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Food Drug Cosmetic Law JOURNAL

Record Inspection 1906-1963 . .

. . . . . GEORGE McKRAY

Public Protection, Private Choices and Scientific Freedom: Food, Drugs and Environmental Hazards

. . . . . ALANSON W. WILLCOX

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Record Inspection 1906-1963.—The first of a two-part article discusses the issue contained in the new bill H. R. 6788, which is currently before Congress. Part 1 deals with the history and present mode of record inspection. Its author, *George McKray*, is a former Food Law Institute Fellow at the New York University School of Law. At the present time, he lectures at the University of California in Berkeley, specializing in the legal aspects of public health and medical administration. Last year the Food and Drug Administration was granted the power to compel prescription drug manufacturers to produce their records for government inspection. Is there justification for expanding this legislation to cover other industries? Mr. McKray says that in seeking the answer to that controversial question, pertinent factors that must be considered are the amount of additional public protection that will be gained by compulsory record inspection, and the legitimacy and desirability of invading the privacy of industry by inspecting its confidential records. The Food and Drug Administration functions according to the 1953 Factory Inspection Amendment currently, except when dealing with the prescription drug industry which is now under regulations contained in last year's drug amendments. "The actual mode of operation of the government and the prescription-drug industry under the new amendments remains to be seen," observes the author. "Of far-reaching significance, however, is the fact that the FDA, as outlined in its proposed regulations, intends to make compulsory record-keeping a part of its program to enforce the Federal Food, Drug and Cosmetic Act through record inspection." This commentary begins on page 301. Next month's issue of THE FOOD DRUG COSMETIC LAW JOURNAL will contain the conclusion, in which Mr. McKray will reappraise the desirability of record inspection.

Charles Wesley Dunn Lecture.—This month's JOURNAL features another Charles Wesley Dunn Lecture. *Alanson W. Willcox* discussed "Public Protection, Private Choices and Scientific Freedom: Food, Drugs and Environmental Hazards" at Harvard University Law School on March 15, 1963. He declared that "[c]onsideration of dangers to health brings us to . . . the most difficult element in the rationale underlying food and drug regulation. Although the public health is obviously a proper public concern, we raise very subtle questions when we dictate to the individual that he may not, though with full knowledge of the facts, expose himself to risks that we deem to be undesirable. The problem rarely arises in the purest form; usually—for example, with the abuse of narcotic drugs—we can find collateral harm to others to buttress our objection to self-inflicted injury. . . . Yet the question remains under what circumstances government may properly dictate, not what we really find necessary for the protection of society, but what we think wiser for the individual than the choices he would make for himself." The article by Mr. Willcox, who is General Counsel of the United States Department of Health, Education and Welfare, begins on page 321.

Information and Education.—*John L. Harvey* described the information and education activities of the Food and Drug Administration to both industry and consumers at the annual meeting of the Institute of Food Technologists in Detroit on May 28, 1963. Mr. Harvey is deputy commissioner of the FDA. He declares that three well-established principles serve as the basis for industry education activities. "The first is that the laws of this land are public laws and citizens are not to be harassed by secret regulations or secret proceedings in the courts. Regulation-making is likewise a public process, and the Administrative Procedures Act has spelled out the responsibilities of law enforcement agencies for public procedures. The second is that intention to violate the Federal Food, Drug and Cosmetic Act and other laws we enforce does not have to be proved as an element of the offense, and ignorance of the law is no excuse. . . . The third principle is especially applicable to laws that protect the public health and safety. We call it 'preventative enforcement,' which simply means activities to bring about voluntary compliance." The best informed consumer, he points out, needs the least help from the government in avoiding unsafe or falsely promoted products. Informed consumer opinion is an essential ingredient of the policy-making process. He lists the various government agencies, and the services that they make available to both industry and the general public. "There is not now and never has been a conflict between an 'enforcement' and 'education' philosophy in the FDA. It is rather a question of how to use both together to attain the objectives of protecting both consumers and honest business," concludes this informative article which begins on page 339.

International Food and Drug Law.—Among current international food and drug law developments, observes *Franklin M. Depew,* are the United States Drug Amendments of 1962, the newly formulated drug program of the Council of Europe Public Health Committee, and the Eighth Latin-American Chemical Congress. He cites the Joint FAO-WHO (Food and Agriculture Organization-World Health Organization) Conference on Food Standards as the most important recent development in the food field. That Conference established the *Codex Alimentarius* Commission, which will soon begin work on formulating international standards for various food products. Mr. Depew, the president of the Food Law Institute and the vice president of the Section of Food, Drug and Cosmetic Law, spoke at the Inter-American Bar Association, Section of Food, Drug and Cosmetic Law meeting in Panama City, Panama on April 23, 1963. His remarks appear on page 349.

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Food·Drug·Cosmetic Law Journal

Record Inspection 1906-1963

By GEORGE McKRAY

This Is the First of Two Parts Discussing the Issue Contained in the New Bill H. R. 6788 Now Before Congress. The Author Is a Lecturer at the University of California in Berkeley Specializing in the Legal Aspects of Public Health and Medical Administration. During 1961-1962 Mr. McKray Was a Food Law Institute Fellow at the New York University School of Law.

DURING THE FIRST HALF OF THIS CENTURY, the Federal Food and Drug Administration, without express congressional authority, gradually began to include inspection of business records as a part of its inspection of the factories of food, drug and cosmetic industries. A decade ago Congress saw fit to exclude record inspection as a part of compulsory factory inspection. Last year legislation was enacted which gave the Food and Drug Administration the power to compel prescription drug manufacturers to produce their records for government inspection. Is there justification for expanding this legislation to cover other industries? In seeking the answer to this question, pertinent factors to consider are the amount of additional public protection to be gained by compulsory record inspection, and the legitimacy and desirability of invading the privacy of industry by investigation of its confidential records.

This article is divided into two parts. The first deals with the history and present mode of record inspection. The second part deals with a reappraisal of the desirability of record inspection and will be concluded in the next issue.

THE HISTORY OF RECORD INSPECTION

Historically the practice of inspecting records of food and drug manufacturers developed as a part of factory inspection, and was affected by a series of laws and judicial decisions.

1899 Act

The first activity of the federal government in the area of inspection came about as an attempt to prevent the importation of adulterated foods.[1] It was instigated according to the Act of 1899.[2] Importers were required to furnish federal inspectors with lists of food products being brought into the country, and the inspectors then took samples from stock shipped into major ports. The samples were chemically analyzed and adulterated food products were prohibited from entering the United States.

1906 Act

It came to be recognized that the process of seeking out contaminated products by collecting an extensive number of samples indiscriminately was wasteful, because it required the sampling and chemical examination of hundreds of items to detect a limited number of those which were unfit. Therefore after the passage of the Food and Drug Act of 1906,[3] which brought domestic as well as imported products under government supervision, a system of factory inspection was devised in order to achieve better consumer protection.[4]

A factory inspection system was not specifically authorized by the 1906 Act. Rather it came into use after the passage of the law because, as a practical matter, violations of standards of purity could best be determined where the product originated—mill, factory or processing plant. Trained inspectors visited plants, studied raw materials and factory processes, and determined likelihood of violations. The sorting of legal from illegal products was done at the source, and collection of samples to be examined for confirmatory purposes was performed only where there was reason to suppose violations existed. Although the government had not been furnished with definite authority

[1] Wharton, W. R. M., "Original Federal Food and Drugs Act of June 30, 1906—Its Inspection Evolution," 1 Food Drug Cosmetic Law Quarterly 348 (1946).

[2] Act of March 1, 1899, Ch. 325, 30 Stat. 947.

[3] Act of June 30, 1906, Ch. 3915, 34 Stat. 768.

[4] Wharton, cited at footnote 1, at p. 357.

to make factory inspections, very few factory owners prohibited it from doing so.[5]

Gradually the scope of factory inspection was enlarged; in addition to the physical plant, factory records were checked.[6] Administrative justification could generally be offered for the expansion of investigational activity; for example, the government could more speedily and completely remove a dangerous product from the market by seizure action if it could inspect shipping records giving facts on the distribution of that product. Since there was no provision for factory inspection existing under the 1906 Act, there was no litigation as to whether the federal government had a right to inspect factories or their records.[7]

1938 Act

By the early 1930's it was generally assumed by food and drug officials that the inspection of establishments dealing with foods, drugs and cosmetics was essential to safeguard the consumer. Although most of industry was voluntarily allowing inspection of their premises, there was a small segment that was refusing inspection.[8] Legislation for the present Food, Drug and Cosmetic Act, as initially introduced in Congress in 1933, included provisions for compulsory factory inspection of concerns dealing in interstate commerce. The proposed legislation was amended, revised and debated extensively over a period of five years.

The first bill, S. 1944 known as the Tugwell Bill, was prepared by the FDA. The bill provided for inspection of ". . . factory, warehouse, establishment or vehicle and all pertinent equipment, *methods and processes,* finished and unfinished material, containers, and labels there used or stored. . . . "[9] During the course of the hearing on S. 1944, many manufacturers objected to the disclosure of formulae, methods and processes. At that time Mr. Campbell, Chief of the Food and Drug Administration, stated:

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[5] Hearings on S. 1944, 73rd Cong., 2d Sess., on Dec. 7 and 8, 1933, as quoted in Dunn, Charles W., "Federal Food, Drug and Cosmetic Act," G. E. Stechert & Co., New York (1938), 1099.

[6] Hearings on H. R. 2769, H. R. 3551, H. R. 3604, 83d Cong., 1st Sess., May 19 and 20, 1953.

[7] No cases were reported from 1908 to 1932, as quoted in White, M. G. and Gates, O. H., "Decisions of Courts in Cases Under the Federal Food and Drugs Act," United States Department of Agriculture, United States Government Printing Office, Washington, D. C. (1934).

[8] Hearings on S. 1944, cited at footnote 5.

[9] S. 1944, 73rd Cong., 1st and 2d Sess., Sec. 13(a). (Italics added.)

It is alleged in connection with this particular action that it is extreme; that it calls upon a manufacturer to make a surrender of property rights in which he has a definitely vested interest; that it requires disclosure of trade secrets. To a large extent that is sheer nonsense. Competitors through observations, expert analysis, and other investigations that may be carried out can easily ascertain the essential composition of various drug products to be found on the market.

The ingredients are not secrets, but there is, I will grant, in the preparation of such products manufacturing techniques which may be of value to manufacturing firms. I have had manufacturers of drug products tell me repeatedly that there was no objection to this requirement; that it was not the ingredients or the composition of the article which constitute the secret, but rather the method of combining the various ingredients.[10]

After the hearing on S. 1944, the words "methods and processes" disappeared from the language of the factory-inspection provisions of the various bills and did not recur.

The outcome of the five-year legislative effort was the Federal Food, Drug and Cosmetic Act of 1938.[11] The procedure for factory inspection was covered in Section 704, but the only express mention of record inspection, in Section 703 was a provision conferring upon inspectors the right to have access to, and to copy, those records of carriers and conduits pertaining to the movement of any food, drug or cosmetic in interstate commerce.

In the legislative debates preceding the passage of the 1938 Act the right to inspect even records of movement had been interpreted as limited to those of the carriers and to information which would establish federal jurisdiction.[12] However, after the enactment of the law, the FDA interpreted Section 704 to include general inspection of records within the authorized scope of inspection. This administrative interpretation was resisted by a large segment of industry;[13] however, case law developed which seemed to favor it.

A federal inspector had first to obtain permission in order to inspect records in accordance with the terms of Section 704.[14] But

[10] Hearings on S. 1944, cited at footnote 5, at p. 1084.

[11] P. L. 717, 75th Cong., 3d Sess., approved June 25, 1938.

[12] Elson, Eugene M., "Inspection of Records," 5 FOOD DRUG COSMETIC LAW JOURNAL 755, 757 (1950).

[13] Cited at footnote 12, at p. 763.

[14] *United States v. Maryland Baking Company*, 81 F. Supp. 560 (DC Ga. 1948). Criminal proceedings had been instituted against the defendant on a charge of shipping adulterated food. The complaint was dismissed, since permission to make an inspection was obtained from an unauthorized person, the plant superintendent. The court held that the inspection did not comply with the terms of the statute because the inspectors did not obtain permission from the manager. The manager was the "operator and custodian" and

if an authorized person with knowledge of possible consequences voluntarily gave permission to inspect records during a factory inspection, then the government was free to use that information as it saw fit, including libel action.[15] Moreover, permission to enter the premises could be tacitly granted, and permission to inspect records implicitly given.[16] These cases did not decide definitively that compulsory inspection of records, other than those of carriers, was within the authority of the FDA, but in a footnote to the opinion in *United States v. Crescent-Kelvan Company,* the following statement appears:

> Comparing the provisions of Section 704 of the Act, 21 U. S. C. A., Section 374 (Supp. 1946), with those of Section 703, 21 U. S. C. A., Section 373 (Supp. 1946), relating to the inspection of drugs in the possession of carriers engaged in interstate commerce it should be noted that the right to inspect shipping records is expressly conferred upon officers of the Administration. Since the right to inspect shipping records is not expressly conferred upon inspectors making inspections of factories, it may be argued that an inspection of a factory under the latter section would not include the inspection of the factory's shipping records. On the other side, it may be argued that inspection of a "factory" includes the inspection of everything to be found therein relating to the business of the factory. The latter view seems to us to be more in accord with the canons of statutory construction but it is unnecessary to decide this question in the case at bar.[17]

This dictum was often referred to by inspectors of the FDA as an indication of their authority to inspect shipping records or any other records found in the factory which had any relation to the business, up to the time that the *Cardiff* case was decided by the United States Supreme Court.[18]

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the inspectors knew she was present in the plant. The 1953 Factor Inspection Amendment substituted the word "agent" for the word "custodian."

