and knowledgeable audience of professional people who can evaluate such ads for what they are—advertisement. The Congress recognized this fact in 1914, and the reasoning behind this exception is even more valid in 1962. With the great advances in medical education and postgraduate education, coupled with improved media of communication, today's medical practitioner is much better informed regarding drugs and drug usages than he was in 1914.

In addition to his training and experience, the physician receives a constant stream of information about available drugs and their effects from the medical literature, from impartial reports by pharmacologist and the medical profession, from informal discussions with colleagues and from numerous reference works.

It is not only medically impossible to include in an advertisement for a prescription drug complete data relative to efficacy, contraindications, and side effects—it is also physically impossible. Any abbreviation of this information could be extremely unwise, as this could only encourage doctors to rely on drug advertisements as a source of complete information.

Thus, in our opinion, these proposals could very easily have the opposite effect from that intended by their proponents. If prescription drug advertising were required to contain the proposed statements as to efficacy, side effects, and contraindications, it could easily result in the mistaken assumption by many physicians that continual study of scientific and authoritative medical literature would be unnecessary.

The AMA, of course, believes that advertising should be truthful. We cannot, however, make the assumption that physicians receive their education on drugs and drug therapy from pharmaceutical advertisements. We make every effort in the scientific publications of the AMA to insure a high quality in the advertisements appearing in our publications. A copy of the principles which guide us in the acceptance of advertising for our journals is attached to this statement as exhibit C. We will not dwell on the details of these principles, but merely indicate that the application of such principles results, in our opinion, in high quality, truthful advertising without distorting the purpose of advertisements by attempting to include the education of our physician readership.

In conclusion, the American Medical Association has endeavored in this statement to comment on those provisions of H.R. 11581 and S. 1552 as passed by the Senate which are of greatest concern to the physicians of America.

We are confident that this committee is aware of the vital responsibility which it bears. Undoubtedly, the legislation recommended by this committee will have serious and far-reaching effects on drug research, the availability of new, life-saving drugs, the practice of medicine and the health of our people. If ever there was a time for serious, considered, dispassionate deliberation, it is now.

We sincerely hope that our comments and suggestions have indicated the concern of the Nation's physicians and will be of assistance to this committee in arriving at a judicious result.

EXHIBIT A

HIGHLIGHTS OF AMA LEADERSHIP AND COOPERATION WITH FEDERAL AGENCIES IN FOOD AND DRUG MATTERS

As early as 1891, the AMA went on record as supporting the first proposals for a Federal food and drug law. It was not until 1905, however, coincident with the establishment of our council on pharmacy and chemistry, later to become the council on drugs, that the association threw its full weight into the struggle for a Federal pure food and drug law. The statute was enacted in 1906 following intensive legislative efforts by the AMA. Through the years, the AMA has closely followed the implementation and effectiveness of the 1906 act. As early as 1911, the association urged Congress to amend the act so as to prevent false statements being made as to the results to be obtained from the use of medicinal agents.

In 1933, the AMA, realizing that the existing act had certain deficiencies, urged "the formulation and enactment of effective national food and drug legislation adequate for the protection of the people." Activities of the association were instrumental in the passage of the present Federal Food, Drug, and Cosmetic Act in 1938. In 1951, we supported the Durham-Humphrey amendment, which is the law controlling the dispensing of prescription drugs. In 1953, the AMA supported a bill, which was enacted as Public Law 217, 83d Congress, authorizing the Food and Drug Administration to inspect pharmaceu-

tical manufacturing establishments without first obtaining the permission of the proprietors. During the 80th Congress, the AMA was one of the chief sponsors and supporters of the Hazardous Substances Labeling Act, which was enacted as Public Law 86-013 and is now administered by the Food and Drug Administration.

AMA has supplemented our legislative activities with a close and continuing relationship with the Food and Drug Administration. Our council on drugs, over the years, has had a number of members from the FDA, and numerous other Government physicians and pharmacologists have served as consultants to the council in its drug evaluation program. Our department of investigation has enjoyed a longstanding close relationship with FDA in developing information on quackery and medicines and devices of questionable value.

On October 6-7, 1961, the AMA and the FDA jointly sponsored the first National Congress on Medical Quackery in Washington, D.C. This was the beginning of a concerted cooperative drive against those practitioners of pseudo-medicine who bilk the public of millions annually. In March of this year, a followup conference was sponsored by the American Medical Association in Chicago. Attending this meeting were key people from the FDA, and other Government agencies and private organizations.

Our committee on cosmetics and the former committee on toxicology have also worked closely with FDA over the years, most recently concerning the above-mentioned Hazardous Substances Labeling Act. The council on foods and nutrition is most active in exchanging information with FDA and in cooperating with it, the Federal Trade Commission, and the U.S. Post Office in sponsoring an aggressive program against food faddism and food and vitamin quackery.

In addition to these cooperative activities, the AMA frequently comments on proposed administrative regulations of the Food and Drug Administration and other governmental agencies. We are now preparing comments on the proposed regulations of FDA for special dietary foods, including vitamin supplements, and the recently proposed regulations pertaining to new drugs for investigational use.

EXHIBIT B

THE AMERICAN MEDICAL ASSOCIATION-UNITED STATES PHARMACOPOEIA COOPERATIVE PROGRAM FOR THE SELECTION OF NONPROPRIETARY NAMES FOR DRUGS

The objectives of this program are to facilitate the selection of a suitable nonproprietary name for each single entity drug and to encourage the use of such selected names wherever indicated in labeling, in advertising, as titles in the official compendia, and in the scientific literature.

A joint committee known as the AMA-U.S.P. Nomenclature Committee has been established to negotiate with the manufacturers. This committee consists of four members. Two members are nominated by the AMA subject to the approval of the U.S.P.; the other two members are nominated by the U.S.P. subject to the approval of the AMA.

The American Medical Association maintains for the committee and will expand, as necessary, its present staff and facilities for receiving proposals of nonproprietary names from all sources, processes these proposals and initiates and conducts such negotiations as expeditiously as may be appropriate to settle upon a tentative name for all new drug entities.

It is probable that in a given number of nonproprietary name negotiations the AMA-U.S.P. Nomenclature Committee and the manufacturer(s) may fail to reach an accord satisfactory to each. The AMA and U.S.P. have appointed a board known as the nomenclature review board to determine the merits of such cases and to make a final decision thereon. This board acts upon the request of either the committee or the manufacturer(s) involved.

The nomenclature review board consists of five individuals of judicial temperament and highly respected status in medicine and pharmacy; the AMA recommended to the U.S.P. several names of potential candidates from which list two members were selected by the U.S.P. to serve on the board. The terms of board members overlap to insure continuity. One member is to be added to the board, on an ad hoc basis but without vote, to represent the firm making the protest. If more than one firm is involved, an ad hoc member from each will be added. The board functions primarily through correspondence.

The decisions of this board, which are final for this stage of the negotiation, is reported to all interested parties.

Tentatively adopted (as a result of above action) nonproprietary names are referred to the cooperating agencies (N.F., WHO, B.P. Commission, French Codex, Nordic Pharmacopoeia) for their consideration and comment, in accordance with past policy leading to the final adoption by the committee for national use in the United States. This name when adopted is referred to as USAN (U.S. Adopted Name).

Names adopted by this nomenclature committee are the designations used in the council on drugs (AMA) monographs on individual drugs and are the nonproprietary names used in the scientific journals of the AMA. The AMA promptly notifies the editors of medical journals and professors of pharmacology of all medical schools in the United States of the adopted name.

The U.S.P. (1) adopts the names so selected as the U.S.P. titles when and if the articles concerned are admitted to the U.S.P.; and (2) undertakes to publish lists of the names at frequent intervals through appropriate channels.

It should be made clear, of course, that adoption of publication of the name implies no endorsement whatever, by the committee, the AMA, or the U.S.P., of the merits of the articles to which the name apply.

Both the U.S.P. and the AMA make reasonable efforts to notify the industry and the professions of medicine and pharmacy that the committee is maintaining this invaluable service on the common names for drugs. The committee also undertakes to notify other national and international agencies of the names selected.

The U.S.P. has organized a concerted campaign to acquaint the editors of all medical and pharmaceutical journals of this service and the availability of nonproprietary names for all drugs that are likely to be the subject of published articles. Efforts are being made to encourage the Food and Drug Administration and the Federal Trade Commission to extend their respective areas of authority to the limit in seeing that the selected names, and only those, are used wherever nonproprietary names appear in drug labeling and advertising.

In the name of the committee, the AMA staff maintains all contacts in connection with the process of selection and negotiation as at present, including all participating in the World Health Organization program.

PRINCIPLES GOVERNING ADVERTISING IN THE AMA SCIENTIFIC PUBLICATIONS

The American Medical Association seeks to promote the science and art of medicine and the betterment of public health. In serving these aims, the AMA communicates regularly with the members of the medical profession, with professional persons in allied fields, and with the public. A substantial part of this communication is carried on through the regular production and distribution of several publications.

In keeping with its avowed purposes, the association will do all it reasonably can to insure the accuracy, comprehensiveness, timeliness, and relevancy of the advertising content of these publications. The evaluation of advertising copy will be based on the consideration of available data concerning the product or service. It will not be based on tests conducted by the AMA.

The appearance of advertising in AMA publications should not be construed as a guarantee or endorsement of the product by the association. The fact that an advertisement for a product, service, or company has appeared in an AMA publication shall not be referred to in collateral advertising without specific authorization from the American Medical Association.

As a matter of policy, the AMA will sell advertising space in its publications when (1) the buyer believes purchase of such space represents a sound expenditure, (2) the inclusion of advertising material does not interfere with or seriously detract from the purpose of the publication; and (3) the advertising copy meets the standards established for that publication.

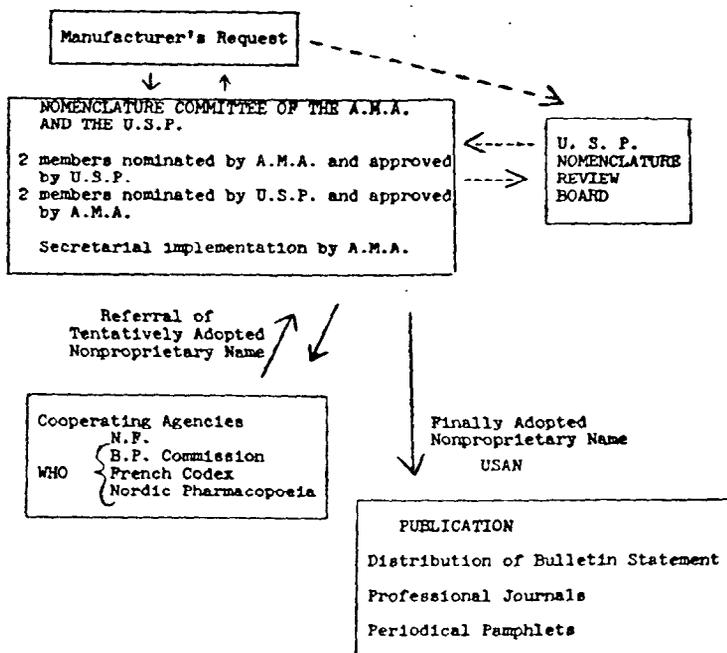
GENERAL PRINCIPLES GOVERNING ADVERTISING IN AMA SCIENTIFIC PUBLICATIONS

The following general principles set forth the criteria which the American Medical Association will follow in screening advertising to be carried in the AMA scientific publications (The Journal and 10 specialty journals). The association reserves the right to change these principles in the light of developments in medicine or in industry.

DRUG INDUSTRY ACT OF 1962

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COOPERATIVE NOMENCLATURE PLAN
of
AMERICAN MEDICAL ASSOCIATION
and
UNITED STATES PHARMACOPEIA



U.S.P. also will publicize program itself and seek out recognition of these activities from both F.D.A. and F.T.C.