[15] *United States v. 75 Cases, etc. of Peanut Butter,* 54 F. Supp. 641 (1944), rev'd, 146 F. 2d 124 (CA-7 1944), cert. denied 325 U. S. 856 (1945). The inspector obtained permission of the president of the company to look at the records of the company's shipment of peanut butter. The information secured from the records was the basis for libel proceedings. The circuit court held that the district court had placed too narrow a construction upon the right of inspection in holding that it was incumbent upon the inspector to make sure that the claimant, in giving his consent, understood the fullest use to which the records might be put by the government.

[16] *United States v. Crescent-Kelvan Company,* 164 F. 2d 582 (CA-3 1948). The defendants had been convicted of shipping, in interstate commerce, certain drugs which were adulterated. Section 704 was discussed in the opinion principally because the inspector had obtained shipping records from which the names of the consignees were obtained, which in turn led to this action. The court held that permission to enter the premises was tacitly granted by the defendant, and in addition, that permission to inspect shipping records was implicitly granted.

[17] Cited at footnote 16, at p. 586, footnote 4.

[18] Elson, cited at footnote 12, at p. 759.

Cardiff Decision [19]

The right of compulsory record inspection, as assumed by the FDA following the passage of the 1938 Act, was dependent upon whether Section 704 of that Act made factory inspection compulsory. It was almost universally accepted by industry that the FDA had the authority to compel industry to allow factory inspection. The legislative history could support this view.[20]

However, some 15 years later a federal food and drug inspector was refused admittance to make an inspection of a plant processing apples at Yakima, Washington, for shipment in interstate commerce. This refusal resulted in the first reported case to raise the issue as to whether authority existed for compulsory factory inspection. The final outcome of this refusal was that in 1952 in the *Cardiff* decision, the United States Supreme Court overturned Section 704.

The court based its decision on the conflicting provisions of the 1938 Act. Section 704 authorized an inspector to enter "after first making request and obtaining permission of the owner, operator, or custodian"; however, Section 301(f) made criminal "the refusal to permit entry or inspection as authorized by Section 704." [21] The court could not find a reasonable way to reconcile the two provisions and held the criminal provisions of Section 301(f) void for vagueness. Without the criminal penalties attached to Section 704, allowing factory inspection by the federal government became wholly voluntary. Lacking authority to make factory inspection compulsory, the government no longer had implied means to compel industry to submit to record inspection.

1953 Factory Inspection Amendment

The *Cardiff* decision had left the FDA without the compulsory factory inspection power which it deemed necessary for the proper performance of its functions.[22] The government's petition for cer-

[19] *United States v. Cardiff*, 95 F. Supp. 206 (E. D. Wash. 1951), rev'd 194 F. 2d 686 (CA-9 1952), aff'd 344 U. S. 174 (1952).

[20] H. R. Report No. 2139, Pt. 1, 75th Cong., 3d Sess., pp. 12-13 (1938). The report implies the compulsory nature of factory inspection.

[21] Earlier drafts of the 1938 Act had combined in one single section the power to inspect upon obtaining permission and the prohibition against refusing to grant such permission. Before the law's enactment the provisions were separated.

[22] In hearings on H. R. 2769, H. R. 3551, H. R. 3604, cited at footnote 6, at p. 80, Commissioner Crawford testified that prior to the 1938 Act approximately 5 per cent of the producers refused to admit inspectors on a voluntary basis,

tiorari in the *Cardiff* case stated its view on the type of authority it needed:

> Factory inspection of a drug plant may include observation, photographing and appraisal of the following factors on the premises: (1) conditions of sanitation; (2) raw materials; (3) formula cards; (4) actual manufacturing work sheets; (5) batch records; (6) weight and measuring controls; (7) packing techniques; (8) sterility and pyrogen control; (9) potency controls; (10) coding system; (11) facilities for maintaining separate identity of each drug; (12) cleaning of equipment between batches; (13) quarantining of drugs until after clearance with control laboratory; (14) qualifications of technical personnel; (15) the complaint file of the firm. In addition, samples and labeling of doubtful materials are purchased from the factory for anaylsis and appraisal by food and drug scientists; and shipping records relating to sources of raw materials as well as to destinations of finished products are examined and copied to facilitate the removal of offensive merchandise from interstate commerce.[23]

In general the regulated industries agreed that legislation for compulsory factory inspection was needed; however, they wanted the new legislation to limit the scope of factory inspection. They were concerned about the FDA's former broad interpretation of Section 704,[24] and believed that the government's petition in the *Cardiff* case asked for authority that was far too extensive.

In 1953 Congress enacted a Factory Inspection Amendment to the Federal Food, Drug and Cosmetic Act,[25] the effect of which was to exclude record inspection from within the scope of compulsory factory inspection.

The legislative history of this amendment, affecting Section 704 of the original act, is confused due to unresolved contradictions between the House and Senate reports on the bill prior to its passage. The House wrote its bill through the Commerce Committee whose chairman and other members interpreted it in the floor debate. The Senate approved the House's bill without any change whatsoever. Confusion arose due to the fact that the conflicting Senate report was not repudiated by the Senate Committee nor by the Senate.

Most authorities disregarded the Senate report and accepted the House interpretation that the addition to Section 704 of the words "within reasonable limits and in a reasonable manner" had the effect of requiring a strict construction of the words "factory, warehouse,

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but that under the 1938 Act, the refusals almost ceased entirely. During the six months immediately following the *Cardiff* case, Commissioner Crawford reported 18 refusals of entry.

[23] Petition for a writ of certiorari to the United States Court of Appeals for the Ninth Circuit, *United States v. Cardiff*, No. 27, Oct. Term (1952), 19.

[24] Hearings on H. R. 2769, H. R. 3551, H. R. 3604, cited at footnote 6, at pp. 94-96.

[25] P. L. 217, 83d Cong., 1st Sess., approved Aug. 7, 1953.

establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling" so that such matters as formulae, methods, processes, complaint files, shipping records, qualifications of technical personnel, and so forth, were not to be included within the scope of the inspection authorized.[26] It has been suggested that the words "within reasonable limits and in a reasonable manner" could have been broadly construed so as to give the FDA the same scope of inspection as if these words had not been added. The difference produced by the addition of these words might then have been that the courts would only require the FDA to show that the request to inspect records had some connection with the enforcement of the Act. This broad construction could possibly have been based upon the contradiction between the debates on the floor and the committee reports which lessened the value of legislative history in interpreting the amendment.[27]

However, the FDA took the tack of the majority of authorities. It publicly accepted the proposition that the Legislature did not intend to include record inspection within the scope of compulsory factory inspection,[28] and thereby waived its prior position expressed in the petition for certiorari in the *Cardiff* case.

Additive Amendments

With the passage of the Pesticide Chemicals Amendment of 1954,[29] the Food Additive Amendments of 1958,[30] and the Color Additive Amendments of 1960,[31] a procedure for gaining information without record inspection was extended. The procedure originally had been outlined in the New Drug Application provision[32] in the 1938 Act. Industry was required to make thorough tests of new products and to submit the results to the FDA. The FDA then investigated the facts and took one of three steps: it approved the product and granted permission for its marketing, it issued a regula-

[26] Dunn, Charles W., "Amended Factory-Inspection Law of the Federal Food, Drug, and Cosmetic Act," 8 FOOD DRUG COSMETIC LAW JOURNAL 792, 797 (1953). Rhyne, Charles S. and Mullin, Eugene F. Jr., "Inspect What? A Study in Legislative History," 9 FOOD DRUG COSMETIC LAW JOURNAL 18 (1954), at pp. 36-37.

[27] Christopher, Thomas W., "Significant Comments," 8 FOOD DRUG COSMETIC LAW JOURNAL 604 (1953).

[28] U. S. Dept. H. E. W. Release, Aug. 27, 1953, CCH FOOD DRUG COSMETIC REPORTS, ¶ 2661.67.

[29] P. L. 518, 83d Cong., 2d Sess., approved July 22, 1954.

[30] P. L. 929, 85th Cong., 2d Sess., approved Sept. 6, 1958.

[31] P. L. 618, 86th Cong., 2d Sess., approved July 12, 1960.

[32] P. L. 717, cited at footnote 11, Sec. 505.

tion prescribing conditions under which the product could be marketed, or it denied approval altogether if it appeared that the substance might be unsafe even when properly used, or that it might deceive the consumer.

For practical purposes the procedure constituted a pre-licensing program. It made available to the FDA extensive information regarding composition, manufacturing processes, and methods of analysis, on products using potentially toxic substances.

Drug Amendments of 1962

In December 1959 the Senate Antitrust and Monopoly Subcommittee (Kefauver Committee) began investigating the pharmaceutical industry. The inquiry concerned economics, dealing with alleged excessive prices and profits on prescription drugs. The Committee conducted several hearings which culminated in an extensive report entitled "Administered Prices in the Drug Industry."[33] At the conclusion of these hearings, S. 1552 or the Kefauver Bill was introduced into Congress on April 12, 1961.[34]

The Kefauver Bill proposed an amendment to Section 704 of the Federal Food, Drug and Cosmetic Act. Under its provisions, the FDA's scope of inspection would be enlarged to include specific records of establishments in which prescription drugs are made, processed, packed or held.[34a] Senate Committees' hearings[35] on the bill produced a number of changes before it was finally voted upon and passed by the Senate. S. 1552 was amended to exempt from record inspection pharmacies, licensed practitioners and persons who prepare drugs solely for use in research, teaching or analysis rather than for sale. In addition specific types of records were excluded from its provisions, such as financial, sales (other than shipping records), pricing, personnel and research data.

An administration bill, H. R. 11581,[36] was introduced by Congressman Harris on May 3, 1962. The Harris Bill would have extended

[33] S. Report No. 448, 87th Cong., 1st Sess., Subcommittee on Antitrust and Monopoly of Senate Committee on Judiciary, Pts. 14-26.

[34] S. 1552, 87th Cong., 1st Sess., Congressman Cellers' bill, H. R. 6245, 87th Cong., 1st Sess., was the companion bill for the Drug Industry Antitrust Act.

[34a] Cited at footnote 34, Sec. 508(c).

[35] Hearings were held on S. 1552 before a subcommittee of the Senate Committee on Judiciary on June 5 and July 5, 1961, and January 30, 1962. In addition, hearings were held on H. R. 6245 before the Antitrust Subcommittee of the House Committee on the Judiciary on May 17, 18, 23 and 24, 1962.

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

the FDA's right of record inspection to cover food and cosmetic concerns. H. R. 11581 would have amended Section 704 to authorize inspection of "all things therein (including records, files, papers, processes controls, and facilities)" of establishments where drugs, food, cosmetics and devices are manufactured, processed, packed or held after introduction into interstate commerce.[37] The sole limitation of the FDA's inspection authority would be that its investigations concern "violations or potential violations" of the Act. Extensive hearings on H. R. 11581 were held by the House Committee on Interstate and Foreign Commerce, during which the food and cosmetic industries strongly opposed the expansion of record inspection authority to cover them.[38]

While the House Committee was still debating H. R. 11581, it received S. 1552 which had been passed by the Senate. About this time publicity on the thalidomide issue[39] reached its peak, and so while industry as a whole resisted the new legislation, manufacturers of prescription drugs seemed reconciled to the fact that for them there would be new controls.[40]

After considering the provisions of both bills, the House finally adopted S. 1552 with amendments in lieu of H. R. 11581. S. 1552, granting the FDA power to inspect the records of the prescription drug industry for information concerning a violation, was signed into law by the President on October 10, 1962.[41]

THE PRESENT MEANS AND EXTENT OF RECORD INSPECTION

Except when dealing with the prescription drug industry which is newly regulated by the Drug Amendments of 1962, the FDA presently operates according to the 1953 Factory Inspection Amendment. Thus it does not have the administrative power to compel industry to produce its business records for inspection. Asserting that it would

[37] Cited at footnote 36, Sec. 201(a). H. R. 11581 differed from other bills on factory inspection proposed at that time in that specific items were in parenthesis rather than in the text of the proposed statute. This statutory construction might have given the phrase "and all things therein" a wider scope of inspection power, especially with the new added phrase "or otherwise bearing on violations or potential violations of this Act."

[38] Hearings were held on H. R. 11581, 87th Cong., 2d Sess., June 19-22 and Aug. 20-23, 1962.

[39] 108 *Congressional Record* 16302-16306; 108 *Congressional Record* 20873 (Senator Hart); 108 *Congressional Record* 20881 (Senator Hruska).

[40] Goodrich, William W., "The Case for the Factory Inspection Amendment," 17 FOOD DRUG COSMETIC LAW JOURNAL 517, 519 (1962).

[41] P. L. 781, 87th Cong., 2d Sess.

be hampered in carrying out its duties if it had no access whatever to business data, the FDA since 1953 has been engaged in a search for indirect means whereby it might exercise the power to inspect industrial records.

Rejected Possibilities for Securing Records from Industry

There were at least three methods explored but not used, that is, search warrant, subpoena by grand jury, and administrative subpoena *duces tecum*. The Fourth and Fifth Amendment of the Federal Constitution would afford industry little protection against such devices. Moreover, under a lawful subpoena or search warrant, officers could be compelled to testify about business matters of their corporations [42] in spite of the fact that they might thereby personally incriminate themselves.[43]

Search warrant.—The use of the first possible method, that of search warrant,[44] was not expressly excluded by Congress as a method of enforcement. It is true that the majority report of the committee conducting hearings on factory inspection prior to enactment of the 1953 Amendment rejected the minority report's suggestion that the entire "inspection" procedure be predicated on a search warrant basis.[45] However, Congress did not specifically forbid the FDA to make use of the general search warrant power to which it is entitled under the federal criminal statutes.

In actual practice the FDA can resort to the use of search warrants where it finds its operations being thwarted.[46] However, two factors inhibit the general usage of search warrants as a means of gaining access to industry records. The first is the difficulty of meeting the detailed requirements for a search warrant's issuance as out-

[42] *Silverthorne Lumber Company v. United States,* 251 U. S. 385 (1920); *Hale v. Henkel,* 201 U. S. 43 (1906); *U. S. v. Philadelphia Railroad,* 225 F. 301 (DC Pa. 1915); Note, 30 *Columbia Law Review* 103 (1930); *United States v. Morton Salt Company,* 338 U. S. 632 (1950); *Davis v. United States,* 328 U. S. 582 (1946).

[43] *Essgee Company v. United States,* 262 U. S. 151 (1923); *Wilson v. United States,* 221 U. S. 361 (1911); *United States v. Wernes,* 157 F. 2d 797 (CA-7 1946); *United States v. White,* 322 U. S. 694 (1944); *Rogers v. United States,* 340 U. S. 367 (1951); *Caroline Products Company v. United States,* 140 F. 2d 61 (CA-4 1944), aff'd 323 U. S. 18 (1944).

[44] Strichartz, Richard, "Problems Relating to the Use of the Search Warrant in the Administration of the Federal Food, Drug and Cosmetic Act," 9 FOOD DRUG COSMETIC LAW JOURNAL 331. (1954).

[45] H. R. Report No. 708, 83d Cong., 1st Sess., p. 5 (majority report), p. 32 (minority report).

[46] Crawford, Charles, "The Retail Druggist and the Federal Law," 8 FOOD DRUG COSMETIC LAW JOURNAL 721, 726 (1953).

lined in Rule 41 of the Federal Rules of Criminal Procedure. The FDA must demonstrate to the court that there are sufficient facts for a reasonably discreet and prudent man to believe that a violation of the Federal Food, Drug and Cosmetic Act has taken place before a search warrant can be authorized. The difficulty of showing "probable cause" that a crime is being committed [47] is a severe limitation. A second inhibiting factor is the knowledge that general use of search warrants to obtain records might readily have a very adverse effect on industry's attitude of cooperation with the Administration.[48]

Subpoena by grand jury.—The legislative history of the original 1938 Act did not indicate that use of the grand jury should be excluded as an enforcement method,[49] nor did the 1953 Amendment.[50] The grand jury has almost unlimited subpoena powers based upon the principle that all citizens must assist the effective functioning of government by making available information which is necessary to the proper enforcement of the law.[51] All records pertinent to the manufacture, distribution, and sale of food, drugs or cosmetics would appear to be within the scope of a grand jury investigation. The only limitation here would be that the information be reasonably relevant to the subject of inquiry.[52]

Administrative subpoena *duces tecum*.—If the FDA were stymied in an important investigation, it could utilize the subpoena *duces tecum* of the grand jury.[53] However, the FDA has never used this method, since as with the case of search warrants, industry would probably resent the use of a criminal procedure for investigating its operations

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[47] Hearings on H. R. 2769, H. R. 3551, H. R. 3604, cited at footnote 6, at p. 218. Commissioner Crawford said, "Since manufacture of misbranded or adulterated drugs is not itself ordinarily an offense under the Federal Food, Drug and Cosmetic Act, such a showing would be a practical impossibility in most cases."

[48] Dunn, cited at footnote 26, at p. 801.

[49] Swertfeger, L. Jack Jr., "Investigations Beyond the Scope of Section 704 of the Federal Food, Drug and Cosmetic Act: The Grand Jury," 10 FOOD DRUG COSMETIC LAW JOURNAL 32, (1955).

[50] 83 *Congressional Record* 7794 (1938), as quoted in Dunn, cited at footnote 5, at p. 904.

[51] Swertfeger, cited at footnote 49, at p. 35.

[52] *Brown v. United States*, 276 U. S. 134 (1928); *In Application of Radio Corporation of America*, 13 F. R. D. 167 (DC N. Y. 1952); *Application of Texas Company*, 27 F. Supp. 847 (DC Ill. 1959); *In re Investigation Conducted by the Attorney General of the United States*, 27 F. Supp. 997 (DC N. Y. 1939); *Penfield Company of California v. Securities and Exchange Commission*, 330 U. S. 585 (1947); *Petition of Borden Company*, 75 F. Supp. 857 (DC Ill. 1948).

[53] Larrick, George P., "Sanitation Provisions of the Federal Food, Drug and Cosmetic Act," 1 FOOD DRUG COSMETIC LAW QUARTERLY 158 (1946).

if other methods are available.[54] This type of subpoena may be issued for less than the "probable cause" required for a search warrant; the sole requirement is a reasonable and relevant purpose.[55] At present, there is no statute granting the FDA authority to use this device, and a bill which would have granted such authority was introduced in Congress but never passed.[56]

Methods in Use for Securing Records Without Inspection and the Industries' Reaction

Instead of relying on negative "enforcement by prosecution" [57] the Food and Drug Administration has chosen to seek data from factory records primarily by encouraging industry to submit them voluntarily, and by using written interrogatories authorized by the federal discovery procedures.

Encouraging voluntary submission of records.—Soon after the passage of the 1953 Amendment the Food and Drug Administration issued the following statement:

> Accordingly, inspectors have been instructed to ask permission to see such records or files whenever there is any need or reason to examine them or to obtain information contained in them.
>
> The inspector may state reasons for asking to examine a particular record or file but will not otherwise press the owner, operator or agent for permission to see it.
>
> The Food and Drug Administration will not attempt to predetermine what action may be appropriate in future situations which seem to necessitate inspection of records, but will endeavor to resolve these problems as they arise, keeping in mind the health, safety and interest of consumers and the congressional intent in the statute as a whole to protect public health.[58]

A reaction from industry was not long in coming. Mr. Charles Wesley Dunn, counsel for the American Pharmaceutical Manufacturers Association, analyzed this statement, gave a warning to industry, and made some long range predictions:

> The foregoing statement referring to the Food and Drug Administration statement above is subject to the following (among other) significant comments: (a) It curtails the inspection information prescribed in the Congressional debate. (b) In enacting the amended law of Section 704, Congress did not expressly authorize the Food and Drug Administration to secure this prescribed informa-

[54] Christopher, Thomas W., "Factory Inspection," 8 FOOD DRUG COSMETIC LAW JOURNAL 101 (1953).

[55] *Oklahoma Press Publishing Co. v. Walling*, 327 U. S. 186 (1946); *Fleming v. Montgomery Ward & Company*, 114 F. 2d 384 (CA-7 1940), cert. denied, 311 U. S. 690 (1940).

[56] H. R. 4572, 81st Cong., 1st Sess. was introduced by Congressman Keefe on May 9, 1949. The bill died in committee.

[57] Christopher, cited at footnote 54, at p. 103.

[58] Commissioner Crawford, in a Dept. of H. E. W. release of Aug. 27, 1953.

tion on a voluntary basis. On the contrary, it plainly indicated in its House report and debate that the Food and Drug Inspection authority under this law does not reach such information. But the Food and Drug Administration may argue, until it is judicially decided otherwise, that Congress has not outlawed its traditional practice to ask for established inspection information on a voluntary basis. (c) A voluntary Food and Drug Administration inspection of an establishment has essentially the same administrative purpose as a compulsory one, to enforce the Food, Drug, and Cosmetic Act. (d) Information given by a manufacturer or dealer in such a voluntary inspection may be used as evidence against him in a criminal proceeding under this Act, and he cannot legally avoid this result by a written disclaimer that it is voluntarily given without prejudice. In short: where a manufacturer or dealer voluntarily gives the Food and Drug Administration information in an establishment inspection to enforce the Food, Drug, and Cosmetic Act, he legally surrenders any immunity from its use as evidence against him in an enforcement proceeding thereunder. (e) A voluntary establishment inspection by the Food and Drug Administration in the area of the prescribed information involves only legitimate manufacturers and dealers, who are willing to cooperate with it; and such inspection does not reach illegitimate manufacturers and dealers, who deliberately violate the Food, Drug, and Cosmetic Act and use the Congressional limitation of amended Section 704 to prevent its enforcement against them. Hence, this voluntary inspection will fail in its major enforcement purpose. (f) An FDA request for a voluntary establishment inspection, made to legitimate manufacturers and dealers, may place them in a difficult position to refuse it; and in that event, it is practically converted into a compulsory inspection under the Food, Drug, and Cosmetic Act. For, in this situation, they may not wish to offend the FDA; or they may fear its retaliatory action; or they may sincerely desire to cooperate with it. (g) In the last paragraph of the above official statement, the FDA plainly serves notice that if a manufacturer or dealer voluntarily refuses to give prescribed information needed to enforce the FDC Act, it will use other available means to secure it; and they importantly include a drastic search warrant procedure.[59]

A series of cases involving voluntary record inspection has substantiated Mr. Dunn's observations. The courts have held that, where a manufacturer or dealer voluntarily allows the federal inspector to examine his records, such information as the inspector acquires may be used as evidence against the manufacturer or dealer in a criminal proceeding.[60] All the defendants in the cases contended that they were immune to prosecution under Section 703 of the Federal Food,

[59] Dunn, cited at footnote 26, at pp. 802-803.

[60] *United States v. Arnold's Pharmacy, Inc.*, 116 F. Supp. 310 (DC N. J. 1953). The failure of pharmacy operators to object when their samples and prescription records were first made available to the government's agents was taken, by the court, as clearly indicative of the operators' willingness to turn them over. The operators' motion to suppress and return the evidence, following their indictment by information charging them with violating the Federal Food, Drug and Cosmetic Act by selling prescription drugs without prescription, was denied since there had been no unreasonable search and seizure in violation of the Fourth Amendment to the Constitution and the immunity clause of Section 703 of the Act was not applicable. However, as dicta, on page 714, the court added that it was equally clear that:

"[T]he section (703) was intended to apply where access to the records

Drug and Cosmetic Act, which immunizes shippers and conduits from whom evidence is obtained by compulsion pursuant to the authority of that section. The courts, not mentioning the fact that Section 703 specifies only shippers and conduits regarding immunity, declared that the safeguard from prosecution did not apply to these defendants because they had opened their records.

In general, the major industries have adopted three policies regarding voluntary submission of records for inspection by the government. The first position is that of cooperation, in which the company makes its records available when good reasons for its doing so are given. Companies taking the second position maintain that the FDA has no right under the 1953 Amendment to request the privilege of inspecting confidential records, and therefore withhold them. The last position consists of a composite of the two preceding policies. Companies maintaining this position are willing to cooperate with the FDA within certain limits, but refuse to show records containing essential production knowledge and confidential information (for example, formulas and processes) when they believe such trade secrets are not essential to proper enforcement. Whatever position they may take, companies generally resent and oppose "fishing expeditions" (by which federal inspectors might seek a basis for enforcing the Act against an industry by examining that industry's records).

Use of written interrogatories.—Under the Federal Rules of Civil Procedure [61] a broad range of discovery devices is available for use by

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was refused the Government. In that event, by proceeding under the statutory provision in question, the Government could obtain access to such records despite such refusal. But, if the Government did so proceed, the 'evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained.'"

Authorities disagree with this dicta. For example, Vernon, David H., "Food, Drug and Cosmetic Law," 29 *New York University Law Review* 401 (1954), at pp. 406-407, states:

"On the basis of this dicta, it might be asserted that where a producer in the course of an inspection, refuses access to his records on the basis of Section 704, and the notice required by Section 703 is presented, the inspector could thus obtain information prohibited him by the former section. On the basis of such information, the Government, while barred from bringing a criminal action, might bring seizure or injunctive proceedings. However, Section 703 was intended to apply to carriers and conduits, and it is doubtful that it will be extended so as to prevent the congressional intention as regards the scope of authorized inspection."

See also *United States v. Scientific Aids Company,* 117 F. Supp. 588 (DC N. J. 1954); *United States v. Lyon Drug Company,* 122 F. Supp. 597 (DC Wis. 1954); *United States v. Herold, t. a. Mayfair Drug Company,* 136 F. Supp. 15 (DC N. Y. 1955).

[61] 308 U. S. 645 (1939) as amended 329 U. S. 839 (1947) and 335 U. S. 919 (1948).

the FDA after an action has been filed. Under the rules facts relevant to any part of a case, whether in issue or not, may be elicited from any party or witness.[62] If a party refuses to answer any question propounded to him by a discovery device, the court may cite him for contempt, refuse to allow him to support or oppose designated claims or defenses, prohibit him from introducing evidence, strike out the pleadings, dismiss the action or render judgment against him by default.[63] The three primary systems of the discovery procedure are depositions,[64] production of documents [65] and interrogatories.[66]

The government is reluctant to make extensive use of depositions, because they are so expensive and time-consuming.[67]

The production of documents under Rule 34 is available only by court order "upon motion of any party showing good cause therefor." Thus, document discovery differs significantly from discovery through depositions and from interrogatories by placing on the party seeking disclosure the necessity of first going to court and establishing his right to the information.[68] However, a shortcut to avoid the "good cause" requirement is Rule 33, under which some litigants have propounded interrogatories requesting that copies of certain statements be attached to the reply. Use of this procedure is based upon the theory that a copy of a witness' statement is not properly a "document." [69]

It appears that the FDA has found written interrogatories as permitted in Rule 33 to be an effective means of gaining extensive information. Interrogatories require no prior court approval and are relatively inexpensive to prepare. Moreover, since a 1946 amendment to Rule 33, there is no limitation to the number of interrogatories that can be made except to the extent that justice requires the recipient to be protected from annoyance, expense, embarrassment or op-

[62] "Developments in the Law—Discovery," 74 *Harvard Law Review* 940 (1961).