Eligibility for advertising

1. Products or services eligible for advertising shall be germane to, effective in, and useful in the practice of medicine and shall be commercially available.
2. Pharmaceutical products will not be eligible for advertising until a new drug application from the Food and Drug Administration has become effective.
3. Institutional-type advertising germane to the practice of medicine and public service messages of interest to physicians may be considered eligible for appearance in the scientific publications.
4. Alcoholic beverage and tobacco products are not eligible for advertising.
5. The association may decide that certain products or services are not eligible for advertising in AMA's scientific journals if advertisements for these products or services in other media consistently, or significantly, depart from the standards set forth in the following section.

ADVERTISEMENTS FOR SPECIFIC TYPES AND CLASSES OF PRODUCTS AND SERVICES

1. Drugs

For convenience, advertisements for drugs (including vaccines and biologicals) may be separated into four categories, as follows:

- (a) *New drugs or new claims for drugs which have not previously been advertised in AMA publications*—A new drug is here defined as a single active in-

redient (examples: reserpine, deserpidine) or an extract from a single source (examples: alseroxylon, rauwolfia). Example of a new claim: use of an established antimalarial drug, such as chloroquine phosphate, in rheumatoid arthritis. In all such cases, the department of advertising evaluation will require six copies of supporting scientific evidence for review. It is suggested that laboratory and clinical data on new drugs be submitted to the American Medical Association at the time a new drug application is filed with the Food and Drug Administration. This will make it possible, in many cases, to obtain product and advertising clearance prior to the introduction of the drug. However, the association will not grant final clearance of advertising until notified that the new drug application has been made effective by FDA.

(b) *Drugs which represent a modification of an eligible product.*—Example: Some modification of a previously eligible drug such as a new salt or ester. Six copies of all pertinent laboratory and clinical data should be forwarded to the department of advertising evaluation.

(c) *Mixtures of drugs which are already considered eligible.*—For example, a mixture of reserpine and amphetamine was regarded as new at one time. Six copies of clinical and pharmacological data should be forwarded for consideration by the department of advertising evaluation. Clearance depends primarily on showing justification for the rationality of the combination.

(d) *Drugs which represent an additional brand of a product that is already eligible.*—Nothing further is needed than the proposed advertising copy for consideration by the department of advertising evaluation.

2. *Apparatus, instruments, and devices*

The department of advertising evaluation determines the eligibility of products and suitability of claims for medical equipment intended for preventive, diagnostic, or therapeutic purposes. Advertisements for new products and new claims should be accompanied by six copies of information presenting full and adequate scientific and technical data concerning the product's safety, operation, and usefulness, including the results of laboratory and clinical examination. These data may be either published or unpublished. Samples of apparatus, devices, equipment, or instruments should not be submitted unless specifically requested by the department of advertising evaluation.

3. *Food products and vitamin preparations*

Advertisements for food products and vitamin preparations may be separated into four categories, as follows:

(a) *General-purpose foods.*—Those foods promoted for use by the population in general. Examples would be bread and processed meats, fruits and vegetables. Advertisers of such products should submit six copies each of descriptive literature, labels, and a statement of composition where pertinent.

(b) *Special-purpose foods.*—These are foods for special dietary uses subject to the labeling conditions imposed by section 403j of the Federal Food, Drug, and Cosmetic Act. Examples are foods manufactured and promoted for use by certain specific segments of the population, such as infants, invalids, as well as others requiring foods with certain properties, i.e., foods for carbohydrate-restricted diets, sodium-restricted diets, and other therapeutic diets. Advertisers of such products should submit six copies of labels, statement of composition, and analytical data. When pertinent they should be supported with data demonstrating the effectiveness of the product for its intended use. If new claims are made for a previously advertised product, six copies of clinical data substantiating such new claims must be submitted.

(c) *Supplemental vitamin preparations: Rational mixtures of the vitamins recognized to be essential in human nutrition or metabolism in amounts not differing greatly from the recommended dietary allowances of the Food and Nutrition Board of the National Research Council are eligible. However, with the exception of iron-containing and calcium-containing preparations that are intended for use during pregnancy, vitamin mixtures to which minerals are added (as contrasted to trace minerals which are inherent in the manufacturing process) are not eligible for advertising.*

(d) *Therapeutic vitamin preparations.*—Rational mixtures of the vitamins recognized to be essential in the amounts not greater than five times the recommended dietary allowances are eligible. However, preparations containing a mixture of all or most of the following antianemic factors—vitamin B₁₂, folic acid, intrinsic factor, iron, ascorbic acid, and copper—are not eligible for advertising. If claims not generally recognized are made for any of the vitamins,

or mixtures of vitamins, such claims shall be substantiated with six copies of clinical studies in support of such claims.

4. *Cosmetics*

For cosmetics with acknowledged sound health claims, only the qualitative formula need be given. In the event that a question of safety arises, quantitative data on the one or more ingredients in question are necessary. In the case of a new cosmetic, or a cosmetic to which new ingredients have been added, six copies of supporting data for the product's safety and ability to perform as claimed should be forwarded to the department of advertising evaluation for review. Since relevancy to medical practice is one of the prerequisite for eligibility, it should be emphasized in each advertisement.

5. *Books*

A book may be requested for review so that its eligibility for advertising may be determined.

6. *Miscellaneous products and services*

Products or services not in the above classification may be eligible for advertising if they satisfy the criteria for eligibility and suitability.

SUITABILITY OF ADVERTISING COPY

After a product or service has been declared eligible to be advertised in the scientific publications of the AMA, the department of advertising evaluation must approve each advertisement. As in the case of eligibility, the AMA makes the final decision regarding the suitability of copy, layout, and artwork. The AMA's decisions on these matters will be guided in all cases by the following principles:

1. The advertisement should clearly identify the advertiser and the product or service being offered. In the case of drug advertisements, the full generic name, including salt and ester designation, of each active ingredient must be shown in appropriate type size. If the generic name of a drug appears in close juxtaposition to the trade name, it should not be unduly subordinated, and under no circumstances appear in less than 8-point type. If the generic name does not appear in close juxtaposition to the trade name, it should not be unduly subordinated and under no circumstances appear in less than 10-point type.
2. Advertisements should not be deceptive or misleading. Layout, artwork, and format should be such as to avoid confusion with the editorial content of the publication.
3. Unfair comparisons of the blatant and unwarranted disparagement of a competitor's products or services will not be allowed.
4. Sweeping superlatives or extravagantly worded copy will not be allowed. Any claims for superiority must be supported by evidence acceptable to the association.
5. Quotations or excerpts from a published paper are acceptable only if they do not distort the meaning intended by the author. Claims made within quotations must conform to the same standards as unquoted claims.
6. Advertisements will not be accepted if they appear to conflict with the principles of medical ethics.

PROCEDURES OF THE AMA DEPARTMENT OF ADVERTISING EVALUATION (SCIENTIFIC JOURNAL)

The AMA Department of Advertising Evaluation is responsible for applying the foregoing principles and standards to advertising copy submitted for publication in AMA scientific journals. It will do so in accordance with the following procedures:

1. *Submission of data.*—The department of advertising evaluation requires that scientific data be submitted to substantiate claims made for new products (such as drugs, devices, or foods) or new claims for products which have previously appeared in AMA scientific journals.
2. *Type of data needed.*—Data should include pertinent reports published and unpublished, favorable and unfavorable, of laboratory and clinical investigations covering the efficacy and relative safety of the product (drug, device, or food) under consideration. These data should be based upon sound studies and should be sufficiently comprehensive to permit a critical evaluation of the

subject matter. While the quantity of the scientific data required will depend on the type of product, the nature of the medical problem involved, and the claims made in the advertising copy, the quality of the evidence is regarded as highly important; in this respect, the importance of suitable controls is emphasized. Compilations of individual case reports are ordinarily not considered acceptable evidence. The unpublished portion of all submitted data will be regarded by the department of advertising evaluation as confidential, and consultants will be requested to treat it accordingly.

3. *Consultation.*—The AMA Department of Advertising Evaluation frequently seeks the opinions of consultants and recognizes the statements formulated by AMA councils and committees in determining the eligibility of products and the suitability of claims. The consultants for the department of advertising evaluation are persons who have been selected for their competence in the field involved. Names and affiliations of the consultants are not made available.

Time requirements for department of advertising evaluation

Although the department of advertising evaluation cannot guarantee adherence, in all cases, to a fixed time schedule, every effort will be made to expedite completion of AMA consideration in the following time intervals:

Advertisements for eligible products with no new claims.—From the time copy is received, 5 working days should be allowed for AMA consideration.

Advertisements involving new claims for or modifications of currently eligible products, or both.—From the time copy and, if necessary, supporting data are received, 15 working days should be allowed for AMA consideration.

Advertisements for new products.—From the time copy and supporting data are received, 20 working days should be allowed for AMA consideration.

In those cases in which AMA consideration cannot be completed prior to the expiration of the foregoing time intervals, the advertiser or agency will be so informed.

As a matter of policy, the AMA will periodically review its principles of advertising with the view of keeping pace with changes that may occur in the industry and the profession. It is hoped by this policy of continuous review and reevaluation to insure and improve the timeliness, relevancy, and appropriateness of the advertising content of AMA scientific publications.

AMERICAN MEDICAL ASSOCIATION,
Chicago, Ill., August 31, 1962.

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

DEAR MR. HARRIS: The purpose of this letter is to supplement the association's comments on H.R. 11581 and S. 1552 submitted to the committee on August 29, 1962.

The American Medical Association is also concerned with those provisions of section 7 of S. 1552 which would give discretionary authority to the Secretary of Health, Education, and Welfare to include in regulations, governing exemptions from the law for drugs used for investigational purposes, provisions for requiring (1) adequate animal tests, and (2) registration with the Secretary of "scientific experts" who would be required to keep records of tests performed and "to furnish to the Secretary simultaneous copies of their reports to the manufacturer and, upon request of the Secretary, reports at other times." We are opposed, at this time, to action with respect to these provisions of S. 1552 inasmuch as there are proposed regulations on these subjects which were published in the Federal Register by the Food and Drug Administration on August 10, 1962. The notice of the proposed regulations invited comments from interested parties.

In view of this fact and the fact that neither the Senate Judiciary Committee nor your committee had an opportunity to receive testimony and to study these provisions in all their effects, we urge that they be deleted from the legislation. Favorable consideration by Congress on provisions of this nature would have the effects of prejudging the validity of the proposed regulation and negating comments on the proposed regulation by interested parties.

The American Medical Association is equally concerned and opposed to favorable action on the remaining provisions of section 7 of S. 1552 and sections 102(b)(5), 103(b), and 106(b) of H.R. 11581, which would require reports on

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effectiveness or efficacy of drugs used for investigational purposes. Our reasons for this position are stated fully in our previously submitted statement.

I appreciate this opportunity to submit these additional comments and would request if possible that they be made part of the record of your hearings.

Sincerely yours,

F. J. L. BLASINGAME.

STATEMENT OF AMERICAN PHARMACEUTICAL ASSOCIATION ON H.R. 11581, BY
DR. WILLIAM S. APPLE, EXECUTIVE DIRECTOR

As the professional society representing individual pharmacists in all facets of professional practice, the American Pharmaceutical Association (A. Ph. A.) is aware of the intense interest of Congress in proper health care for the people. We assure you that pharmacists share this interest and wish to cooperate to the fullest extent in all activities which best serve public health, safety, and welfare.

Since its inception in 1852, the American Pharmaceutical Association (A. Ph. A.) has never had a financial interest in any drug product, drug manufacturer, drug wholesaler, or drugstore. The first objective of our members, as stated in our constitution, is: "To improve and promote the public health by aiding in the establishment of satisfactory standards for drugs, and to aid in the detection and prevention of adulteration and misbranding of drugs and medicines, and to take such steps as an association and in cooperation with other organizations as will assure the production and distribution of drugs and medicines of the highest quality."