[63] Cited at footnote 62, at pp. 985-991.

[64] Fed. R. Civ. P. 30(a) says that a party may examine any person on oral depositions. Fed. R. Civ. P. 31 says that a party may take a deposition of any person by means of written interrogatories.

[65] Fed. R. Civ. P. 34.

[66] Fed. R. Civ. P. 33.

[67] Cited at footnote 62, at p. 953.

[68] *Heckman v. Taylor,* 329 U. S. 495, 67 S. Ct. 385, 91 L. Ed. 451; *Alltmont v. United States,* 177 F. 2d 971 (CA-3 1950), cert. denied 339 U. S. 967, 70 S. Ct. 999, 94 L. Ed. 1375; *Pennsylvania Railroad v. Julian,* 10 F. R. D. 452 (DC Del. 1950); *United States v. 88 Cases etc., Bireley's Orange Beverage,* 5 F. R. D. 503 (DC N. J. 1946); 4 Moore, *Federal Practice,* ¶ 24, 26, at pp. 1152-1159 (2d ed. 1950).

[69] Cited at footnote 62, at pp. 965-966. The pro and con arguments as to this technique are given and it is concluded that any substantial easing of the restrictions now imposed on document discovery by Rule 34 must come by way of Supreme Court decision or amendment.

pression.[70] The so-called "continuing duty" on the interrogated party assures the truth of answer to interrogatories up to the time of the trial.[71] They can be used by the FDA after an action has been filed, and are drawn up so that detailed facts on records and documents are gained.

In a series of cases industry has resisted use of Rule 33 interrogatories, but a review of the litigation shows that governmental usage has been backed by the courts in seizures, in issuing injunctions, and indirectly in criminal actions.

An early case[72] held that libels for seizure of adulterated products under the Federal Food, Drug and Cosmetic Act were subject to admiralty rules, and that the Federal Rules of Civil Procedure were inapplicable. Later this view was overruled. In *United States v. 88 Cases of Bireley's Orange Beverage*[73] the court stated that such libel actions, although in form under admiralty procedure, were common-law actions and subject to the Federal Rules of Civil Procedure in instances where the seizure took place on land.[74]

The government's interrogatory procedure was used in an injunction action brought under the Federal Food, Drug and Cosmetic Act in *U. S. v. Wilson-Williams, Inc. and Jack Elliott.*[75] The district court held that there is nothing in the act that expressly or impliedly makes the usual discovery procedures inapplicable to an injunction action. Congress did not intend the investigatory powers enumerated in the act to be exclusive and thereby preclude the government's use of the discovery procedure, under the Federal Rules of Civil Procedure, in a plenary action for an injunction.[76]

Under the Federal Food, Drug and Cosmetic Act, the government may institute both an *in rem* action against adulterated or misbranded goods and criminal proceedings against anyone who shares in the responsibility for the distribution of the illegal products. Recent cases have considered whether a corporation could avoid answering written interrogatories under Rule 33 because the individual chosen to answer

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[70] See 4 Moore, *Federal Practice*, ¶ 33.01(1), (2d ed. 1950).

[71] Cited at footnote 62, at p. 961.

[72] *U. S. v. 720 Bottles . . . Vanilla Extract*, 3 F. R. D. 466 (DC N. Y. 1944).

[73] 5 F. R. D. 503 (DC N. J. 1946).

[74] Contra: Bobker, "Discovery Under the Federal Food, Drug and Cosmetic Act," 2 FOOD DRUG COSMETIC LAW QUARTERLY 344 (1947). Emphasis on information sought from government by claimant.

[75] 24 F. R. D. 468 (DC S. D. N. Y. 1959).

[76] Cited in footnote 75.

elected to protect himself through the Fifth Amendment.[77] The corporation's argument has been that the act of answering might tend to make an individual the responsible person and liable to the criminal penalties of the Act. The courts have held that, although a "responsible person" within a corporation would be entitled to exercise his privilege against self-incrimination,[78] a corporation as a whole could not claim the Fifth Amendment. The corporation would have to answer interrogatories and do so by choosing someone who in no way participated in the questionable transaction.[79] Thus, interrogatories may be used to gain information for criminal proceedings.

In other areas also the Food and Drug Administration has had a greater number of favorable decisions in the judicial development of Rule 33 than has industry. Initially interrogatories could not be used by the FDA as "fishing expeditions" to hunt for evidence the government could use in support of its case.[80] However, the objection that interrogatories amount to a "fishing expedition" is no longer sustained if "the party is seeking information to aid him in establishing a claim." [81] Increasingly the use of Rule 33 interrogatories by the FDA has become a method for obtaining extensive information from the defendant or claimant,[82] whereas discovery most often has not been

[77] *United States v. 42 Jars, etc., "Bee Royal Capsules,"* 264 F. 2d 666 (CA-3 1959), aff'g 160 F. Supp. 818 (DC N. J. 1958); *United States v. 3963 Bottles, etc., "60 Capsules Lot No. 30019 Enerjol Double Strength . . .,* 265 F. 2d 332 (CA-7 1959) aff'g 172 F. 2d 470 (DC Ill. 1958), cert. denied 360 U. S. 931 (1959); *United States v. 49 Jars of Tranquilease,* 23 F. R. D. 192 (DC of D. C. 1958); *United States v. Dotterweich,* 320 U. S. 277 (1943); *United States v. Parfait Powder Puff Company,* 163 F. 2d 1008 (CA-7 1947), cert. denied 332 U. S. 851 (1948); *United Sttaes v. 47 Bottles, More or Less, Each Containing 30 Capsules of Jenasol R. J. Formula "60,"* 26 F. R. D. 4 (DC N. J. 1960).

[78] *United States v. 47 Bottles . . . Jenasol,* cited at footnote 77.

[79] See 4 Moore, *Federal Practice,* ¶ 33.07, at p. 2277 (2d ed. 1950). Under the amended rule the agent who answers on behalf of the corporation does not need to have personal knowledge of the facts. For example, an attorney may answer.

[80] *United States v. 998 Cases of Tomato Puree* (DC Mich. 1943). CCH Food Drug Cosmetic Law Reports ¶ 6351.48.

[81] 4 Moore, *Federal Practice,* ¶ 33.10, at p. 2291 (2d ed. 1950); *Hickman v. Taylor,* 329 U. S. 495, 67 S. Ct. 385, 91 L. Ed. 451, 10 FR Serv. 26 b. 211, Case 1 (1947); *Nichols v. Sanborn Company,* 24 F. Supp. 908, 1 FR Serv. 33.311, Case 1 (DC Mass. 1938), *Glick v. McKesson & Robbins, Inc.,* 14 FR Serv. 30 b. 352, Case 1 (DC WD Mo. 1950).

[82] *United States v. 400 Cases, etc., "Quick Frozen Sunshine Brand Sliced Strawberries . . ."* (DC N. Y. 1949), CCH Food Drug Cosmetic Law Reports ¶ 6351.482. In an action alleging the misbranding of packages of strawberries labeled in part ". . . Net Weight 14 oz. —This one-pound package serves 4." Interrogatories relating to the following were allowed: The date claimant first began packaging strawberries in this manner; the dates of all shipments; the ratio of sliced strawberries to sugar in the goods under seizure; the selling price; the meaning of certain code num-

allowed as a means of eliciting information from government experts.[83] If the interrogatories are relevant, the fact that it may require work, research, and expense on the part of industry in order to answer them is insufficient to render the interrogatories objectionable.[84]

New Regulations for Inspecting Records of the Prescription Drug Industry

The new drug amendments[85] provide for the registration and inspection of all establishments engaged in the manufacture of prescription drugs, regardless of whether they are engaged in interstate or intrastate commerce. All registered drug establishments are required to be inspected by FDA at least once every two years. The area of inspection is enlarged to include all records, files, papers, processes, controls and facilities relating to prescription drugs. The

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bers; whether claimant had conducted a survey to ascertain consumer reaction to the fill of the containers; the number and names and addresses of persons interviewed and the question asked on the survey; and claimant's packing procedure. (Interrogatories relating the following was disallowed: The variety of strawberries used and the locality in which they were produced; the price per pound to claimant of the strawberries and the sugar used; the selling price of goods shipped along with the goods under seizure; details of claimant's system of coding frozen sliced strawberries with sugar; exact replies of persons questioned in claimant's consumer-reaction survey; the number of and names and addresses of persons questioned, the questions and answers in such survey, and the names and addresses of the persons conducting the survey.)

[83] *United States v. 720 Bottles, etc.,* 3 F. R. D. 466 (DC E. D. N. Y. 1944); *United States v. 88 Cases, More or Less,* 5 F. R. D. 503 (DC N. J. 1946); *United States v. Five Cases, etc.,* 9 F. R. D. 81 (DC Conn. 1949). (No good cause was shown as claimant could make its own analysis.) Contra: *United States v. 300 Cans, etc., of Black Raspberries,* 7 F. R. D. 36 (DC N. D. Ohio 1946). (Government records were not privileged.)

[84] *United States v. Nysco Laboratories, Inc.,* 26 F. R. D. 159 (DC E. D. N. Y. 1960). The defendants made general objections to the written interrogatories served by the government consisting of 32 pages, 73 interrogatories and approximately 800 separate questions. The district court held that interrogatories as a whole were not burdensome or oppressive, although there were some limitations made. In general the court held that defendants can refuse to answer relevant interrogatories only when the information is not within their knowledge. The following cases show that the courts generally will not deny discovery merely because trade secrets will be disclosed, if it is clearly shown that the information is relevant to the issue, not otherwise available, and necessary in the proof of case: *Bleachers v. Bristol-Myers Company,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 20,761.07 (Del. 1960); *Putney v. DuBois Company,* 240 Mo. App. 1075, 226 S. W. 2d 737 (1950); *Hyman v. Revlon,* 100 N. Y. S. 2d 937 (1950); *Lenerts et al. v. Rapidal Distributing Corp.,* 3 F. R. D. 42 (1942); *Pierson v. Roux Laboratories, Inc.,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 20,761, 125 *New York Law Journal* 634 (1951); *Silver v. Pepsi Cola,* 144 N. Y. S. 2d 301 (1955).

[85] P. L. 781, cited at footnote 41.

only exceptions are financial data, sales data other than shipping records, pricing data, and personnel and research data not pertinent to drug safety, effectiveness, manufacturing and control. Consulting laboratories doing work for prescription drug firms on a fee basis are included as establishments subject to inspection.

In addition, the new amendment defines prescription drugs as adulterated (illegal) if they are not produced in a plant established, equipped and operated in conformity with current "good manufacturing practice." Since the passage of the amendment the FDA has issued proposed regulations to establish criteria for such good manufacturing practices, and record-keeping is one requirement.[86]

Within the proposed regulations records on manufacture, processing, packing, labeling, control and holding are specified. A master formula record shall be properly maintained for each drug product. Batch records showing each phase of production and distribution shall be maintained and identified by number, making it possible to trace the history of the batch's manufacture and dispersion. If the information required by the proposed regulations turns out to be insufficient for the purposes of enforcement, then the FDA has the right to require the maintenance of additional records in conformity with good manufacturing practices.

The actual mode of operation of the government and the prescription-drug industry under the new amendments remains to be seen. Of far-reaching significance, however, is the fact that the FDA, as outlined in its proposed regulations, intends to make compulsory record-keeping a part of its program to enforce the Federal Food, Drug and Cosmetic Act through record inspection. **[To Be Concluded]**

[86] *Federal Register,* Vol. 28, at pp. 1447-1461, Feb. 14, 1963.

Public Protection, Private Choices and Scientific Freedom: Food, Drugs and Environmental Hazards

By ALANSON W. WILLCOX

The Author Delivered This Charles Wesley Dunn Lecture at the Law School of Harvard University, Cambridge, Massachusetts on March 15, 1963. The Author Feels That Present Government Control Necessarily Limits Scientific Freedom at the Fringe Where Freedom Turns into License. This Restriction Is Inevitable if We Are to Protect the People in Matters That the Laity Cannot Fully Understand. He Believes That There Is Not Much Danger That We May Prevent a Potentially Significant Discovery from Reaching Fruition. In the Area of Environmental Hazards the Scope of Policy-Making Decisions Broadens Because So Much More Is Still Unsettled Than in Food and Drug Regulation.

IT IS A NOVEL as well as a pleasant experience—not merely to find myself in a Harvard Law School classroom, where I have often been—but to find myself on this side of the footlights, so to speak. It is altogether appropriate, I think, that this school should on occasion pay special attention to the law governing food, drugs and cosmetics, and it certainly is appropriate that this should be done in the name of Charles Wesley Dunn who devoted so much of his life and his energy to the development and exposition of this branch of the law. The subject would be important if only for the sheer magnitude of its impact, but, beyond that, it provides intellectual challenge in assessing the proper relation of government to citizen in our present complex world and promises to provide even sharper challenge in the years ahead.

When I first entered this law school and sat where you are sitting, I labored under the illusion that the man who sat up here

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knew all the answers. I do not recall how many weeks that illusion survived, but I do recall vividly the shock of discovering that two of the patently omniscient, Professors Williston and Beale, took diametrically opposite views of a small point of law. I remember, too, Professor Scott's remark that the best examination paper he ever received was one in which he thought nine of the ten questions were answered wrong.