It is for this reason that we presented extensive testimony on S. 1552 and H.R. 6245, as they were originally proposed, on December 19, 1961, and May 24, 1962, respectively.

Because the basic objective of the profession of pharmacy is serving and safeguarding public health, we endorse the objectives of H.R. 11581. Because we recognize that this committee is making its appraisal in the public interest—present and future—the American Pharmaceutical Association (A. Ph. A.) believes that this committee will be interested in our opinions regarding specific sections of H.R. 11581.

ADVERTISING PRESCRIPTION-LEGEND DRUGS

H.R. 11581 would amend the section of the Federal Trade Commission Act concerned with definitions and, in particular, the term "false advertisement" as used in the act. In effect, the bill would require every advertisement to the medical profession to carry full information on side effects and contraindications as well as the common or usual name of each ingredient.

Another advertising matter to which committee attention is invited is the promotion of prescription-legend drugs to the public. Such advertising disregards the inherently dangerous nature of drugs and results from a misunderstanding of the professional services involved in prescribing and dispensing prescription medication. Our profession is gravely concerned by the advertising and trading of prescription-legend drugs as commodities in commerce.

As expressed in the regulations proposed by the Food and Drug Administration in the Federal Register of August 10, 1962, the American Pharmaceutical Association (A. Ph. A.) endorses the position of the Federal Government proscribing the advertising or promotion of investigational drugs. It now appears only logical for the Federal Government to similarly proscribe the advertising or promotion of prescription-legend drugs to the public. Both the Federal Food, Drug, and Cosmetic Act and the Federal Trade Commission Act provide an appropriate means for the Federal Government to make known that it will not condone a practice many of our States, and numerous other nations, already condemn.

Because an investigational drug is not available to medical practitioners for general treatment, there is no valid reason for either a sponsor of the drug, or any person on his behalf, to disseminate advertising, public relations statements, or news releases representing the drug to be safe or useful for the purposes for which it is intended.

Similarly, because a prescription-legend drug is not available for general sale to the public, there is no valid reason for either a pharmacy, or any person on its behalf, to disseminate advertising, public relations statements, or news releases representing the drug to be available for the purpose for which it is intended.

If the drug is available for general treatment or general sale, the purpose of advertising or promoting it is to induce, directly or indirectly, the use or purchase of the drug. The advertising or promotion of a drug which is not available for general treatment or general sale—investigational or prescription-legend—is both false and misleading.

FEDERAL REGISTRATION AND "FACTORY" INSPECTION

A Federal registration of all interstate drug manufacturers has the obvious advantages of identifying sources of origin, inviting inspections, and fostering control of manufacturers in the public interest. However, we urge that any language incorporating a Federal registration and inspection for drug manufacturers provide that such Federal registration and inspection shall not preempt or preclude States from licensing, controlling, or otherwise regulating manufacturers doing business within such States. Nor should such Federal registration of drug manufacturers and factory inspection permit Federal invasion of confidential patient health files, including prescription records.

The dispensing of prescription medication by pharmacists in pharmacies is a matter of licensing and regulation which States exclusively control under their police power. Therefore, we want to be certain that any Federal registration is not intended to invade areas of authority heretofore exclusively exercised by States over professional activities which have always been intrastate in nature. These activities include:

- (1) A doctor, licensed by a State, administering a drug to a patient in that State; and,
- (2) A pharmacist, licensed by a State, compounding or dispensing a drug for a patient in that State.

The fact that the particular drug employed by these practitioners may have moved in interstate commerce should not be used as the entering wedge for Federal control of the professions.

We note that John L. Harvey, Deputy Commissioner, Food and Drug Administration, whose American Bar Association speech was entered in the August 13, 1962, Congressional Record, analyzed provisions of H.R. 11581. He stated: "These requirements, however, would not apply to licensed practitioners who dispense such drugs in the course of their professional practice." (Par. 1, col. 3, p. 15239.)

The pharmacist dispenses prescription-legend drugs only in the course of his professional practice. To clarify the intent of Congress, we urge the following language for appropriate inclusion within H.R. 11581:

"The provisions of this act shall not apply to persons who are lawfully entitled under State law to compound, dispense, prescribe, distribute, or administer drugs to patients within that State, nor shall the provisions of this section confer rights or privileges to conduct business or engage in professional pursuits contrary to State law."

This specific language embraces both the prescribing and the dispensing professions without affecting the intended registration and factory inspection of drug manufacturers, wholesalers, and others.

ANTIBIOTIC CERTIFICATION

In the earliest days of their preparation, penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin were concentrates of extractives from culture media containing micro-organisms. Variations in the strength, quality, and purity of these concentrates originally made it difficult or impossible to establish adequate standards under which identity, strength, quality, and purity could then be determined and assured.

However, through modern methods of production, synthesis, and purification, these substances which may be called antibiotics, are essentially pure substances, frequently recrystallized salts, possessing the same degree of purity as any other fine chemical. Existing certification procedures and proposals to extend such certification procedures do not take into account advances in analytical techniques which can provide more accurate methods of analysis.

Under such conditions, where adequate standards can be set to assure the identity, strength, quality, and purity of a substance, we oppose continuing the certification process.

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NOMENCLATURE—STANDARDIZATION OF DRUG NAMES

When a new compound is discovered or synthesized, it is important that the name assigned to the compound be informative, convenient and distinctive. This is necessary in the interest of advancing science, be it medical, pharmaceutical, chemical, or any other science. Such a determination in nomenclature, if it is to have maximum utility to those professional and scientific persons who must work with and use the article, must be determined in relation to all other compounds available and the informative, convenient, and distinctive considerations mentioned above.

It is both scientifically and economically important to one who has synthesized a new chemical entity to establish a permanent, useful, official, nonproprietary name at an early date. In so doing, clinical and scientific reports and other pertinent data are more easily followed and the potentialities of the accomplishment, therefore, are more easily assessed.

The general principles of nomenclature followed in the revisions of the United States Pharmacopoeia and the National Formulary are consistent with sound scientific principles and provide that the primary title of each drug monograph shall be in English and shall be, as far as possible, convenient for prescribing and dispensing and in harmony with general usage.

These guiding principles further provide that short titles wherever needed shall be coined for synthetic organic chemicals with cumbersome names, and shall be based upon rational chemical names.

Commonly used names may be inserted in the United States Pharmacopoeia and the National Formulary as synonyms in the official monograph after the official title. Botanical and zoological names conform to the rules of the International Botanical Congress and the International Zoological Congress. This system of nomenclature is designed to be most useful to practitioners who must rely upon and work with these compounds. It has proved most satisfactory for over three quarters of a century.

Further, drug name standardization can be achieved under H.R. 11581 by employing the specific procedures described in addendum II.

UTILIZATION OF EXISTING AUTHORITY

The thalidomide incident has resulted in proposed regulations strengthening controls over investigational drugs. These regulations afford additional safeguards and are being promulgated by FDA pursuant to its existing authority under the Federal Food, Drug, and Cosmetic Act.

Unfortunately, the proposed regulations only concern new, investigational drugs. They do not relate to drugs which have been approved by FDA for general use by physicians, dentists, veterinarians, and other related practitioners. For this reason, the American Pharmaceutical Association (APA) cautions against the illusion that the proposed regulations will give the degree of patient or consumer protection necessary with drugs.

A drug which may be investigational today may be marketed tomorrow. The investigational legend is soon replaced by the prescription legend. This can be hazardous because a defect in drug distribution exists. Frequently, drugs bearing the legend "Caution: Federal law prohibits dispensing without prescription" are made available through persons other than pharmacists and from places other than pharmacies. The health of our citizens is fully protected only when all drugs are distributed to the pharmacist and personally dispensed by him.

All drugs today are more potent than ever, and the consequences from misuse, or abusive use, are more serious than ever. In drug matters, the knowledge, skill, caution, responsibility, and ethics of a pharmacist are more important than ever before. As the FDA stated in FDA Leaflet No. 12 (1960):

"A pharmacist is more than a purveyor of drugs—he is a member of the team of experts who have been scientifically trained to provide medical care to the people. As a consultant to the prescriber and the custodian of drugs for the community, he is licensed by law to dispense them according to the prescriber's instructions and the requirements of law.

"If we did not have the pharmacist, it would be necessary to invent him."

But the pharmacist does exist and he does not need to be invented. The pharmacist only seeks the opportunity to serve through the legitimate practice of his profession.

STATEMENT BY FRANK T. DIERSON, GENERAL COUNSEL, ON BEHALF OF GROCERY MANUFACTURERS OF AMERICA, INC., ON H.R. 11581, DRUG AND FACTORY INSPECTION AMENDMENTS OF 1962

1. OPPOSITION TO UNLIMITED INSPECTION

The bill H.R. 11581 would amend the Federal Food, Drug, and Cosmetic Act by adding an unlimited power of factory inspection which is unnecessary, detrimental to public interest, and probably unconstitutional. Therefore, Grocery Manufacturers of America, Inc., a national, nonprofit trade association representing some 300 food and grocery product manufacturers, urges the House Committee on Interstate and Foreign Commerce to drop title II of the bill, which proposes the objectionable grant of additional inspection power.

2. GMA—A SUPPORTER OF MANDATORY FACTORY INSPECTION

Ten years ago the Supreme Court of the United States ruled in the *Cordif* case (344 U.S. 174, 1952) that the Federal Food, Drug, and Cosmetic Act did not authorize the Food and Drug Administration to inspect a factory except by voluntary permission of the owner. At that time Grocery Manufacturers of America, Inc., appeared before this congressional committee and supported the enactment of legislation for compulsory factory inspection; such enabling legislation was urged as required by the public interest, and appropriate congressional limits on the inspection power were approved to assure its fairness and constitutional validity. Both Houses of Congress subsequently passed a bill to enact what House Report No. 708 (83d Cong., 1st sess.) described as "compulsory, but limited inspection authority." The authoritative House report explained that addition of the new statutory language "within reasonable limits and in a reasonable manner" was intended "for the purpose of confining the scope of inspection to factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, containers and labeling therein." The Food and Drug Administration has successfully administered the act in this form since that time, and we are aware of no development in the food industry which calls for the extraordinary expansion of factory inspection now proposed.

3. TITLE II OF THE PENDING BILL

In contrast to the foregoing congressional definition of a "reasonable" factory inspection power, title II of H.R. 11581 would expand such power beyond anything reasonably required for enforcement of the Federal Food, Drug, and Cosmetic Act. For it would amend section 704 of the act, first to reach a manufacturer's consulting laboratory, in addition to his own factory; and second, to permit inspectors of a factory to examine "all things therein (including records, files, papers, processes, controls, and facilities)" bearing on violations or even potential violations of the act.

4. CONGRESSIONAL RULE OF REASONABLE INSPECTION

The itemized scope of the proposed new inspection power is reminiscent of the record inspection cases which Congressman Hinshaw described as "obnoxious" in House debate on the 1953 Factory Inspection Amendment. Messrs. Wolverton, Harris, Bennett, Priest, and Younger were of a similar mind. In House Report No. 708, and in statements on the floor, they determined that the language of the 1953 amendment represented a reasonable rule of factory inspection, and in doing so, they specifically insisted that the scope of such inspection does not include formulas, methods, processes, shipping records, complaint files, qualification of technical personnel, and prescription files.

5. UNREASONABLE SCOPE OF PROPOSED INSPECTION

Apart from its specific enumeration of records, formulas, etc., subject to inspection, title II of the bill enlarges inspection power to reach "all things" in a factory "bearing on" violations or potential violations of the act. This language is so broad as to lend itself to unlimited application by administrative interpretation. It is unsuitable for use in the Federal Food, Drug, and Cosmetic Act, first, because the act is an unusually drastic penal law whose violation can be punished by personal criminal conviction of a corporate agent, even in

the absence of any guilty knowledge or intent on his part; second, because such broad language affords no intelligent basis for a manufacturer's resistance to excessive demands by a field inspector, and puts him to unjustified legal hazard where he attempts it. It may well be that by routinely invoking this broad grant of power inspectors could force disclosure of valuable private information about manufacturers' production, packaging, labeling, advertising, marketing, pricing, and financial position.

C. INDUSTRY OPPOSITION—PRIVATE CONSIDERATIONS

In this situation a food manufacturer opposes unlimited factory inspection, not because he has something to hide, but because he believes he has a constitutional right to protect from disclosure and loss his private property in patents, formulas, processes, and other trade secrets. His understandable fear of such disclosure is increased by knowledge of the fact that State and local officials may be commissioned by the Food and Drug Administration to supplement the inspection activities of Federal agents. As a practical matter he knows that inspectors frequently leave Government service to take employment in the food industry, perhaps with a rival processor. In all such cases it would be difficult if not impossible to prove an unlawful breach of official confidence, and the manufacturer is therefore reluctant to disclose information which is not clearly pertinent to the statutory purpose of public protection.

The foregoing considerations apply equally to the proposal for unrestricted inspection of a manufacturer's independent laboratory. Traditionally entrusted with secret information in a professional, consultant-client relationship, the independent laboratory, if subjected to such inspection, is even less able under the proposed authority to assert appropriate resistance to excessive demands of a field inspector. When it is remembered that independent laboratories are not producers or distributors of food products and that such professional testing, research and development organizations do, as a matter of policy, cooperate with the Food and Drug Administration and other Government scientific agencies, there appears to be no good reason for extending the proposed inspection controls to their operations and records.

D. OPPOSITION—PUBLIC CONSIDERATIONS

The keeping of accurate corporate records relating to manufacturing process, quality controls, consumer complaints, personnel qualifications, etc., is a voluntary practice normally and faithfully observed by the food manufacturer. He follows these procedures in order to maintain and improve the quality of his product, to correct any deficiencies as quickly as he can discover them, and by experience and training to develop the finest professional staff to conduct skillful research, development, production, and distribution in the field of his food technology. It requires little more than a statement of the food manufacturer's reasons for keeping these records to demonstrate that they indirectly but importantly contribute to the welfare of consumers, and that anything which needlessly discourages the keeping of these records operates to the detriment of the public interest. Therefore Congress should carefully consider the possibility of progressive neglect of recordkeeping as an adverse and undesirable consequence of the unlimited factory inspection authority proposed.

Reference has already been made to the drastic criminal punishment which may be visited upon individuals for even inadvertent violations. In *U.S. v. Dotterweich* (320 U.S. 277, 1943), the Supreme Court of the United States noted the fact that under the Federal Food, Drug, and Cosmetic Act, penalties serve as effective means of regulation, and it spoke as follows of a prosecution under the act in which guilt was imputed to a defendant solely on the basis of his authority and responsibility as a corporate officer:

" * * * Such legislation dispenses with the conventional requirement of criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. * * * "

E. REGULATION VERSUS PROSECUTION

The food manufacturer sees in this inspection proposal a shift from traditional agency inspection practices to a system of search and seizure in which inspection becomes a "fishing expedition" designed to obtain evidence for civil

and criminal prosecutions. Who can say that even a reputable manufacturer will ignore this danger in deciding whether or to what extent he should make and keep records with respect to complicated problems he is working to solve within the letter and spirit of the act. The greatest incentive for production of wholesome and nutritious food in the United States is the competitive rivalry among manufacturers to produce the finest products by applying modern advances in food science and technology. Punitive provisions should not be permitted to overshadow a sound regulatory and educational administration of the Federal Food, Drug, and Cosmetic Act which maximizes voluntary compliance. Such administration of the act is to be preferred as a constructive enforcement policy which best assures the attainment of its great social and economic objectives.

9. ADEQUACY OF EXISTING POWER

It remains to emphasize that the Food and Drug Administration already possesses ample powers of inspection and investigation which are sufficient to protect the public interest. In addition to its authority for mandatory factory inspections under section 704, the Food and Drug Administration can, where necessary, take advantage of regular search warrant procedure upon showing evidence to a court that a violation is probably taking place. The agency may also invoke the subpoena power of a grand jury. Furthermore, in bringing court action against a violator the agency can obtain all the information it requires by written interrogatories and other discovery procedures authorized by the Federal Rules of Civil Procedure.

10. CONCLUSION

For all of the foregoing reasons, Grocery Manufacturers of America, Inc., respectfully urges the House Committee on Interstate and Foreign Commerce to strike out title II of the bill, H.R. 11581, which proposes the objectionable grant of unlimited factory inspection power. The present language of section 704 of the Federal Food, Drug, and Cosmetic Act was, after careful congressional deliberation, designed to authorize a compulsory but reasonable form of factory inspection. Ten years of experience with that section have confirmed the soundness of its draftsmanship by this committee. Arguments for adoption of title II of this bill are substantially the same as those pressed upon Congress by earlier advocates of unrestricted inspection power. We hope that Congress will maintain its original position; namely, that the Food and Drug Administration should have authority for a reasonable factory inspection, and that section 704 of the act as now written, confers it.

STATEMENT OF NATIONAL ASSOCIATION OF REFRIGERATED WAREHOUSES RE H.R. 11581 TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBMITTED BY JOSEPH H. COLQUITT

The National Association of Refrigerated Warehouses consists of nearly 500 member plants throughout the United States representing approximately 80 percent of the public refrigerated warehouse space in the country.

Both this association and its members believe that a strong and effective Food, Drug, and Cosmetic Act—including adequate inspection authority—is necessary for the protection of the consuming public. We believe that the existing inspection authority is adequate to provide this protection. We are, therefore, strongly opposed to the provisions of section 201 of H.R. 11581 which would extend this inspection authority to include "all things * * * (including records, files, papers, processes, contracts, and facilities) * * *."

H.R. 11581 is concerned with the manufacture and marketing of drugs and antibiotics, not with foods. In fact, except as it appears in the name of the act which this bill would amend, the word "food" is never even mentioned in title I of the bill. Yet title II would amend the act so as to impose far more stringent inspection provisions on warehouses storing solely food as well as drug and cosmetic warehouses. It is grossly unfair to penalize perishable food warehouses with these almost limitless inspection provisions when it is not necessary.

Present provisions of the law covering warehouse inspection give FDA inspectors access to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein."

These provisions have proven completely adequate insofar as food inspection is concerned. This is attested by the food industry's excellent record in providing Americans with the greatest quantities of the most healthful foods in the world. In particular is the record of the public refrigerated warehousing industry an outstanding one in annually handling billions of pounds of perishables with a near perfect record.

Another reason we oppose such all-inclusive inspection authority as that provided by H.R. 11581 is its inherent dangers. It would open up to inspection confidential company files, personnel records, correspondence, and anything else which in the opinion of individual inspectors might be pertinent. Such authority could not possibly be exercised uniformly with fairness to all and the possibility of excesses would be substantially increased over that now existing.

Finally, an unusual situation exists with respect to public warehouses. The goods stored in public warehouses belong not to the warehousemen, but to his customers. The public warehouseman has no interest in the goods in his warehouse other than to give them proper care and protection. He is merely a custodian.

As agent for the owner of the goods, the public warehouseman can legally and morally act for him with respect to his goods only on his instructions. In addition there is a certain confidence between the public warehouseman and his customers similar to that between a banker and his depositors. An inspection authority which extends to "all things" in the warehouse is viewed by all conscientious warehousemen as a violation of these principles.

The present law under which inspectors may enter a public warehouse, inspect the goods stored, and take samples has proven effective. Anything further is an infringement of personal or business privacy, is subject to excesses and is a violation of the public warehouse-customer relationships.

We emphatically urge that there be no further extension of inspection authority under the Food, Drug, and Cosmetic Act.

STATEMENT OF PERRY R. ELLSWORTH, ASSOCIATE DIRECTOR, MILK INDUSTRY FOUNDATION, WASHINGTON, D. C., REGARDING H.R. 11581, TITLE II, RELATIVE TO CLARIFICATION AND STRENGTHENING OF FACTORY INSPECTION AUTHORITY OF FOOD AND DRUG ADMINISTRATION

The Milk Industry Foundation is opposed to title II of H.R. 11581, 87th Congress, 2d session, which is designed to broaden existing authority of the Food and Drug Administration, Department of Health, Education, and Welfare, to conduct inspection of food establishments. It is the position of the Milk Industry Foundation that existing authority of the Secretary of Health, Education, and Welfare in this area is already sufficient to enable him to fulfill his responsibilities.

This statement is submitted pursuant to authorization of the board of directors of the Milk Industry Foundation, which is a national trade association of fluid milk processors and distributors, with member companies in every State of the Union. These members range in size from the large national dairies to small local companies.

In submitting this statement, the Milk Industry Foundation is presenting the views of its members as processors and distributors of one of the most important foods of the Nation; namely, milk and milk products, which are considered basic to the health and diet of the people of this country.

As the "milkmen of the Nation," the industry represented by the Milk Industry Foundation has a vital personal stake in preserving the purity and wholesomeness of the products which it provides to the public. The industry takes this responsibility very seriously. No governmental agency, Federal or State, can possibly be more concerned with the wholesomeness and the purity of the product which the milk industry purveys than the milk industry itself.

This is mentioned because it is very pertinent to the issue of whether the Congress should enact title II of H.R. 11581. The need for external regulation is less where the enlightened self-interest of the industry is such that the industry, itself, assumes full responsibility for the distribution of wholesome products.

The keen responsibility felt by the members of the milk industry is a responsibility shared by the vast majority of American food manufacturers.

The living standard of this country is, of course, one of the highest in the world, and this is particularly true with respect to the diet of the American

people. This result could not have been achieved had the members of the food industry, including the milk industry, not taken a personal responsibility for the type of food products which are sold to American consumers.

It is also recognized that Government has played its part in the highly developed existing system for the production and distribution of food to the people of this Nation. Perhaps, however, more than in any other area of our national life, it can be said that the Government has not played the dominant role in this magnificent development.

The Federal Government already possesses ample authority in the present provisions of the Food, Drug, and Cosmetic Act of 1938, as amended (21 U.S.C. 321 et seq.) to enter and inspect any place where food is kept or manufactured or held for shipment in interstate commerce. Section 704 of that act is the key provision of the present law which would be amended by title II of H.R. 11581. Section 704 is divided into four subdivisions. Each of these subdivisions is important, but subdivision (a) leads all the rest.

It permits an inspector of the Food and Drug Administration to enter, at reasonable times, any factory, warehouse, or establishment, and to inspect, at reasonable times and within reasonable limits, and in a reasonable manner, the establishment, itself, and any equipment, materials, and labeling which he finds therein.

Subdivision (b) provides that the FDA inspector must give the owner of the establishment a report of any practice observed by the agent which shows that, in his judgment, any food in the establishment consists, in whole or in part, of (1) any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under unsanitary conditions.

Subdivisions (c) and (d), respectively, provide that samples may be collected and that, if an analysis is made of the sample, the FDA inspector must give the person from whom the sample was taken a report of the analysis.

These are extremely broad powers. The Committee on Interstate and Foreign Commerce discussed them at length in a report which it filed during the 83d Congress when in 1953, it amended the factory inspection provision of the 1938 act to avoid the necessity of securing the permission of the owner of the establishment (report of the House Committee on Interstate and Foreign Commerce, House of Representatives, Report No. 708, 83d Congress, July 6, 1953). In that report, the committee noted that almost every person in the food industry voluntarily permitted inspections to take place but, in view of the fact that there were a few who refused, and in view of the then recent decision of the Supreme Court of the United States in *United States v. Cardiff*, 344 U.S. 174 (1952), holding that it was not unlawful for a factory owner to refuse to give permission to enter and to inspect, it was decided by the Congress to amend the law so as to remove the necessity of securing the permission of the owner of the establishment.

But the Congress did more than this in the 1953 amendment. The committee report, referred to above, shows that the Congress gave careful and detailed consideration to the whole philosophy upon which inspections by FDA inspectors are based.