We bureaucrats, like the student taking his finals, have to answer the questions that are put to us, but unlike him we are graded on our ability to persuade others that our answers are right. It is refreshing, then, to revisit your world where one can throw out questions with no pretense that he knows the answers, and I mean to take full advantage of your academic hospitality in this regard. If we dig a bit into the present Federal Food, Drug and Cosmetic Act and the reasons that underlie its development to date, we shall unearth questions that no one can answer with assurance, but in the process we may clarify the nature of some issues that must be faced in the very near future. Hopefully, also, we may derive a sense of direction for changes which will be as controversial as—in one form or another—they are inevitable.

Regulatory Control Is Essential

We may start our examination with the simple and self-evident truth that strict regulatory control of our supply of foods, drugs and cosmetics is essential to the health and the well-being of the American people. On this truth has been built, over the last half century, a regulatory program of broad reach and great depth which in this year, 1963, will apply to the distribution and sale of some $100 billion worth of goods, perhaps a quarter of the personal consumption expenditures of the people. If we have moved a long way from the free competitive

enterprise of earlier days and from the common law principle *caveat emptor,* the move has been unavoidable because food and drugs—yes, even cosmetics—are necessities of life and because impurities or other abuse can have such disastrous effect. The regulated industries, by and large, accept the need for strict controls as a matter of course. The most vigorous critic of the welfare state would not wish to restore the patent medicine man and the purveyor of poisonous food preservatives to the freedom they enjoyed in 1900.

But if the need for such regulation is self-evident in the twentieth century, why was it less self-evident in the nineteenth or the eighteenth? Food has been a necessity of life, and bad food has been a threat to health, ever since life began. Drugs, however primitive or even useless, were probably prized by our ancestors in times of illness as much as we prize the miracle drugs of today, and a wrongly concocted potion could be lethal then as now.

Need for Modern Regulation

As I considered why we need regulation now that we did not need a century ago, it occurred to me to examine the rationale offered then for the rule *caveat emptor.* Chancellor Kent wrote in the 1820's:

> The common law very reasonably requires the purchaser to attend, when he makes his contract, to those qualities of the article he buys, which are supposed to be within the reach of his observation and judgment, and which it is equally his interest and his duty to exert.

When the housewife of today makes her selection from the shelves of a supermarket, how far can her observation and judgment take her toward knowing what she is buying? When the physician of today prescribes and the pharmacist dispenses a prepackaged drug, what assurance does even their skilled professional judgment afford that the patient will receive what the doctor ordered?

An essential element in the justification of our elaborate scheme for regulating food, drugs and cosmetics is the fact that modern methods of manufacture and distribution have whittled down, often to the vanishing point, the opportunity of the consumer to protect himself. The debatable question is not whether, but how far the consumer's diminished ability to choose intelligently warrants us in limiting his exposure to misrepresentation or the results of ignorance. A large part of the day-to-day grist of the Food and Drug Administration consists of determinations of one kind and another concerning the truthfulness and the sufficiency of representations made to the public at large or to the medical profession.

Informing the Consumer

I will postpone, because I want to discuss in a broader context, the most pervasively troublesome aspect of this regulatory function, the necessity of imposing governmental judgments in matters on which informed and disinterested opinions may differ. I should first like to illustrate, however, the broad reach of governmental insistence merely that the consumer be fairly informed, and the kind of intriguing question which even this relatively simple regulatory responsibility entails.

When vitamin and mineral deficiencies came to be recognized as a serious flaw in the American diet, powerful support developed for the enrichment of certain staple foods to supply the missing elements. But it was easy to foresee the chaos that would result if each producer were left free to outbid his competitors in adding—and in advertizing quite truthfully that he had added—a different or larger variety, or larger amounts, of these esoteric ingredients. In theory, perhaps, the consumer might be expected to learn what vitamins and minerals, and how much of each, he needs for the preservation of his health, but even in theory he could hardly be expected to translate his requirements into the appropriate content, let us say, of a loaf of bread. At any rate, if his education on these matters had been left to the competitive blandishments of producers it is a certainty that confusion would have outrun elucidation. And so, exercising the then newly conferred authority to establish standards of identity for foods in order to promote honesty and fair dealing, the Federal Security Administrator (the predecessor of the present Secretary of Health, Education and Welfare) prescribed the vitamin and mineral content of "enriched" cereal products, specifying the required ingredients and certain optional ones, and the minimum and maximum quantities of each. The validity of this regulation was sustained by the Supreme Court over constitutional protest, even though the regulation had the effect of forbidding the interstate shipment of nonconforming products. Here was the government, in the interest of consumer understanding, driving certain cereal products entirely off the market, even though they were wholesome foods and their labeling was altogether truthful.

Somewhat similar administrative action is now pending to restrict the confusing multiplicity of vitamin and mineral pills which are currently being sold in very large volume as dietary supplements.

A Current Example

Another example is the current controversy, which we hope may not have to be resolved, over the proposed marketing of a so-called fish flour made from whole fish including all their contents. The product would supply a cheap source of protein, and the process is said to render it altogether safe from the standpoint of health. But many of us consider parts of the fish, and the contents of their innards, as constituting filth which, however harmless, we should not care to eat. The same product, substantially, has actually been on the market for a long time, but has been sold as fertilizer. Work is now going on in search of an economically feasible way to remove the unsavory elements of the fish, and we hope the issue will become moot. But already it has engendered a lively debate over the propriety of keeping off the market, wholly on esthetic grounds, a wholesome and otherwise useful article of food. When one eats a sardine or a chocolate-covered ant he knows what he is eating; by contrast, there could be no assurance that fish flour, once it was on the market, would not make its way into a wide variety of foods without the knowledge of the consumer. Here again, therefore, it seems to us that the key to the problem lies in the need to enable the consumer to know what he is getting.

The Protection of Health

Supplementing the consumer's observation and judgment is not a simple or noncontroversial task even in the realm of economic cheats. When we turn to the other major purpose of food and drug legislation, the protection of health, the problem becomes largely one not of supplementing but of providing a substitute for the consumer's ability to make appropriate decisions for himself. Here, keeping nonconforming products wholly off the market is routine regulatory procedure. The consumer is really helpless against many hazards to which careless or unscrupulous producers may expose him, and here the harm may be irreparable. Indeed, it was resentment against these invisible dangers, more than anything else, that led to enactment of the first food and drug legislation early in this century.

In the case of food, banning a product that is dangerous to health is really no more drastic a procedure than would be a requirement—assuming that it could be made effective—that the consumer be fully informed. Not many of us would buy a can of beans knowing that it contains even a little poison. With drugs, however, the case is quite

the reverse, since practically all drugs are dangerous in some degree and are used despite their dangers. The problems, first, of weighing the advantages against the risks, and, second, of assuring adequate information to the lay public for over-the-counter drugs and to physicians for prescription drugs, are difficult and complex in the extreme.

Individual Rights

Consideration of dangers to health brings us to the final and by all odds the most difficult element in the rationale underlying food and drug regulation. Although the public health is obviously a proper public concern, we raise very subtle questions when we dictate to the individual that he may not, though with full knowledge of the facts, expose himself to risks that we deem to be undesirable. The problem rarely arises in purest form; usually—for example, with the abuse of narcotic drugs—we can find collateral harm to others to buttress our objection to self-inflicted injury. Our noble experiment in abolishing alcohol was motivated in part by belief that others besides the drinker himself were hurt, and certainly our present effort to curb the illicit sale of "pep pills" draws support from the highway accidents traceable to this kind of stimulation. Yet the question remains under what circumstances government may properly dictate, not what we really find necessary for the protection of society, but what we think wiser for the individual than the choices he would make for himself.

No one has objected to proscribing the addition to food of substances found capable of causing cancer. Yet no one, as far as I am aware, has suggested that the sale of cigarettes be forbidden, and I doubt that even confirmation of their suspected complicity in cancer would produce much sentiment in favor of banning them. If there is a risk, people should be made aware of it, but if they choose to run the risk, that is their business. Let us now suppose, however, that a filter should be developed which, without interfering with the taste or the other pleasures of smoking, removed all the harmful elements. Ought government, in that case, to require all cigarettes to be equipped with this new device, and ban those that are not? Or should the smoker still be free to continue his unfiltered smoking if he wishes? And if so, does it follow that people who want to eat carcinogenic food should be permitted to do so?

In real life, of course, questions rarely present themselves with the stark simplicity of classroom examples. But even in theory, and

still more in practice, the task of enabling the consumer to make an intelligent choice often becomes blurred by a temptation to make the choice on his behalf. I think it behooves us to keep this distinction in mind as best we can, and to prohibit only when we are satisfied that, for some good reason, to inform is not enough.

Fluoridation of Public Water

Many of you will have heard the hue and cry about the fluoridation of public water supplies, believed by most authorities to be helpful to dental health. Opponents of such action charge that it is a flagrant instance of forcing governmental views on nonassenting individuals—"compulsory medication," they call it. I do not agree that this presents the issue so sharply. Since the municipal water supply is what it is for all the people in the town, this action involves judgment of what is best for a group, not what is best for individuals. Since the recommended limit of fluoridation is well within the natural levels existing in some areas of the country, I would question the accuracy of its description as medication. But with these reservations it still remains true that government—in this instance local government—is tinkering with the environment because public authority is convinced that it knows better what is good for people than do those individuals who take a different view. This is a question that has to be decided one way or the other for the community as a whole, and my own view is that it should properly be left to the democratic processes of decision. But those who disagree do so with vigor.

Pollutions and Poisons

Fluoridation is an isolated instance, an example of governmental action to change the natural environment in order to improve man's health. By contrast, there is a vast and growing concern with changes in the environment brought about by man which may be deleterious to health. The prevalent pollution of our water supplies and of the air we breathe, the poisoning of our soil which Miss Carson has described so eloquently, the radioactive contamination of the earth and everything on it—slight at present but worrisome for the future—these things in combination, if powerful remedial action is not taken soon, can produce an environment far less hospitable to man than that with which nature endowed him. Here the case for remedial action, you will note, demands no delicate choice between informing the consumer, on the one hand, and shielding him from exposure, on the other.

The consumer of air and water, which is to say every one of us, is totally incapable of self-protection; knowledge of the hazards can alarm him but that is all it can do.

If the relevance of these problems to food and drug regulation is not at once apparent, I could remind you that pollutants from water or the soil or from radioactive fallout, even from the air, can readily find their way into foodstuff. But there are larger reasons for considering in a single framework the totality of our exposure to chemical or radiological hazards. Commonly it matters little whether man receives a quantity of poison through his nose or his mouth or his skin, or through all three. With the enormous advance of the chemical industries since the war, with the proliferation of synthetic materials of all kinds for all sorts of uses, with the cumulative toxic effect that multiple exposures may produce, we can no longer safely treat each source of trouble separately from the others, either in appraising the risks or in measures of control. Although to us as lawyers the problems remain separate and distinct—you cannot file a libel of condemnation against a cubic mile of polluted air, as you do against a parcel of adulterated food—to the scientists whose conclusions must underlie all enforcement programs it no longer makes sense to isolate food and drug chemistry from the rest of the chemical world. Finally, it is likely that developing patterns of control over other environmental hazards, despite their formal dissimilarity, will present challenges to the effective organization and operation of government that will closely parallel the challenges now emerging in food and drug regulation.

Recent Food and Drug Regulations

Food and drug law, to some extent in the statute enacted in 1938 and increasing with several of the recent amendments, has shifted away from reliance primarily on sanctions imposed after the fact, and toward the establishment of specific rules in advance and in some cases predetermination of compliance. A hundred deaths from a carelessly concocted drug finally convinced Congress, during the long struggle preceding the Act of 1938, that after the fact was too late, and gave us the first effective control over the distribution of untested drugs. A few other predeterminations of safety were provided for in that Act as originally passed, and the authority to prescribe food standards involved predetermination of some questions of honesty and fair dealing. Similar prejudgment, this time of individual batches of drugs, followed in amendments with respect to insulin and the early antibiotics. In the past decade new authorities have been added to

set tolerances for pesticide residues in food, to control food additives, and to regulate the use of coloring materials. Last year Congress required that new drugs be approved for efficacy as well as for safety, and in the wake of another disaster it strengthened the hand of the Administration in controlling the clinical use of investigational drugs. We have recommended, and hope that Congress will enact this year, preclearance procedures with respect to the safety and efficacy of therapeutic devices and the safety of cosmetics. (No one, let me hasten to add, has ventured to suggest that the government become arbiter of the efficacy of cosmetics, either before the fact or afterward.)

The sheer volume of the regulations flowing from the provisions now on the statute books is staggering. The FDA, I believe, is by a wide margin the largest contributor to the *Federal Register*. Fortunately, procedures have been authorized which cast the initial scientific burden upon the proponent of a regulation, and which reduce to a minimum the need for hearings and the occasion for judicial review; otherwise, the administrative load would be wholly unmanageable. Complaints about procedures are voiced from time to time, but they are not very frequent or very loud. The mechanisms that Congress has provided may want adjustment here or there, but we are not aware of need for major overhaul, and we should cast a wary eye on any proposal that would add materially to our workload. Procedures are important, but unless there are more serious flaws than I am aware of, we have larger problems to worry about.