The Committee on Interstate and Foreign Commerce, in the report cited, took the view that the purposes of these inspections are not based on any prior suspicion or notion that the law has been or is being violated, but that the inspections contemplated are a matter of routine checking to determine sanitary conditions and to assist regulated persons by advising them of legal requirements. In the light of these purposes, it was concluded that the Congress should not then limit FDA inspectors to the use of a search warrant type of procedure.

The committee report upon which the 1953 amendment is based reveals clearly that the Congress felt that it was giving the Food and Drug Administration the utmost authority which it needed to perform the job which was assigned to it; namely, to see that food is processed under the sanitary conditions and properly labeled as required by law. It is equally clear that the Congress did not then feel that it would be warranted in giving FDA agents the type of authority to inspect which would now be conferred upon them by title II of H.R. 11581.

There can be no doubt that if the amendments to section 704 of the act proposed by title II of H.R. 11581 are adopted, it will turn that section of the law into a license to permit an unrestrained attempt by FDA inspectors to ferret out violations of law upon the basis of mere suspicion and without the safeguards of a search warrant type of procedure.

H.R. 11581 would convert this provision of the law from a mechanism for conducting routine investigations to spot check on sanitary conditions and for assist-

ing the food industry in its compliance with the act into a provision which would authorize FDA inspectors to operate as a kind of roving grand jury, a concept which is at total variance with our system of law and with the established sense of justice and fairplay.

H.R. 11581 would do this by amending section 704 so as not only to permit FDA inspectors to do what they now may do; namely, to enter factories, warehouses, and establishments at reasonable times and to conduct reasonable investigations of the sanitary conditions in such establishments, as well as the equipment and materials found therein, but also to permit FDA to look at all the "records, files, papers, processes, controls, and facilities" bearing on whether articles are possibly adulterated or misbranded within the meaning of the act. This particular provision of the amendment frankly states that such investigations may be made to determine "violations or potential violations" of the act.

Furthermore, for the first time, FDA inspectors would be permitted to extend their search to "consulting laboratories" and to the records, files, papers, processes, controls, and facilities of such "consulting laboratories" performing services for food manufacturers.

One of the remarkable features of the food industry to which frequent reference has been made over the years—including a reference by the committee in its 1953 report, referred to above—is that over 95 percent of the industry has voluntarily permitted inspection of its facilities. This was true even prior to the 1953 amendment which, for the first time, clearly permitted compulsory inspection. In view of this impressive record, it is difficult to grasp why more inspection power is now needed.

A roving inquiry into all records, files, papers, processes, controls and facilities to determine potential violations of the law will endanger valuable trade secrets and processes.

Many members of the American business community have their own trade secrets, processes, controls, and facilities. These are trade secrets because they are not disclosed. In many cases, special processes have been patented, which means that, in return for disclosure, a limited monopoly has been conferred by the Government for a limited period of time. The Government, however, has no inherent right to force the business community to divulge its trade secrets and processes, especially where such disclosure is not necessary in order to perform public purposes.

If FDA inspectors are permitted to have free access to all of the files of the company, including its secret processes, these will cease to be "secret" in an absolute sense the minute they are disclosed. An ex-FDA employee later employed by a food company can hardly be expected to forget what he had picked up under the protection of his badge.

This proposed legislation poses the question whether it is necessary, in the public interest, to require the business community to give up its trade secrets and processes to FDA inspectors.

The answer to this question is clearly that there is no such overwhelming public interest, and for a very simple reason which derives from the basic purpose of the Federal Food, Drug, and Cosmetic Act of 1938, as amended.

The purpose of inspections under that act is primarily to make certain that the food which is distributed to the consumers is pure and wholesome and is not misbranded and to assist companies in compliance with the law. These facts can be determined by examination of the food and labels, and it is unnecessary to go into the secret processes underlying the manufacture of food.

FDA inspectors already have the authority to inspect food for sanitary conditions and, of course, to examine labeling. They have authority to inspect the equipment and the finished and unfinished materials used in the manufacture of the food as well as the containers and labeling of the food. What more authority does FDA need to carry out its functions? It is submitted that it needs no further authority and that all of its responsibilities may be accomplished by inspecting the product before it leaves the plant.

The fear of the business community over the divulging of its trade secrets is not exaggerated. Section 202 of title II of H.R. 11581 would amend section 301(j) of the act which at present provides that the following acts are prohibited: (In the following quotation, the underscored language would be added by H.R. 11581, sec. 202, and the material in brackets would be omitted:)

"Sec. 301(j). The following acts and the causing thereof are hereby prohibited:

• • • • •

"(j) The using by any person to his own advantage or revealing, other than to the Secretary or officers or employees of the Department, or to the courts where relevant in any judicial proceeding under this act, or as authorized by law, any information acquired under authority of section 404, 409, 505, 506, 507, or 70 (concerning any method or process which as a trade secret is entitled to protection)."

In other words, the bill would eliminate from the above-quoted section the very language concerning trade secrets which is found in the present law and, at the same time, would, by the underscored language, open up the possibility of revealing any type of information secured by FDA inspectors, not only in judicial proceedings under the Food and Drug Act, but in any other instance "authorized by law."

No one knows what this would lead to. It would certainly seem to open the way to subpoena FDA officials in private litigation brought by competitors if they could convince courts that secret information in the possession of FDA inspectors was pertinent to the issues involved in the litigation.

Also, this very provision involves the point, earlier made, that a trade secret once divulged is no longer a trade secret. The statute just quoted shows clearly that the FDA inspector could legitimately reveal any secret obtained by him to the Secretary of the Department of Health, Education, and Welfare or to any of the thousands of officers and employees of that Department. And this is before one reaches the provision which authorizes the divulging of these secrets in judicial proceedings involving the act or, if the amendment is to be adopted, in any other manner "authorized by law."

This proposed legislation, in short, would sound the death knell to trade secrets in this Nation. Small wonder, therefore, that the business community is alarmed at this grab for power in an area where this very committee, less than 10 years ago, said that such power was not necessary. Nothing has happened during the intervening years since 1953 to render these broader powers necessary.

On the contrary, the passage of the 1960 color additives amendments render such power even less arguably necessary than it was in 1953. Both of these amendments are based upon the philosophy that before a substance may be added to a food—either as a food additive or as a color additive—the safety of the ingredient must have been established by a regulation of the Food and Drug Administration. This shifts the burden of proving the safety of the food supply from the Food and Drug Administration to the food industry itself—a responsibility which the food industry has always willingly received. Therefore, if the Food and Drug Administration is executing its responsibilities effectively under the basic 1938 act, as well as under the 1958 and 1960 amendments, there can be no serious argument that it needs these broader powers.

Another circumstance which renders added powers even more ludicrous is the extraordinary power which the FDA already possesses to seize and condemn food which it determines to be misbranded or adulterated. These seizures may be made in advance of judicial determinations as to legality of the seizure. The history of the enforcement of the Food and Drug Act shows that FDA has not been timid in using these powers. At any moment that FDA has reason to believe that any food is adulterated or misbranded, it can take a sample of that food, make a spot check determination and, if necessary, order its seizure.

Why, therefore, does FDA need to have the power to dig into the files of a company and to turn its normal task of routine sanitation investigations into a search warrant type of investigation without the benefit of search warrant type procedures?

Furthermore, in a search warrant type of procedure, an agency exercising such power is limited in the scope of the examination which can be made to specific places and things which may be investigated. The pending bill, however, would permit these FDA inspectors, as has been said, to roam at large. They would only need to say that they wanted to see something because they thought it might potentially have a bearing on a violation of the act. They would not necessarily have to say they wanted to look at a particular place or at a particular thing. They would have the right to come in and say "We want to look around, because we think we might find something in violation of the Federal Food, Drug, and Cosmetic Act of 1938, as amended. Where are your files?"

Insofar as the milk industry is concerned, it should also be pointed out to this committee that, in addition to the Federal Food, Drug, and Cosmetic Act of 1938, as amended, the dairy processing industry complies with a variety of State

and local laws and ordinances dealing with sanitation and related matters. It can be said with utter confidence that there is absolutely no need for additional legislation in order to assure a wholesome and pure supply of milk for the people of this Nation.

In this statement on behalf of the Milk Industry Foundation, a frank presentation of the views on this proposal has been made because we feel that the proposed legislation is absolutely unnecessary in order to protect consumers. Anyone who feels otherwise simply does not understand the facts and the existing law.

One of the quickest ways to destroy the confidence of business in Government is by the passage of unnecessary and burdensome laws which serve no purpose other than to increase the powers of Government agencies. Already, in our day and age, the Government has assumed a dominant role and frequently a necessary role in the business life of this Nation; but we must never forget that the principal role is that played by the business community itself. The quickest way to destroy the kind of Government which we want and cherish is to undermine the confidence of the business community in the Government. The proposed legislation would do just that.

The Milk Industry Foundation urges that title II of H.R. 11581 be disapproved.

STATEMENT OF FLAVORING EXTRACT MANUFACTURERS' ASSOCIATION

My name is Charles P. McCormick, Jr. I am chairman of the legislative committee of the Flavoring Extract Manufacturers' Association of the United States. Our association was organized in 1909. It consists of more than 175 firms concerned with, or engaged in, the manufacture of flavors, extracts, flavoring extracts, essences, bases, mixes, and related products which are sold both to manufacturers of foods, drugs or cosmetics, and to the general public for household use.

The flavor industry wishes to take this opportunity to express its views on this proposed legislation. We have long supported the work of the Food and Drug Administration and worked closely with the Administration in the development of analytical methods relating to our products. We testified before this committee in support of the food additives amendment, and, in that testimony, recommended certain provisions, such as ad hoc scientific advisory committees which, although not included in the food additives amendment, have been a part of later similar legislation. We share with the Food and Drug Administration, and with the great majority of industrial concerns and the consuming public, the desire to see the Food and Drug Act thoroughly, fairly, and effectively administered.

We wish, however, to register our strong opposition to some of the features and implications of the proposed legislation. We are primarily concerned by the fact that this bill would give inspectors of the Food and Drug Administration access to many company records which they now can view only by permission of the company involved, or by showing sufficient cause to warrant the issuance of a court order. As others have pointed out, the proposed bill would authorize "fishing expeditions" on which Congress and the courts have always frowned. Product formulas are of minor concern to some companies, while to other companies, they are important. But to firms in the flavoring industry, formulas are absolutely vital. They are their whole stock in trade; they are all they have to sell; they are their sole reason for existence.

Even a small flavoring house will have several thousand formulas, and a large company may have in its active files between 50,000 and 100,000. Some of these represent only minor variations from other formulas, and are arrived at quickly with little cost in time or effort. Other formulas or groups of formulas represent the expenditure of literally hundreds of thousands of dollars of research and development work.

It is standard policy for the flavoring industry to take extreme precautions to safeguard the confidential nature of these records. Many of them are complex mixtures made up of subassemblies, so arranged that only a few of the most responsible employees can possibly know the entire composition. The only case in which disclosure of flavoring formulas to the Food and Drug Administration is now legally required, is in the case of new drug applications. While flavor manufacturers certainly use formulas adequate for this purpose, no manufacturer would use a formula he considers of particular value, simply because of the hazards involved in the disclosure.

Our attitude here is based on concern, both for the possibility of inadvertent revealing of confidential material, and also for the possibility of deliberate abuse of such confidential information. In some cases, the key to a particularly valuable formula may involve the use of only one or two unusual or unexpected substances. A premeditated attempt to gain such information is not necessarily implied, but one cannot wipe out key recollections from a man's brain. Officials of the Food and Drug Administration have occasionally pointed out, in justifying this request for information, that no known case of the release or abuse of confidentially submitted information has even occurred. Such a statement, however, merely serves to illustrate the difficulty of proving such an occurrence, rather than the fact that the event has not occurred. We are not imputing any bad faith, past or present, to Food and Drug Administration employees. We are merely saying that they are human. Many former employees of the Food and Drug Administration have left Government service for industrial and academic posts. Others have established themselves in consulting firms or in private legal practice. The opportunity for abuses exists, and we are simply concerned to see that that opportunity is kept to the absolute minimum unavoidable in effective administration of the act.

One of the bases cited by the Food and Drug Administration in support of their request for this legislation is that such extensive inspection powers are necessary to police the use of food additives. While there are many different flavoring ingredients in use, their usages, with few exceptions, are, in the words of the food additives amendment, "generally recognized as safe." Because of this, they are legally not food additives, and they do not come under the specific regulatory provisions of the food additives amendment. Hence, no regulations involving tolerances apply. Their use is governed instead by other provisions of the basic Food and Drug Act. Since there are no tolerances, there has been no necessity to develop analytical methods.

On the other hand, when a food additive, in the legal sense, is involved, the Food and Drug Administration issues a food-additive regulation. This states how a substance may safely be used, and usually contains a tolerance or limitation on maximum use. The regulation and the petition for the regulation must also include a practicable analytical method, so that the Food and Drug Administration may be certain that the tolerance is not being exceeded. It is apparent that the results of an analysis are vastly more useful than the self-serving records of a company. If the Food and Drug Administration were concerned about the use of a specific substance, they certainly would not be so easily satisfied as to stop with consideration of a company's formula, but would analyze the product in any event. That is, and must remain the only effective determination of whether the provisions of the food additives amendment have been fulfilled. The important point concerns what is in the final food as eaten. The composition of an intermediate product, such as a flavor formulation, may be relevant, but certainly is not final. Thus, when a food additive is not involved, there is no tolerance because there is no significant hazard, and formula inspection is unnecessary. Where a tolerance and analytical method for a food additive are involved, analysis is needed in any case. Formula inspection is unnecessary because it is superfluous.

We are further concerned at the provision which would permit inspectors to inquire about the qualifications of technical and production employees. There are no standards in this field, and even professional associations have not been able to arrive at effective standards. In the absence of standards, such judgments would be personal and arbitrary at best, and it is appropriate for us to ask, and to doubt the qualifications of Food and Drug inspectors who would make such judgments.

Finally, we wish to join in the views of others who have opposed the inclusion of the records of consulting laboratories in this legislation. We agree, of course, that the files of consulting laboratories, dealing with quality control and product characteristics, are pertinent to the enforcement of the act, and should be available through normal judicial processes, just as are the records of the company itself. But the proposed legislation even fails to distinguish between records dealing with research and development on new products and quality control on present ones. We feel that this is so patent a flaw that it could not intentionally have been included in the proposed legislation.

We have dealt in this statement with those aspects of H.R. 11581 of particular interest and concern to the flavor industry. In general, however, we wish to associate ourselves with the views expressed by Mr. Samuel A. McCain in

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articles in the March 1962, issue of Food Processing and the April 1962, issue of The Business Lawyer. We are grateful for this opportunity of presenting our position.

STATEMENT OF THE NATIONAL HAIRDRESSERS AND COSMETOLOGISTS ASSOCIATION
IN OPPOSITION TO SECTION 201(a) OF H.R. 11581, SUBMITTED BY ROBERT A.
COLLIER, COUNSEL

This statement is submitted by the National Hairdressers and Cosmetologists Association, Inc., in opposition to section 201(a) of H.R. 11581, the "Drug and Factory Inspection Amendments of 1962." The association represents more than 65,000 beauty salon owners and operators with a total employment of more than 150,000 trained and licensed cosmetologists.

The present inspection provisions of section 704 of the Food, Drug, and Cosmetic Act authorize Government agents to enter any establishment, including beauty salons, in which cosmetics are held. Section 201 of H.R. 11581 would expand this authority to permit inspection of "all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether articles which are adulterated or misbranded within the meaning of the act, or which may not be manufactured, introduced into interstate commerce, or sold or offered for sale by reason of any provision of this act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violations of this act." The effect of this section of the bill is to provide carte blanche inspection. Under such broad language, it would not be possible for anyone to refuse inspection of anything.

We are not opposed to inspection per se. However, we do feel that any statute which imposes criminal penalties upon an unknowing violator, as does the Food, Drug, and Cosmetic Act, should provide for limitation upon unwarranted Government fishing expeditions. Not only does this proposal authorize an invasion of the business privacy of beauty salon operators, but it would also raise serious questions as to whether it is unconstitutional under the fourth amendment as an unlimited, and therefore unreasonable search and seizure.

We recognize that some legislation may be necessary to permit inspection of those few businesses who have been able to successfully evade it. However, we respectfully submit that any such need is not based upon any alleged violations of the Food, Drug, and Cosmetic Act by NHCA members. To include these beauty shop owners within the coverage of this bill would be an unjustified and unwise extension of governmental inspection authority.

STATEMENT OF PINEAPPLE GROWERS ASSOCIATION OF HAWAII ON H.R. 11581,
SUBMITTED BY R. L. CUSHING, PRESIDENT

This statement is submitted on behalf of the Pineapple Growers Association of Hawaii, the members of the association being Baldwin Packers, Ltd., California Packing Corp., Dole Corp., Hawaiian Fruit Packers, Ltd., Kaula Pineapple Co., Libby, McNeill & Libby and Maui Pineapple Co., Ltd.

The member companies operate eight pineapple canneries in Hawaii. An affiliated company of one of the members operates a pineapple cannery in Puerto Rico. The companies produce all but a small part of the U.S. annual production of approximately 185 million cases of canned pineapple and 123 million cases of canned pineapple juice, a total of 308 million cases. The canned pineapple pack is approximately 15 percent of the total U.S. canned fruit pack and the canned pineapple juice pack is approximately 23 percent of the total U.S. canned fruit juice pack.

As producers of a major canned fruit product, the pineapple canners are concerned over the additional, and, we believe, unwarranted factory inspection authority proposed for the Food and Drug Administration under title II of H.R. 11581.

We are advised that Commissioner Larrick of the Food and Drug Administration stated before the Senate Appropriations Subcommittee:

"A few years ago the Food and Drug Administration submitted a bill to the Congress which was believed to provide for inspection authority permitting FDA to make complete studies of the production procedures and controls employed by firms, the complaints received concerning their products, and the

qualifications of their employees (especially scientists) However, the legislative history of the bill indicated that it was not the intention of the law to give FDA access to this type of information. Consequently, FDA has had to operate with rather serious limitations ever since."

The pineapple canning industry in Hawaii has a long history of cooperation with the Food and Drug Administration and has consistently supported legislation which appeared to be reasonable and necessary for that Administration to discharge its responsibilities.

The Food and Drug Administration now has authority to inspect food factories, warehouses, establishments, and vehicles used in transporting the products of such factories, and to inspect all pertinent equipment, finished and unfinished materials, containers and labeling, and to take samples of products for analysis. The Secretary of Health, Education, and Welfare, under whose jurisdiction the Food and Drug Administration operates, has power of seizure of adulterated or misbranded products. The Secretary may publicize the facts in any case in which he believes there is danger to the public health, as was done in the cranberry incident. Furthermore, there is available the search warrant procedure whereby the Food and Drug Administration, upon presentation of reasonable evidence of a violation in a food-making establishment, may obtain a search warrant which will enable the FDA to obtain all files, records, documents, formulas, and anything else relating to the violation which FDA believes is being committed. After the search, FDA could have the factory padlocked if it can convince the judge this is a proper procedure.

The additional authority which would be granted FDA under title II of H.R. 11581 would empower it to have access, on a routine basis, to all things in a food factory, including records, files, papers, processes, controls, and facilities.

We do not believe there is any demonstrated need for such unrestricted governmental access to food plant files and records of production procedures and quality controls. Existing authority of the FDA to inspect plants, to draw random samples of the product, to subject such samples to any analyses seen fit, and to seize products it determines do not meet the standards, provides sufficient authority for the FDA to insure the purity and conformity with standards of quality of canned goods.

Commissioner Larrick cites the greatly increased use of food additives as a new argument for the increased factory inspection authority. The safeguards of the additive law itself and the FDA regulations on its administration reveal no need for additional legislation to protect the public health.

The preservation of competition between companies manufacturing canned goods depends upon the maintenance of competitive advantages based on production methods, production equipment, and product formulae. Unrestricted access by the FDA to the confidential records covering these matters could result in, although possibly inadvertently, the disclosure of proprietary production methods and could thereby lessen competition.

Access to personnel records would be, presumably, to determine the qualifications of a food processor's employees as Commissioner Larrick had indicated that the FDA inspectors should be able to determine that an employee is qualified to do his job. The specialized skills and knowledge required in the food-processing business are such that only those directly and finally responsible for operation of the business can evaluate the qualifications and day-by-day performance of their employees.

As food manufacturers we object to the proposal which would subject our confidential records to search under inquisitorial powers just as, as individuals, we would not want to be denied the benefits of the fourth amendment to the Constitution which insures us protection in our persons, houses, papers, and effects against unreasonable searches and seizures.

STATEMENT OF THE U. S. TRADEMARK ASSOCIATION IN OPPOSITION TO THE TRADEMARK ASPECTS OF H.R. 11581, SUBMITTED BY MR. THACHER H. FISK

The U.S. Trademark Association opposes H.R. 11581 insofar as its provisions have some impact upon the entire field of trademark law and practice.

The association is a membership corporation organized under the laws of the State of New York, with offices located at 6 East 45th Street in the city of New York. Its membership comprises regular (or voting) members, who are owners of trademarks, and associate members, who are lawyers, advertising firms, pub-

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lishers, and others interested in trademark law, trademark protection, and trademark practice. A printed list of members as of August 1, 1961, is attached.

The association now has 204 regular (or voting) members. Thirty-one of them are pharmaceutical manufacturers; and of the 33 members of the board of directors under whose direction the association operates, 5 are executives of pharmaceutical manufacturers. These data are given because of the short title of the bill under consideration, the "Drug and Factory Inspection Amendments of 1962."

The association is 84 years old, having been founded in 1878. Its purpose, generally stated, is to aid in the dissemination of information pertaining to trademarks and to afford a means of cooperative activity in protecting them. It publishes the Trademark Reporter®, a monthly journal containing judicial opinions in litigated cases and articles of research and commentary. The association has worked for uniform State trademark legislation, which has been adopted in many States.

Although the position of the association as presented here is limited to what might be termed the trademark aspects of H.R. 11581, failure to comment upon other aspects of the bill is not to be construed as approving or disapproving such other aspects.

Specifically, the U.S. Trademark Association is opposed to section 112(a)(4) of H.R. 11581. The section, if enacted, would require the manufacturer of a drug to use the drug's "established name" in a position of precedence over and in type of equal size and prominence as the drug's trademark on labels and in informational and promotional material. This subordination of the trademark, if accomplished, would profoundly alter and seriously abridge the fundamental legal and economic principles upon which the trademark system of product identification is founded.

The trademark system, possessing both a rich history and a great contemporary importance, enables merchants and manufacturers to compete vigorously and encourages them to endeavor to earn the fair competitive advantages that stem from creativity and quality. Therefore, the association strongly urges that the system be preserved from the dangerous sort of incursion embodied in H.R. 11581, and to support its position presents these reasons:

In the first place, the trademark-related provisions of H.R. 11581 discriminate against the pharmaceutical industry. No other industry is subject to comparable restrictions having to do with product identification. And the association believes that the splendid achievements of drug manufacturers deserves congratulation and not discrimination. Moreover, the precedence in position and equal prominence requirements appear to be outside the ambit of the Federal Food, Drug, and Cosmetic Act. The act properly deals with important matters of public health and safety, but its focus should not be made less clear by seeking also to deal with independent commercial practices.