The Case for Governmental Prejudgment

The case for governmental prejudgment is fairly clear, I should suppose, when we are discussing the marketing of a new drug. To oversimplify the case: somebody has to decide whether the drug is safe and whether it accomplishes what it is said to accomplish, and we can agree that it is better to vest this decision in a disinterested public official than in an interested producer. Actually, of course, the decision is less simple; it requires a delicate weighing of the relative safety and the degree of efficacy, and arrival at a truly sophisticated judgment. The subtlety of the job, however, only makes more imperative its impartial performance.

The same sort of argument, in essence, applies to several other areas of regulation. In the case of food additives, for example, or of pesticide residues, disinterested determination of safety before the product is marketed is as essential as it is with respect to drugs. These

are all matters in which the consumer's observation and judgment can help him not at all, and they are matters in which error or bias in a producer's appraisal of safety might do vast harm before regulatory action could bring about correction. Congress, therefore, has required premarketing approval.

Difficulties of Control of Environmental Hazards

There is a weak link in our control of food supplies, however, which illustrates a difficulty in controlling other environmental hazards. You remember the cranberry scare of a few years ago. The Department of Agriculture requires labeling of dangerous pesticides such that, if the instructions are followed, residues on crops will be within tolerances set by the FDA. The difficulty is that we can be sure the farmer has obeyed the instructions only by sampling what he ships and making delicate tests for compliance with the tolerances. I am not disparaging the farmer. How many of us read the fine print before we use a household insecticide; how many of us, having read, invariably abide by the rules? If one application in accordance with instructions does not succeed altogether, the temptation to try a second application is considerable, and may outweigh the risk that the crop will be seized by a federal marshal.

Outside the area of food and drugs, and apart from our new and unique concern with radiological hazards, effective predetermination of safety is still more the exception than the rule. Like the farmer, the householder and the gardener are given instruction for the safe use of deadly poisons, but they are not subject even to the sanction that may restrain the farmer. Efforts to clean up our water supplies are focused largely on correction of abuses already in existence. Control of smoke and other noxious emissions is spotty and inadequate. The only general attempt thus far to limit the harmful output of motor vehicles is the agreement of manufacturers to install the so-called "blow-by" in future models. Much is astir, in Congress and elsewhere, but for the most part we are talking of abatement and not of prevention. And even in correcting existing evils, progress often seems discouragingly slow.

Examples of Problems

The reason for our hesitancy to act, let me add, is not merely indifference or apathy. Partly it is ignorance of how to deal with many existing nuisances; partly it is the huge cost of dealing with

them by methods now known. A paper mill in a one-industry town has for generations been dumping its evil-smelling wastes into a river, creating a stench throughout the valley for many miles below, but its owners say that to desist from this practice would force the mill out of business and throw the town's population on the unemployment rolls. This story, in all its variations, is repeated time after time in place after place. Decision is not easy. The threat may be a bluff, but often it is not. I need not expand on the commotion that would be caused by a regulation that forbade even ten per cent of our automobiles the use of the highways.

Take the case of detergents. Apparently to the housewife they have marked advantages over the old-fashioned soap, but they cause our tap-water to foam and they interfere with various legitimate water uses. One member of the United States Senate has suggested that the so-called "hard" detergents be banned altogether because we have at present no effective way to remove them from water, and last week a member of Congress introduced a bill to require synthetic petroleum-based detergents to meet standards of decomposability. Several states also are considering action to mitigate this problem. But it is safe to predict that any such proposal will encounter more than a little resistance.

The case of detergents not only suggests the magnitude of the interests at stake and the difficulty of balancing gain against loss, but it also highlights the lack of any mechanism for striking this balance before interests have built up which may make remedial action all but impossible. If danger to the user of detergents had been involved we could have called a halt, and the Administration's current recommendations would require preclearance of such items with respect to the safety of the user. But no one had legal responsibility to appraise in advance the effect on our water supply of the use of these detergents in enormous volume throughout the land, and no authority to make such determinations now exists or has been recommended.

The point was tellingly made by Professor Barry Commoner at the National Conference on Air Pollution last December:

> One can also argue that the hazards of modern pollutants are small compared to the dangers associated with other human enterprises—such as automotive traffic. But no estimate of the actual harm that may be done by smog, fallout or chemical residues can obscure the sober realization that the risk was taken before it was fully understood. The importance of these issues to science lies not so much in the technical difficulty of estimating the associated hazards, but in that they warn of an incipient abdication of one of the major duties of science—prediction and control of human interventions into nature.

Our vulnerability to the popularization of new chemicals is serious enough already, but still more serious is the certainty that our troubles will be aggravated by the increasing tempo of research and development. As Professor Commoner went on to point out:

> The true measure of the danger is not represented by the present hazard, but by the disasters that will surely be visited upon us if we dare to enter the new age of science that lies before us without repairing this basic fault in the scientific enterprise.

New Forms of Governmental Control

The time may be coming when we shall have to devise entirely new forms of governmental control, aimed at prejudgment of the hazards and the appropriate conditions of use of new chemicals, and perhaps even at something akin to licensure of those who use the more dangerous of them. My imagination does not stretch to the point of suggesting how this might be done—the problems of method, of legal procedure, of administration and enforcement are staggering—but I think there is a great likelihood that we shall find ourselves driven in this direction by the sheer force of necessity. Such new controls are apt to come bit by bit and step by step, rather than in one grand design, and this, although it courts aggravation of our troubles while we hesitate, has at least the advantage that our mistakes in devising remedies will not be so costly. We shall have to learn as we go, but the present intense interest of Congress in water pollution and air pollution control, if nothing else, persuades me that we cannot wait for all the answers before we make a start.

Already, our authority over food and drugs is coming to pose a challenge, in some very basic ways, to the ability of government to govern. The challenge will be made sharper if anything of the sort that I am supposing comes to pass. Two facets of this challenge I want to suggest to you before I finish.

Legal procedures I do not intend to discuss. In food and drug regulation, as I have said, they seem to be reasonably well in hand, and they can be tinkered with if need be. In the larger areas that I have mentioned, it is too early even to speculate what regulatory methods may be appropriate. With all deference to our profession, moreover, I would rank procedure in a lower order of importance than other problems that face us. The crucial issue on which this kind of regulation must stand or fall is the quality of its decision making, and the crucial decisions will not be made by lawyers, even by those who wear judicial robes. Twice in recent years, when the pesticide and

food additive amendments were being framed, representatives of the Judicial Conference spoke out in opposition to industry proposals that the ultimate decision be left to trial *de novo* in the district courts. Lawyers can help and judicial review can help in assuring full opportunity to present all relevant material and to have it considered, and can correct truly arbitrary action if that should ever occur—important points, all of them. I am not belittling their significance when I say that, nevertheless, they go to the periphery and not to the heart of our problem.

Governmental Organization and Staffing

The first problem that I want to discuss may sound like a dull concern of dull bureaucrats. This is simply the problem of governmental organization and staffing, of bringing to bear on the day-to-day regulatory decisions, directly and immediately, the best scientific brains available and the last word in scientific knowledge in all the multitude of specialties that may be involved. In part, it is a problem of communication; we are indebted to Senator Humphrey for the vigorous prodding he has been giving us to examine our shortcomings in the interchange, and thus in the effective availability, of our huge store of scientific knowledge. In part, the problem is to attract and hold enough scientists of enough ability against the competitive lure of industry and the academic world. But still another part of the problem, stemming from the sheer size of government, may ultimately prove to be the most intractable of all.

We have in downtown Washington the national headquarters of the FDA, an agency that has grown up in the enforcement business but has been compelled in recent years to guide much of its activities by scientific judgments of the utmost subtlety—for example, in determining what fraction of a part per million of a deadly poison mankind can safely admit to his diet. We have a dozen miles away in suburban Bethesda the National Institutes of Health, the nerve center of our total national effort in medical research, which with the National Library of Medicine next door, I suppose, constitutes the greatest repository of scientific knowledge in medical matters that exists in the world, but which has little experience in law enforcement and no wish to be distracted from its primary function. The President has recommended, and we hope to have somewhere in the vicinity of Washington, an Environmental Health Center dedicated to the development of knowledge in the fields which its name suggests, and to serve also as a focal point in the regulatory efforts which are destined to expand so rapidly.

I have been told by excellent authority that no one these days can be a first-class scientist unless, if not actually engaged in research himself, he is at least in day-to-day or week-to-week touch with those who are. I suppose that, otherwise, he is in the position of a lawyer cut off from access to the advance sheets; sooner or later his skills will begin to rust. But law enforcement is a full-time job, and it is not easy to see how scientists assigned to that job can be kept adequately attuned to the on-going work of their peers. Your true research scientist, on the other hand, is apt to be impatient of the demands that are made on him by a concern with enforcement—notably the timetables and deadlines, and the digressions from any systematic development of his own research. Human problems accentuate the organizational ones. I believe that we can find ways to pool on occasion the knowledge needed to deal with major and broad-range questions as they arise in the processes of enforcement, but I have greater difficulty in seeing how we can assure adequate decision making in the run-of-the-mill cases that will continue to make up the grist of the FDA.

These problems are being wrestled with by persons skilled and experienced in the arts of administration, and I have no doubt that they will come up with improvements of the *status quo* if not with ideal solutions. But I would caution against belittling these questions of organization and staffing because they may seem at first blush to be not of the essence. Though ours is a government of laws it is also a government of men, and it can be good government only as we have the right men doing the right jobs in the right places. I do not envy those who must draw the organization charts and staffing patterns and devise the channels of communication needed for the tasks we have today—let alone the tasks that I see ahead.

Increased Governmental Responsibility

My final set of issues is related, and such answer as we can give hinges in part on devising the best organization and equipping it with the best staff of which we are capable.

When I contemplate the responsibility cast upon government by the duty to police our food and drug supplies, and the broader duties which I think government must soon assume, I sometimes feel appalled. To understand what I mean, you have only to remember how narrowly we escaped having thousands of hideously deformed babies; you have only to imagine that you had the responsibility of

deciding—and of acting on the decision—whether Miss Carson is or is not exaggerating the danger from pesticides to which we are exposed. Except only those great decisions that lead to peace or war, it is difficult to think of any that affect so many lives for so long to come or affect them in such important ways.

My concern is not limited to the difficulty or the importance of such decisions which obviously call for the utmost in talent that it is possible to bring together. My concern goes also to the necessity for making official choice between conflicting medical or other scientific views, and to the danger of developing a sort of medical orthodoxy imposed from on high. As the drug industry is fond of reminding us, medical history is sprinkled with the names of heretics posthumously beatified. Can we stop quacks in their quackery without stopping also that occasional genius who may hold a key to the future? I can offer no altogether happy answer to this question, but the impossibility of giving free rein to experiment on human guinea pigs makes it all the more important, I would suggest, that officialdom keep its mind open to dissenting views and to the possibility, however remote, that an unorthodox opinion may contain the germ of truth.

Drug Amendments of 1962

The line between either ignorance or charlatanism on the one hand and mere unorthodoxy on the other is bound to be a vague and wavering line. Insofar as a statute can draw the line, it was well drawn, I believe, in the Drug Amendments of 1962 which added the requirement that a new drug, before it may be marketed, be shown to be effective as well as safe. The Administration had proposed simply that the government decide whether efficacy had been established; industry urged that the existence of substantial evidence of efficacy should suffice. Since frequently the only tests would be those of the producer, we felt that the industry proposal would force us to act on evidence which, though substantial, might fall a very great deal short of being complete. In adopting the substantial evidence approach Congress made this significant addition which, to my mind, produced a result better than either of the proposals that had been put before it:

> . . . the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have . . .

This provision states, in effect, that there must be bona fide, responsible and adequately based medical judgment in support of efficacy before a drug may be put on the market, but that if this condition is met, a minority view may prevail. A similar criterion underlies the regulation recently issued for control of investigational drugs during the period before permission is sought to market them commercially. In the development of a drug, animal experimentation can take the investigator a considerable way, but commonly it can give no sure measure even of toxicity to humans, and still less can it foretell the therapeutic effect. Clinical trials, therefore, necessarily involve an element of risk. Before such trials may start, we ask for evidence that they will be responsibly and competently conducted, but we do not interpose official judgment of the probable or likely outcome. We do require, as Congress bade us, that the physician inform the patient or his guardian that an experimental drug is to be used, unless the physician in his professional judgment considers this inimical to the patient's welfare; but here again, we will not go behind the judgment of the individual practitioner.

Illustrations of Problems

The sharpest illustration of these problems, perhaps, lies in drugs put forward as delaying or curing cancer. At the one extreme we have the drug administered to the late Speaker Rayburn in his last days, a drug known to be highly toxic but believed by all to offer some possibility of help. At the other extreme is an utterly useless concoction, so adjudged by all medical opinion save that of defendant's witnesses, and by several courts, against which we have waged a costly ten-year campaign that has finally succeeded—we hope—in consigning the product to oblivion.

Perhaps you will wonder, as we have asked ourselves, what is the difference—why deny to the dying whatever hope even a wholly fake nostrum may provide? We are spared this moral issue by remembering the victims who are not beyond genuine medical help if invoked in time, and the lives that are lost by delay in seeking proper treatment. We must remember also the person who suspects that he may have cancer and whom the quack has no wish to disillusion—the easiest cures to demonstrate are among those who never had the disease in the first place. When we think of the harm done in these cases we can withstand the protests of those whose last illusory hope we are destroying.

Neither the admittedly useful but dangerous drug nor the plainly useless one poses us, in any true sense, the issue that I am concerned with. Obviously, a great many cases are not so clear. In dealing with them, it is true, no group of persons and certainly no individual has that absolute power that corrupteth absolutely; there is a large element of safety, indeed, in the very fact that most governmental decisions reflect collective rather than individual judgments. But even organizations develop points of view, and with the best will in the world it is not always easy to appraise dissent with complete objectivity, particularly when the dissent is enveloped, as it so often is, in an atmosphere surcharged with emotion.