Shifting to broader considerations, however, and apart from the possible particular consequences for the one industry, the association is genuinely concerned that the trademark-related provisions of H.R. 11581 might establish a perilous legislative precedent. They contain the genesis of the erroneous notion that trademarks are superfluous or inappropriate whereas experience and commonsense show the contrary to be true. Indeed, by identifying and distinguishing the worthy product, a trademark provides a true form of protection for the public. The precedence in position and equal prominence requirements would emphasize the generic name every time the trademark for the worthy product is promoted. The result will be at least as much public acceptance for the generic name as for the trademark. Thus, the requirements of H.R. 11581 with respect to use of the generic name will provide a means by which the marketer of an inferior product may confuse and deceive the public as to the quality and source of his product.

Then, too, any legislation of this character would dilute or discount the important identificatory values that established trademarks represent. In a very real sense there would be effected an uncompensated taking of the valuable goodwill that resides in these business assets.

If the product identification theory of H.R. 11581 were generally accepted, an incentive to promote a superior product and inform the public of its availability would be destroyed. Two consequences would be the reduction of quality of products to the lowest common denominator and the discouragement of new product development.

The association realizes, of course, that nonproprietary nomenclature can and does fulfill an important function and that, in the pharmaceutical industry as is true for nearly all industries, the disclosure of generic or common descriptive names is legally sound and advisable. It is not, however, in the best interest of the general purchasing public or trademark owners for the Government to coerce its citizens against the use of trademarks or brand names either with respect to drugs or any other commodity.

STATEMENT OF JAMES F. FORT, COUNSEL, PUBLIC AFFAIRS, AMERICAN TRUCKING ASSOCIATIONS, INC., ON H.R. 11581

Mr. Chairman and gentlemen of the committee, my name is James F. Fort. I am counsel, public affairs, of the American Trucking Associations, Inc., with offices at 1616 P. Street, NW., Washington, D.C. The association, as most of you know, is a national federation representing all forms of motor carriers, both private and for hire, and having affiliated associations in 49 States and the District of Columbia.

We appear today in support of part C of title I of H.R. 11581 which relates to the control of amphetamine and other stimulant habit-forming drugs.

In 1954 the trucking industry first obtained concrete evidence that amphetamine drugs were being sold illegally at highway stops and establishments near highways. Since that time we have cooperated with the Food and Drug Administration, we have conducted extensive educational campaigns among our employees, and we have for a number of years sought legislation similar to that before you today to effectively control these drugs.

The committee has already heard testimony as to the detailed provisions of the bill and as to the improper uses which are made of stimulant drugs, so it is not our purpose today to review these technical points. Rather, we think that the committee would be more interested in a brief description of the problems which we have had in this area.

It is our wish initially to make it clear to the committee that the use of amphetamines by truckdrivers is far more of a health problem than it is a safety problem. We have followed closely over the years the Interstate Commerce Commission's investigations of motor-vehicle accidents, and of their many, many investigations we are able to find less than 10 Commission proceedings in which the use of amphetamines has been held to be the cause of a highway accident. This is not to minimize the problem, for it is a problem and it has been our effort for a number of years to educate our drivers on the dangers to their overall health, as well as to educate them as to the driving hazard which may result from unsupervised or excessive use of these drugs.

According to published reports, the Food and Drug Administration estimates that production of amphetamine drugs annually is sufficient to produce about 5 billion pills or capsules. Commissioner Larrick has stated that a large proportion of these go into illicit channels. Against this background it is obviously illogical to assume that the truckdrivers of the Nation's approximately 700,000 tractor-semitrailer trucks could conceivably be the prime users. Further, National Safety Council and ICC statistics substantiate the fact that truckdrivers, as a group, have the finest safety record of any type of drivers. This record is steadily improving. Let me cite just one statistic to verify this: Trucks constitute a little over 10 percent of all registered motor vehicles. However, they comprise only 11 percent of vehicles involved in accidents. This is involvement, not necessarily fault. A major insurance company several years ago made a study of 100,000 truck-involved accidents and found that in 70 percent of the cases the truck was not at fault, so obviously our record is one of which we are very proud.

The committee knows that under the ICC's safety regulations all interstate drivers must meet, periodically, the strict physical qualifications established by the ICC. They must have in their possession at all times, when driving, a copy of the medical certificate issued by a doctor at the time of their most recent examination. Habitual use of amphetamines or related drugs obviously would keep any driver eventually from passing his physical examination. Also, as the committee knows, the ICC has very strict regulations which govern the amount of time which a driver may spend on the road. Currently this requirement is 10 hours of driving time between minimum 8-hour off-duty periods with

weekly maximum limitations. Further, every interstate driver must maintain a "driver's log" to record his hours. In addition to these stringent Government regulations most trucking companies schedule their drivers' runs so that they will be well within the maximum allowable driving time. Thus a driver complying with the ICC's safety regulations and his own company's policies should not need any "stay awake" type stimulus.

Our cooperation with the Food and Drug Administration goes back many years since shortly after we first became aware of the problem. The Enforcement Division of FDA has joined with us in our efforts to stamp out illegal sales. Their agents have been trained by our member companies as drivers and helpers in order that they could make purchases and subsequent arrests. Enforcement officers have ridden thousands of miles on our trucks and have made hundreds of arrests while they were posing as employees of trucking companies throughout the United States. This, of course, could only have been accomplished with the complete cooperation of the management of our companies. It is a truly exciting story which has been, to date, largely untold.

This mutual effort between the trucking industry and FDA has resulted in a large number of arrests being made at truck stops and other highway type installations, and at the same time it has resulted in a great deal of bad publicity for the trucking industry and its drivers. Our files are replete with lurid, sensational stories based upon suspicion, hearsay, and pure fiction which purport to relate that truckdrivers generally use these drugs and thus are responsible for a major traffic hazard. This, as I have stated, cannot be borne out by ICC records.

FDA has also worked with us in producing hundreds and thousands of pamphlets which have been distributed through our members across the country. Attached to this statement is the latest publication produced by the Food and Drug Administration with our cooperation. About 50,000 copies of this pamphlet have been distributed through our industry in the last month. A previous pamphlet produced by ATA several years ago was distributed to over 500,000 drivers throughout the country.

We are most hopeful that the committee will act favorably upon the pending legislation to the end that this problem will be eliminated both for our industry and for the public as a whole.

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DRUGS AND DRIVING—SOME PRECAUTIONS FOR HIGHWAY SAFETY

Drugs that produce no unusual symptoms in most people may cause abnormal reactions in some individuals, making it unsafe for those persons to drive. This is true regardless of whether the drug is self-administered or taken at the direction of a physician. No one should drive when taking drugs unless he is certain they will not impair his driving ability.

High on the list of highway killers and traffic safety violators is the drunken driver. But alcohol is no longer the only cause of "intoxication."

The Food and Drug Administration is concerned over the increasing threat to highway safety from drivers "under the influence" of drugs. The drugs involved range from true narcotics to stimulants, tranquilizers, sleeping pills, and even some cold remedies (e.g., anti-histamines). Some are widely used in such common ailments as nervousness, overweight, high blood pressure, and hay fever. Because of these common uses many people do not realize the effects drugs may have on driving ability. They may innocently contribute to the danger on the streets and highways.

And, because some dangerous drugs can be obtained without prescription—despite legal requirements to the contrary—some people use them for their "side effects" or for reasons other than their intended medical purpose. One example is the use of stimulant drugs to keep awake while driving.

Controlled use of drugs by a person under his doctor's care brings with it safeguards that avoid danger. Uncontrolled use of the drugs discussed here is a danger to the health and welfare of the user and the safety of others. Here are the facts about the dangers and precautions to be taken when driving.

AMPHETAMINES

Amphetamine drugs have many nicknames, some innocent sounding—"bennies," "pep pills," "thrill pills," "copilots"—which conceal the seriousness of uncontrolled use.

The amphetamines are useful in treating certain illnesses when used under medical supervision. Carelessly used they can be very harmful to the health of the user, and make it unsafe to operate a motor vehicle.

Legally, amphetamines can be sold only in drugstores and then only upon a doctor's prescription. This is for the protection of the user. Anyone who uses bootleg channels to avoid the prescription requirement not only contributes to a violation of the law, but also runs the risk of being "hooked" to habitual use, with all the degradation and misery that follow.

Common beliefs about amphetamines are: "They are no more harmful than a cup of coffee"; and "you can drive without sleep and never miss it." Both are false and both are dangerous.

Amphetamine may increase alertness and efficiency for a short time; but this effect may be followed by headache, dizziness, agitation, irritability, decreased ability to concentrate, and marked fatigue.

The most important fact for drivers to consider is that excessive, unsupervised use interferes with the body's normal protective symptoms of drowsiness and fatigue. The feeling of exhaustion is short-circuited, causing a driver to use up reserves of body energy until a total and sudden collapse may occur. But before collapse there may be a period of decreasing driving ability and alertness, even though the driver thinks he is driving very well.

Another often reported effect is that of seeing things in the road that are not really there—mirages or hallucinations similar to the delirium tremens of the alcoholic. Such "visions" may cause the driver to swerve into oncoming vehicles or off the road. Bennies can kill.

Truck drivers and many others who constantly use the highways are victimized by unscrupulous and illegal dealers in amphetamine drugs for the enormous profits involved. Such drug bootleggers promote the false belief that bennies are helpful to drivers. They place personal profit above human life.

Rest is the only safe remedy for fatigue. Reliance on stimulant drugs can result in anything from a badly overworked heart to sudden death.

BARBITURATES AND OTHER SEDATIVES

Barbiturates are very useful medicines to calm nervousness and produce sleep in persons with medical problems. However, they are habit forming and by law may be sold only upon prescription. Uncontrolled use can lead to addiction more serious in some respects than true narcotic addiction. Barbiturates are often "pushed" by underworld peddlers promoting experimentation knowing it may lead to habitual use, addiction to true narcotics, and another "hooked" customer.

Barbiturates also often follow excessive use of amphetamine drugs, in an effort to slow down and get off the "jag." Amphetamine-barbiturate use may thus become a vicious cycle causing serious emotional and physical damage.

The excessive use of barbiturates produces symptoms similar in some respects to alcoholic intoxication. The person affected becomes drowsy and confused. He cannot coordinate his muscular action when he walks or stands and sometimes reaches the point of collapse. He may experience tremor of his hands, lips, and tongue, and he has difficulty in thinking or talking clearly. A person so affected is obviously unfit to drive.

But even the occasional user of barbiturates will become drowsy and less alert. Effects vary greatly in different individuals. Even if the dose is small and the time under the medication is short, the person should make sure he knows how the drug will affect him before driving. Follow your doctor's advice in the use of these potent drugs. It is up to the doctor, of course, to give the necessary instructions where the drug is not identified to the patient.

TRANQUILIZERS

This descriptive term is applied to a group of preparations that are, generally speaking, muscle relaxants affecting some reflexes to relieve mental apprehension. While some of them are also used to reduce high blood pressure, their effect is largely on attitude and outlook.

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However, in normal or larger doses, or with other drugs or alcohol, tranquilizers may result in sedation to the point of dizziness or drowsiness. Obviously, these preparations may also pose a danger to the driver and should be taken only under adequate medical supervision, with the doctor knowing that driving is contemplated.

ANTIHISTAMINES

These drugs are used for relief of nasal congestion due to colds, to combat allergies, and for other purposes. Some may be purchased without prescription; others are too dangerous for use without medical supervision.

These drugs may also cause side effects such as inattention, confusion, and drowsiness. In fact, some of them are available for use as an aid to sleep. If the drug produces such results in a particular individual, then that individual should not drive or operate machinery. Observe label directions carefully, or follow your doctor's advice about driving.

NARCOTICS

Since the true narcotics are used primarily by doctors in seriously ill, usually hospitalized patients, these patients are not likely to be driving at all. In the unusual situation where narcotic medication is indicated and the doctor permits driving, he will undoubtedly advise necessary precautions.