Scientific Freedom Limited

The kinds of government control we now have, and probably even more the kinds we will have in the future, do necessarily limit scientific freedom at the fringe where freedom turns into license. This much restriction is inevitable if we are to protect the people in matters that the laity cannot fully understand. I believe there is not much danger, although there always will be some, that we may prevent a potentially significant discovery from reaching fruition. The danger will be less if an informed public is alert to the problem and to the very great difficulty of neither permitting too much nor restraining too much.

I have spoken as though regulatory decisions were made entirely by scientists, and for practical purposes this is true in a good share of the workaday cases. Even at this level of decision, however, I would not belittle the guidance and supervision that are given by lay officials. We all work for a nonmedical Secretary, and the upper echelons of the Department are staffed largely by nonprofessional people.

When we look at the larger questions involved in establishing the guidelines, the gravamen of the decision-making process shifts away from the technician and toward the political officer. Congress fixed the rules for determining the efficacy of new drugs; the recent regulation on investigational drugs, drafted by technicians, was very thoroughly reviewed by the Secretary's immediate staff. This is of course as it should be, since these guidelines reflect a blend of scientific and social judgments.

Broadened Scope of Policymaking Decisions

As we move into the area of environmental hazards the scope of policy-making decisions broadens because so much more is still unsettled than in food and drug regulation. If it is true, as the preponderant scientific opinion now holds, that there is no threshold level of exposure to radioactivity which can be pronounced safe, the decision what level is tolerable, though it must be informed by the best scientific appraisal of the total problem, will rest on an essentially political judgment. If use of radioactive materials should in the future approach the point of significant jeopardy, the final balance between gain and risk of harm can only be struck at the very highest level of our governmental process. If it is true that we are endangering our future by contamination with ingenious and deadly poisons, the question at what point the boon to agricultural production from modern insecticides is outweighed by the multiple threats portrayed by Miss Carson is not for the technicians alone to answer. In these matters and others like them, of course, scientists are major and indispensable participants, contributing knowledge and appraisal of both risks and gains, informing the decision makers and, so far as they are able, the people at large. But questions that are with us today, and others of like magnitude that surely will be with us tomorrow, can be resolved —insofar as they ever are resolved—only by Congress or the political officers of the Executive Branch, and ultimately by the electorate which is the final political decision maker.

The one thing certain is that these problems will not go away. Government is going to be an interesting place to work for a good many years to come. **[The End]**

Information and Education Under the Food and Drug Laws

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I AM PLEASED to have this opportunity to discuss the information and education activities of the Food and Drug Administration because I believe that our efforts under this heading are far greater than is generally understood or appreciated.

The importance of better communication with both our consuming public and our industry public has been pointed up by two Citizens Advisory Committees that have studied the FDA since 1955. All of the major recommendations of the 1955 group have not only been met, but have been exceeded by generous margins.

On the other hand, the need for better communications has also increased. New industries have been brought under regulation. Existing laws have been changed; regulations have been strengthened; scientific methods have been improved.

It is said that the sum total of published scientific knowledge is now doubling about every 15 years, and that 90 per cent of all scientists who have ever lived on this earth are living today. A large proportion of these scientists are working in fields that directly or indirectly affect the production of foods, drugs, devices, cosmetics or household chemical aids.

The new information that comes out of this scientific universe must be assimilated, applied to FDA's regulatory responsibilities, and recommunicated back to the public and the regulated industries in terms of new laboratory procedures, new regulations, new policy, new programs, or perhaps, a need for new legislation to cope with new problems.

In order to meet the new communication needs, we have created some new organizational units, and have expanded others. We are still in an early stage of growth and development, looking forward to still further progress in the years to come, but we are proud of what we have done so far. I will tell you about some of these achievements.

INDUSTRY EDUCATION

Our industry education activities are based on three well-established principles.

The first is that the laws of this land are public laws and citizens are not to be harassed by secret regulations or secret proceedings in the courts. Regulation-making is likewise a public process, and the Administrative Procedures Act has spelled out the responsibilities of law enforcement agencies for public procedures.

The second is that intention to violate the Federal Food, Drug and Cosmetic Act and other laws we enforce does not have to be proved as an element of the offense, and ignorance of the law is no excuse. We as the enforcement agency are glad that this is so, and believe enforcement would be greatly hampered if the situation were otherwise. But the businessman also has reason to appreciate his responsibility under law, for the alternative is regimentation. Freedom and responsibility are two inseparable aspects of a government of laws.

However, when the second principle as stated is considered in relation to the first, it becomes obvious that the enforcement agency has an added responsibility to see to it that the one does not nullify the other. As a practical matter, this means that we must be able to show to the courts, to the Congress and the political heads of government that the regulated industries collectively have been given every reasonable opportunity to know what the law and regulations require. This is a great and growing responsibility. Much of the activity which I shall describe under this heading is designed to see that these two principles do not come in conflict. There are many checks and balances in our system of government operating to assure that civil servants do not let enforcement zeal render the first principle null and void.

The third principle is especially applicable to laws that protect the public health and safety. We call it "preventive enforcement," which simply means activities to bring about voluntary compliance. From the consumer point of view, the idea of preventive enforcement or voluntary compliance is aptly expressed by the homely phrase that

"an ounce of prevention is worth a pound of cure." To illustrate, it is of little consolation to the mother of a child who may have been injured by a faulty or mislabeled drug to know that the manufacturer can be prosecuted for inadequate manufacturing controls. And the public is not fully protected by seizure of a shipment of a contaminated food after other shipments of the same product have already been consumed. Preventing any such shipment would have given far better protection.

Profoundly significant is the fact that the law itself has largely become a *preventive* rather than a *punitive* law, and has a great deal of industry education built into it. Movement in this direction began with the New Drug provisions of the 1938 Act and has continued at an accelerated pace through the Pesticides Amendment of 1954, the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960.

These amendments have firmly established the principle that manufacturers have a moral responsibility for determining the safety of their products before they are tried out on the public. This is undoubtedly one of the great social ideas of our time. The trend to a preventive law is continuing, as demonstrated by its extension in the 1962 Drug Amendments to cover efficacy as well as safety of new drugs.

The mere mechanics of compliance with these premarketing requirements have greatly increased communication between industry and government. This has contributed importantly to mutual understanding, and has tended to eliminate a great deal of litigation that might otherwise have been necessary to resolve questions of public safety. But such preventive laws require much interpretation as well as postings of "speed limits" and "Keep off the Grass" signs. Still more elaborate educational programs are in order in other areas.

Here are some examples that illustrate our industry education activities:

Division of Advisory Opinions

The Division of Advisory Opinions in the Bureau of Enforcement offers free consultation and advice in person, by telephone, or by mail on compliance matters for any individual or firm requesting it. Labeling of products, suitability of ingredients, application of the law to particular situations—these are merely illustrative of the range of subject matter on which the Division is able to give helpful advice to manufacturers seeking to comply voluntarily with the law.

The Division is currently handling about 40 telephone inquiries, answering 50 letters, and holding numerous individual conferences with industry representatives every working day.

Many other such inquiries and conferences—on more technical subjects—are handled in the various divisions of our Bureau of Medicine and Bureau of Biological and Physical Sciences. Consumer inquiries are answered by a Consumer Inquiry Section in the Division of Public Information.

Such are the activities that have given rise to the phrase "open door policy" to describe FDA's policy of free access to industry and the public for discussion of compliance problems. This policy has prevailed as long as I can remember, but the services we have been able to render have naturally increased as our budget and staff have grown. The demand for these services has also increased with new amendments to the law and with industry's increasing acceptance of voluntary compliance as a matter of self-interest.

Office of the Commissioner

Of course the Commissioner and the staff of the Office of the Commissioner are included in the "open door policy" consultations sought by industry. Beyond that, however, the Office of the Commissioner frequently takes the initiative in setting up conferences for industry briefing or for an exchange of views on proposed regulations or policy matters. Notable among such recent conferences was one held on February 15, 1963, with over 600 representatives of drug industry groups to discuss regulations proposed under the Kefauver-Harris Drug Amendments of 1962.

Also noteworthy in this connection is the series of conferences held annually since 1958 under joint sponsorship with the Food Law Institute. These have served the purpose of briefing food industry representatives, along with consumers, on matters relating to pesticides, food additives and color additives amendments, and other new or proposed legislation.

Many other conferences have been held with smaller groups for similar briefings on such matters.

Division of Public Information

The Division of Public Information is the arm of the FDA which is most directly and continuously concerned with education and information. This unit in FDA has a broader function than most

government information agencies. There is a growing need to apply modern methods of communication in administering an increasingly complex law. The Division of Public Information is being staffed to meet this need.

The Division of Public Information seeks to communicate with industry organizations to learn their problems and to help them by providing publications or other information materials for mass distribution. Such materials are often prepared with the help of association representatives and are distributed by the associations themselves. Here are some examples selected to illustrate the wide range of projects undertaken:

Drugs and Driving.—A pamphlet designed to reduce illegal traffic in dangerous drugs. It was originally suggested by the American Trucking Associations to help acquaint truck drivers with the dangers of using "pep pills" to stay awake while on the highways.

The American Trucking Associations, the National Association of Truck Stop Operators, and the National Safety Council helped to prepare and distribute the leaflet. Since then, many insurance companies and driver training organizations have joined in the distribution of the pamphlet not only to the industry, but to the driving public. The printings since 1962 now total 450,000.

Petroleum Products and the Law—How to Comply with the Federal Hazardous Substances Labeling Act.—This was prepared for gasoline stations which fill customer containers. The first printing of 35,000 was almost instantly used up and a quarter of a million have now been ordered to enable every retailer of petroleum products in the country to have one. Most of the distribution is being done by the major oil companies.

Keep Residues of Drugs and Pesticides Out of Milk.—This little leaflet, known as a "milk check stuffer," tells milk producers what steps they can take to keep their milk free of drug and pesticide residues. It was prepared with the cooperation of the Dairy Industry Committee, representing major national dairy organizations, and was distributed by these organizations. Almost every dairy farmer in the country received it. The total distribution is over 1½ million copies to date.

This flyer helped to stimulate a multiple phase attack through education on the problem of drug and pesticide residues in milk, and this effort is still going on. It has achieved notable success in virtually eliminating residues of penicillin from market milk.

The Rx Legend.—A professional manual to advise the retail druggist regarding the proper handling of prescription drugs. It was prepared with the advice and help of the American Pharmaceutical Association and the National Association of Retail Druggists and distributed through the State Boards of Pharmacy to every licensed pharmacist in the United States. Total printing to date is 160,000.

Cream and Butter—How to Meet the Requirements of the Federal Food, Drug and Cosmetic Act.—This circular was prepared and distributed in cooperation with the American Butter Institute to help maintain and improve the sanitary quality of cream for buttermaking. About 110,000 have been printed to date.

Restricted Drugs.—A color chart for the identification of amphetamines and barbiturates, two types of drugs which are frequently involved in criminal acts, juvenile delinquency and other misconduct. This chart was originally prepared for state and local law enforcement agencies, but has also been found useful by many industry traffic and safety officers. The printings to date total 123,000.

The cost of printing these special publications is usually very small—less than the cost of one routine seizure proceeding in the courts. Much more expensive, of course, is the printing of a technical book such as the one which is officially listed as Food and Drug Technical Bulletin No. 1. The jacket title is "Microscopic Analytical Methods in Food and Drug Control." It has 270 pages including the index, and 289 illustrations, but the Government Printing Office will sell you a paperback copy for only $2.00. For any technologist who has an interest in such problems as insect infestation it is a "must."

One of our latest and most timely projects is a motion picture soon to be released under the title, "The Safe Use of Pesticides." This film is a joint venture of the FDA and the Agricultural Research Service of the United States Department of Agriculture. Work started almost two years ago when the Division of Public Information proposed a training film for farmers emphasizing the importance of careful use of pesticides. It explains how the law is administered by the two departments of government. It tells what is back of the pesticide label and why it is important for the farmer to follow the directions given in the label. Distribution will be handled by the USDA film network which includes the Land Grant College film libraries.

I expect that very few of this audience have heard of these various educational activities I have mentioned. This may be due to

the fact that for the most part we are making use of direct channels which reach only the groups who are particularly concerned. Industry organizations can be especially helpful in this regard. It does little good to prepare a message unless there is a good way to deliver the message.

And here is a good place to pay a deserved tribute to the trade and professional press, which does a truly remarkable job in reporting our operations to the different industries. They are one of our most effective means of communication.

There are many ways to cooperate in educational activities. Those I have mentioned are merely a few illustrations. A recent check showed that almost 3½ million copies of industry education circulars and the like had ben printed from 1955 to date. This does not include almost 300,000 copies of laws and General Regulations printed during the same period. The accelerated pace of this activity is illustrated by the fact that the 1955 and 1956 printings of industry education pamphlets were only 25,000 and 37,000, respectively.

The Division of Public Information also prepares press releases which describe in simple terms all important proposals for new or amended regulations, and on request they prepare articles for trade journals on special subjects. In recent weeks trade releases have been prepared on proposed regulations covering new drugs, good drug manufacturing practice, advertising and labeling of drugs, and drug registration requirements. In addition, trade magazine articles have been prepared on the retailers' responsibility under the Federal Hazardous Substances Labeling Act, the FDA's program on radioactivity in foods, the growers' responsibility in handling pesticides (2 articles) and FDA activities of interest to the foreign physician.

A major industry education service often overlooked is that provided in the distribution of *Federal Register* reprints in loose-leaf or manual form.