However, a narcotic addict—or a person "experimenting" with the wares of the dope peddler—is a real threat to highway safety. These drugs affect judgment, produce drowsiness, interfere with concentration, impair vision, and release inhibitions against reckless driving and other improper behavior.

DRUGS PLUS ALCOHOL ARE ESPECIALLY DANGEROUS

Everyone knows the dangers of driving while under the influence of alcohol. Not so many know how the drugs discussed above threaten driving safety. But still fewer know that the combined effects of these drugs and alcohol may be exceedingly dangerous.

The combined results may be much more dangerous to health and to highway safety than the effects of either the alcohol or the drugs alone. The scientific term for the reaction effect is "synergism."

The old adage, "If you drink, don't drive," is still good. But here are some additional rules that may save your life—or the other fellow's:

1. If you are ill, see your doctor.
2. If your doctor prescribes drugs, ask him about driving while on the medication.
3. If you drink, don't drive; but ask your doctor about the combined effects of alcohol and any medicine he prescribes.
4. Don't ask your druggist to violate the law by selling dangerous drugs without a prescription, and don't buy from one who will.
5. Don't allow filling station or truckstop operators to sell you any drugs. These operators may be good mechanics for your automobile or truck, but your body is a much more valuable—and delicate—machine.

The organizations of professional drivers and of persons serving the driving public endorse this policy as being in the best interest of the driver.

If you are offered any of these drugs under circumstances which arouse your suspicions, get in touch with the Food and Drug Administration office serving your area or the headquarters office at Washington 25, D.C.

STATEMENT OF ADOLPH K. SCHWARTZ ON BEHALF OF THE ASSOCIATED DRUG & CHEMICAL INDUSTRIES OF MISSOURI, INC., RE H.R. 11581 (AND S. 1552)

My name is Adolph K. Schwartz. I am a member of the bar of the State of Missouri. I am a native of St. Louis and have been engaged in the general practice of law there since 1939. My address is 721 Olive Street, St. Louis, Mo. My statement here is on behalf of the Associated Drug & Chemical Industries of Missouri, Inc.

The association was incorporated by pro forma decree under the laws of Missouri in 1930. It has 156 member companies, all of whom are engaged in the manufacture and distribution of drugs and chemicals and allied industries.

St. Louis is one of the larger drug centers and many of the association member companies manufacture and distribute nationally known products.

In the interest of brevity we adopt the statement of James F. Hoge made on behalf of the Proprietary Association before this committee on August 21, 1962, with the addition of a few points which we believe should be emphasized.

EFFICACY OF EFFECTIVENESS

The two bills use the words efficacy and effectiveness as though they were synonymous, in connection with new drug applications. Present law on this subject provides for safety of all such products. We do not believe that addition of efficacy or effectiveness to the definition of drugs requiring a new drug application, is either necessary or desirable. So long as the safety in a new drug application is established, the economics of the marketplace will, as it does at present, take care of any drugs that are not effective or efficacious. Moreover, under present law, if claims are made for a drug product which cannot be substantiated, the manufacturer is subject to sanctions for mislabeling or misbranding; and is also subject to prosecution by the Federal Trade Commission.

Finally, if such a requirement must be made, we urge that careful consideration be given to the difference in meaning between the words efficacy and effectiveness. Using common cold remedies as an example, effective would mean that the drug would relieve those common cold symptoms for which claims are made; but efficacy might be construed to mean that the product must cure a cold. We would, therefore, prefer the word effective as used in S. 1552 rather than efficacious as used in H.R. 11581.

GRANDFATHER CLAUSE

If the definition of "new drug" is changed to include effectiveness as efficacy, then it is essential that a "grandfather clause" be included so that old established drug products will be exempted and not have to go through elaborate and costly new drug procedure. S. 1552 contains such a grandfather clause but H.R. 11581 does not.

ADULTERATION

Section 101 of H.R. 11581 provides in effect that the FDA, by regulation, can establish methods of manufacture and qualifications of personnel, and then if a company or a product does not, in the opinion of an inspector comply, FDA could find that the product was "adulterated" notwithstanding that the purity or safety or quality were unquestioned, and the labeling was proper. We think this amounts almost to licensing by the FDA, is the concentration of too much authority in an administrative agency, and places an unfair burden upon industry. The provisions in S. 1552 are less stringent and are adequate.

TRADEMARKS AND ESTABLISHED NAMES

Section 112 of H.R. 11581 provides that FDA may require all products to use an "established" or "official" name on a given product. Proprietary drugs, sold over the counter without a prescription, are known by their trademarks. They are mostly compounds of several ingredients and could not sensibly have a "generic name." Proprietary medicines should be exempted from this provision.

LABELING

Section 112 of H.R. 11581 also requires that the label contain quantitative listing of all active ingredients in type the same size as the trademark, and requires that they be given a position of precedence on the label. Quantities of each ingredient in a compounded medicine in other words the formula, is a trade secret. To require this on the label serves no purpose of safety to the public, yet it would destroy many small medicine manufacturers who depend upon secret formulas which they have developed and marketed for many years. It would, of course, also destroy the value of a trademark, without any accompanying benefit to the public. Furthermore, the requirement in this section that the names of the ingredients be printed in type of the same size as the trademark (or in type of at least 50 percent the size of the trademark as provided in S. 1552) imposes an impossible condition for many products. For example, the product Anacin, marketed in a small tin of 12 tablets (and in other packages) contains, as shown

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on the label, acetophenetidin, aspirin, caffeine. Certainly these ingredients could not be printed in the same size type as the trademark Anacin. Another example is mentholatum which contains, according to its label, menthol, camphor, boric acid, petrolatum, oils of sweet birch, pine, and eucalyptus. Still another example is murine which contains, according to its label, potassium borate, berberine hydrochloride, boric acid, glycerin, hydrastine hydrochloride, merthiolate and sterilized water.

FACTORY INSPECTION

Section 201 of H.R. 11581 authorizes an almost unlimited inspection which would include not only plant and personnel, but also all records, financial reports, trade secrets, manufacturing processes and "know-how," and anything else. Under the existing law it is a criminal offense to refuse "to permit entry or inspection." There is no need for these broad vague powers of inspection of things which have no bearing on the safety, or purity, or effectiveness of a drug or medicine. Its constitutionality is questionable and it would constitute another unnecessary and unfair interference with and burden upon industry. We see no need for amendment of inspection powers under existing law, however, if they are to be broadened, they should be clearly defined and be limited to items bearing upon the safety and purity, and perhaps the effectiveness, of drugs and medicines.

CONCLUSIONS

It is hoped that the foregoing will be of assistance to this committee in understanding the broad scope and unnecessarily burdensome nature of some of the provisions in H.R. 11581, and that the committee will amend these provisions as we have suggested.

STATEMENT BY SIERT F. RIEPMA, PRESIDENT AND TREASURER OF NATIONAL ASSOCIATION OF MARGARINE MANUFACTURERS

The National Association of Margarine Manufacturers respectfully opposes those provisions of H.R. 11581, 87th Congress, 2d session, which seek to broaden the existing statutory authority of the Food and Drug Administration, Department of Health, Education, and Welfare, to make inspections of factories and other food establishments, including "consulting laboratories." Specifically, the opposition of the National Association of Margarine Manufacturers is directed to those amendments contained in title II of H.R. 11581, as to which the association requests this committee to report unfavorably.

The National Association of Margarine Manufacturers is a nonprofit trade association organized under the Illinois Not-For-Profit Corporation Act and composed of most of the margarine manufacturers in the United States. Margarine manufactured by the members of the association is produced and distributed in accordance with the provisions of Federal and State laws, including the Federal Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. 321, et seq. Under this act, the Food and Drug Administration of the Department of Health, Education, and Welfare has issued a Federal definition and standard of identity for margarine (17 F.R. 4613 and 21 F.R. 6566).

In those instances in which animal fat is used in the production of margarine, the product is also produced and distributed in accordance with the meat inspection regulations of the Secretary of Agriculture issued pursuant to the Meat Inspection Act, as amended (21 U.S.C. 71-91), and section 306 of the Tariff Act of 1930 (19 U.S.C. 1306). The Secretary of Agriculture has also issued a Federal definition and standard of identity for margarine similar to that issued by the Food and Drug Administration of the Department of Health, Education, and Welfare.

It is the position of the National Association of Margarine Manufacturers that the various Federal and State laws, including the present provisions of section 704 of the Federal Food, Drug, and Cosmetic Act of 1938, as amended—the so-called "factory inspection provision"—afford ample authority to governmental officials, including officials of the Food and Drug Administration of the Department of Health, Education, and Welfare, to inspect adequately the premises of any food establishment for sanitary and related conditions and that no satisfactory need has been demonstrated for expanding the factory inspection powers of the Food and Drug Administration in the manner proposed by title II of H.R. 11581.

At the present time section 704(a) authorizes the Secretary of Health, Education, and Welfare, through such officials or employees as he may duly designate, to enter, upon presentation of proper credentials to the owner, operator or agent, at reasonable times, "any factory, warehouse or establishment" in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in interstate commerce. Therefore, the present law already authorizes Food and Drug inspectors to enter into any place where food is kept or held for shipment in commerce.

For what purposes may such entry be made?

Section 704 provides specifically that the purpose of such entry is to permit inspection at reasonable times within reasonable limits and within a reasonable manner, such factory, warehouse, establishment, or vehicle and pertinent equipment, finished and unfinished materials, containers, and labeling therein. This is an extremely broad power as it now stands. Food and Drug inspectors have, under this provision, ample power to inspect all material and equipment used in connection with the production of food as well as the food itself.

Section 704(b) provides that, upon completion of any such inspection of a "factory, warehouse, or other establishment," the inspection official must give to the owner, operator, or agent in charge of the premises a report in writing "setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device, or cosmetic in such establishment, (1) consists in whole or in part of any filthy, putrid, or decomposed substance or (2) has been prepared, packed, or held under insanitary conditions." It also provides that a copy of such report will be sent to the Secretary of Health, Education, and Welfare.

But the present law does not end here. Under section 704(c) the inspecting officer is permitted to take a sample obtained in the course of the inspection for which he must give a receipt to the person from whom the sample was taken.

Under section 704(d), if an analysis is made of the food sample taken, a copy of such analysis must also be furnished to the person from whom it was taken.

Certainly these powers, already in the hands of the Food and Drug Administration of the Department of Health, Education, and Welfare, individually and in combination, constitute a powerful enforcement weapon which enables that Agency to deal with any conceivable situation in which the wholesomeness of the food supply of the Nation is involved.

The present inspection powers, just described, did not come about overnight but rather are the product of a long evolutionary history in the development of adequate legislation in the food and drug field on the Federal front.

The 1906 Food and Drug Act, the first major legislation in this field, contained no provision authorizing so-called "factory inspection." Even in the absence of compulsory inspection powers, the Nation's food industry cooperated by voluntarily permitting inspection by the persons charged with the administration of the early Food and Drug Act. It has been stated that more than 95 percent of the food and drug manufacturers invariably gave permission to inspect their premises.

In 1938 when the law was changed, there were included provisions which permitted inspection of premises where food is manufactured "after first making request and obtaining permission" of the owner of the factory. These provisions did not prove entirely satisfactory in operation because of the necessity of Food and Drug inspectors first obtaining permission of the owner before undertaking to inspect his premises.

In *U.S. v. Cardiff*, 344 U.S. 174 (1952), the Supreme Court held that the provisions in the 1938 act dealing with this question were fatally inconsistent and did not clearly provide that refusal to admit a Food and Drug Inspector constituted a violation of the act. Accordingly, in 1953 the Congress amended section 704 to its present form, eliminating the necessity for obtaining permission of the owner before inspection of his premises.

The controversy and litigation, to which allusion has just been made, concerned only those provisions requiring preinspection permission of the owner of the premises to be inspected. There has never been any question until now but that the 1938 act gave ample authority to Food and Drug inspectors to carry out their enforcement responsibilities. An examination of the legislative history of the 1953 amendment, for example, reveals that the overriding concern of the