We supply separate manuals of regulations on Food Additives, Pesticides, Color Additives, New Drugs and Antibiotics, as well as the General Regulations. Another manual deals only with suggested labeling statements for drugs. Each manual is distributed on a mailing list to persons requesting to receive the changes and supplements.

Mailing list distribution is also provided for all other *Federal Register* notices, press releases, Notices of Judgment, and the Monthly Report on Enforcement and Compliance. The latter is worthy of particular attention as an industry education document. In it we

report all major enforcement actions or campaigns during the month, a summary of industry voluntary compliance actions that came to our attention, and a list of all terminated prosecutions. This report is free upon request.

In calendar year 1963, we have so far distributed over ½ million pieces of printed matter designed to keep industry informed on our industry mailing lists alone. This was exclusive of the Monthly Report (45,324 copies) and Notices of Judgment (28,322 copies).

The Entire Organization Takes Part

Another major industry education effort sometimes overlooked is one participated in by the whole organization—field and headquarters, scientists, inspectors and administrators. This is the speech-making activity.

During the last two calendar years (1961 and 1962), the FDA staff made 2,338 speeches.

Of these, 555 were made to industry or trade groups and others, 1,084 to consumer groups, and 126 to radio-TV audiences. During the same period, FDA staff members authored 294 articles for publication in outside journals. Most of these (273) were published in scientific or professional journals.

So much for the statistics of our efforts in industry education.

The real payoff as to the value of this type of program is measured in terms of how industry uses the educational services. One way to measure this is by the number of people and firms which have requested to be put on our various mailing lists. Today we have almost 18,000 names on our major lists for industry information. This compares with slightly over 3,000 in 1938—approximately a sixfold increase. Our food additive information list alone has more names (3,715) than we had on all our major industry lists in 1958.

Last fall we asked a number of industry associations to report what they had done by way of promoting voluntary compliance with the law. We were truly gratified at the response. We prepared an exhibit of some of the materials submitted for presentation at the 1962 FDA-Food Law Institute Conference. The exhibit demonstrated convincingly that industry does take its responsibility for compliance seriously, and that it makes good use of the existing channels of communication with government.

CONSUMER EDUCATION

Our consumer education program is also based on several underlying principles. One is that the best informed consumer needs the least help from the government in avoiding unsafe or falsely promoted products. Consumer education has helped greatly to reduce the market for worthless cancer remedies and for phony medical devices. But consumers often do not know how to benefit from the protection provided by the law, as for example through careful reading of labels. Government information services can spark or catalyze the education process.

Another side to the coin is that informed consumer opinion is an essential ingredient of the policy-making process, as for example in the setting of food standards or the determination of what a label means to the consumer. In order to sample informed consumer opinion, we must have informed consumers.

A Consumer Education Branch has recently been established in the Division of Public Information. The head of that Branch is also the Special Assistant to the Secretary of Health, Education and Welfare for Consumer Protection.

Almost a million copies of consumer leaflets and booklets were printed in 1962, compared to 17,500 in 1955. Some of these have been found useful in the consumer education programs of your industry. For example, our "Read the Label" booklet, which tells consumers how to make use of label information, was widely distributed by the National Canners Association. And our booklet, "What Consumers Should Know About Food Additives," was reprinted by the Manufacturing Chemists Association and sent to food editors, teachers, librarians and home economists throughout the country.

Another medium of communication is through exhibits. Coincidentally, it happens that a very large FDA exhibit is now on display at the Detroit Historical Museum, at Woodward and Kirby Streets. We are hopeful that it will be displayed at many other museums of science and industry throughout the country during the next several years. The six-month showing in Detroit will end on July 8, after which it will next be seen in Washington.

More use of radio-TV as a medium of communication with consumers is planned, and a specialist has been employed to see that the senior citizen is not neglected in the information program. The student, representing tomorrow's wage earner and homemaker, is also getting special attention in a school information program.

The feedback of consumer opinion is an objective of the Consumer Consultant program in the Office of the Commissioner. That program is being expanded considerably next year, when it is expected that each of FDA's 18 field Districts will employ a full-time Consumer Consultant in addition to the part-time Consultant now employed. This program contributes significantly to the outflow of information from FDA to consumers, as well as the inflow.

CONCLUSION

From the activities I have described to you it is clear that information and education are used as indispensable tools for promoting industry compliance and providing consumer protection.

There is not now and never has been a conflict between an "enforcement" and an "education" philosophy in the FDA. It is rather a question of how to use both together to attain the objectives of protecting both consumers and honest business.

The Institute of Food Technologists provides a particularly important channel of communication with the food industry, and we are indeed grateful for your interest and your cooperation in these efforts. **[The End]**

CONSUMERS' HEALTH PROTECTION

Health protection for consumers was the objective of five seizure actions in May.

Six carloads of soybeans contaminated with poisonous crotalaria seeds were seized in two actions at Memphis, Tennessee. They were shipped from Arkansas. Crotalaria, a legume, was first planted in the 1920's as a soil-improving crop for sandy soil. This soil, originally used primarily for cotton, was later used more extensively for soybeans.

Following reports in 1960 that mortalities in poultry flocks were due to crotalaria remaining in feed, FDA investigated the extent to which the seed remained in grains and soybeans during harvest and its toxicity to animals. When it was found injurious to rats, 2,332 tons of contaminated soybeans were seized late in 1960 and state and federal agencies began an educational campaign to discourage the planting of crotalaria seed. However, the plant is self-seeding and many fields remain contaminated with it for years after the seed was last planted.

Two seizures were made of products that contained food additives for which no tolerance or exemption from a tolerance has been prescribed by food additive regulation. A New York-manufactured product, which was shipped to San Francisco, contained approximately 20 per cent potassium nitrate. A dietary supplement, manufactured in New York and shipped to Ohio, contained more folic acid than is permitted in such products.

Current Food and Drug Law Developments in the International Field

By FRANKLIN M. DEPEW

Mr. Depew Presented This Paper at the Meeting of the Food, Drug and Cosmetic Law Section of the Inter-American Bar Association in Panama City, Panama, on April 23, 1963. He Is the President of The Food Law Institute, Inc., As Well As Vice President of the Section of Food, Drug and Cosmetic Law.

SINCE OUR LAST MEETING in Bogota, Columbia in February, 1961, there have been a number of important international developments in the food and drug law field. Not the least important of these is the adoption by the Congress of the United States of the Drug Amendments of 1962. This legislation will have quite a profound effect on the development of drug law throughout the world. In addition this law importantly affects the food industry as will hereafter be pointed out.

It is gratifying to be able to report that this legislation was fashioned into final form in accordance with the best United States tradition of industry-government cooperation. The law as enacted maintains the fine balance between public protection and the preservation of a private enterprise system. The law as passed has been generally accepted by industry as in the public interest even though some have observed incidental defects of significance for further research. Some suggest that we should be careful not to become so occupied with fulfilling the letter of the new law that we forget that only through continued research and experimentation can we really achieve safety in drugs.

The new law establishes additional requirements with respect to new and experimental drugs and strengthens the factory inspection authority of FDA in respect of prescription drugs. A most important provision of the law is that requiring the registration and periodic

inspection of all domestic drug manufacturing establishments, regardless of whether they are engaged in interstate or intrastate commerce. Federal legislation of this type in the United States must be based on the power of the Congress to regulate interstate commerce. The Congress has indicated that in its opinion the distribution of drugs intrastate sufficiently affects the interstate commerce therein to be subject to federal control. The legislation may be expected to be sustained on this ground.

The law also importantly affects the food industry. For instance, the federal courts are given jurisdiction to issue injunctions against refusal to permit the Food and Drug Administration to make any plant inspections authorized by the Federal Food, Drug and Cosmetic Act. Previously, the only remedy for refusal to permit inspection was criminal prosecution. The law also extends the inspection powers of the Food and Drug Administration to include places where articles of food and drug are processed or packed after interstate shipment. Previously, only places where such articles were held after interstate shipment were subject to inspection. This confined inspection to places where the articles had not been further manipulated after the interstate movement. Another provision permits the use in animal feeds of ingredients which could cause cancer, provided any such ingredient in such feeds causes no harm to the animal and further provided there are no residues of the ingredient in the meat or other products reaching the consumer.

Public Health Committee's Program on Drugs

Another important development in the drug field is the program begun in 1962 by the Public Health Committee of the Council of Europe. This Council has 16 Western European nations as members. The Council has no power to enforce its decisions, but it is sufficiently highly regarded that its recommendations may be expected to carry considerable weight with its member governments. The Public Health Committee program is aimed at getting member countries to exchange information on drugs and securing harmonizing legislation which will secure standard regulations for controlling drugs. From Europe, the movement could spread to the whole world.

Latin-American Food Code Translations

Turning now to the food law field, a number of important developments can be reported with respect to the Latin-American Food

Code. The official Revised Spanish Edition of the Code, as adopted by the Seventh Latin-American Chemical Congress on April 3, 1959 and published in Spanish in August, 1960 has been translated in part into English. The English translation of the Introduction was published in 15 FOOD DRUG COSMETIC LAW JOURNAL 678; Chapter IV, Utensils, Receptacles, Containers, Wrappers, Machinery, and Accessories in 16 FOOD DRUG COSMETIC LAW JOURNAL 121; Chapter X, Sugar and Sugar Products in 16 FOOD DRUG COSMETIC LAW JOURNAL 297; Chapter XVI, Correctives and Improving Agents (Additives) in 16 FOOD DRUG COSMETIC LAW JOURNAL 641; and Chapter XII, Nonalcoholic Beverages and Refreshing Foods and Drinks in 17 FOOD DRUG COSMETIC LAW JOURNAL 355.* In addition Chapter XIV, Distilled Alcoholic Beverages and Liquors, was translated and distributed among members of the distilling industry. Comments by representatives of industry were invited and received. These were passed on to Dr. Carlos A. Grau, President of the Permanent Committee for the Code, who has graciously made appropriate revisions. The revised copy of this Code was submitted to the Eighth Latin-American Chemical Congress which was held in Buenos Aires, September 16-22, 1962.

At this Congress a meeting was held of the Special Committee of the Latin-American Food Code. In the course of its meeting a Resolution was adopted changing the name of the Permanent Latin-American Food Code Committee to the Latin-American Food Council. Dr. Grau, present Chairman of the Committee was appointed Chairman of the new Council. It was further resolved that future Latin-American Chemical Congresses shall have a new section named the Latin-American Food Council. Amendments of various chapters in the Latin-American Food Code were reviewed and approved. Finally, it was resolved to recommend to government agencies and special organizations the unification of existing food standards on the basis of the Latin-American Food Code and to publicize the suggestions approved by this meeting as widely as possible.

Dr. Enrique E. Bledel, Secretary of our Section, attended this Congress and will give us a more complete report of what occurred on that occasion.

At our 1961 Section meeting a resolution was adopted commending the outstanding work done by the Drafting Committee for the

* The April, 1963 issue of this magazine (18 FOOD DRUG COSMETIC LAW JOURNAL 194) contains the following translations: Chapter I, General Provisions; Chapter II, General Requirements for Food Factories and Outlets; Chapter III, The Storage, Preservation and Processing of Foods; and Chapter V, Labeling.

Latin-American Food Code, suggesting the Section members devote special attention to the Code and providing that the Section submit the 1960 edition of the Code to the Directors-General of the Food and Agriculture Organization and World Health Organization of the United Nations, and other interested organizations for their study and comments on the legal aspects of the Code. Pursuant to this resolution, as Vice-President of the Section, I requested such comments from B. R. Sen (FAO) and M. G. Candau (WHO), the Directors-General of these two United Nations Organizations. Under date of January 2, 1963, Dr. Norman Wright, Deputy Director-General of FAO, responded in behalf of both Directors-General as follows:

> Thank you for your letter of 19 October addressed to myself and to the Director-General of the World Health Organization setting out a resolution of the Inter-American Bar Association at its Bogota session in January 1961 requesting FAO and WHO to study and comment on the legal aspects of the *Codigo Latinoamericano de Alimentos.*
>
> Since this matter falls within the purview of the new Joint FAO/WHO Program on Food Standards, I have consulted with the Director-General of the World Health Organization and am now, in agreement with him, replying to you jointly on behalf of our two agencies.
>
> In accordance with the recommendations of the Joint FAO-WHO Conference on Food Standards held at Geneva in October, 1962 and subject to endorsement of these recommendations by the appropriate bodies of WHO, I shall convene, together with the Director-General of WHO the first session of the *Codex Alimentarius* Commission to meet at FAO Headquarters in Rome in June, 1963. The session will have on its agenda the question of the follow-up to be given to the *Codigo.* We therefore propose to defer commenting on the legal aspects of this remarkable and comprehensive food code until the *Codex Alimentarius* Commission will have been able to consider it with particular reference to the possibility of its application in practice and to the machinery necessary to amend it in the light of changing technological and economic requirements.

It seems appropriate to mention at this point that at the Joint FAO-WHO Conference on Food Standards held in Geneva, Switzerland, October 1-5, the assembled delegates lauded the work done under the leadership of Dr. Carlos A. Grau in preparing this Latin-American Food Code. Dr. Grau attended the Geneva Conference as the representative of Argentina and I attended as an observer in behalf of the Inter-American Bar Association, as Vice President of this Section, and in behalf of The Food Law Institute as President, thereof.

It was my pleasure to advise the delegates that The Food Law Institute was making available one copy each, of the 1960 Edition of the Latin-American Food Code in Spanish, together with copies of the Introduction and Chapters IV, X, XII and XVI in English, to each delegation. As most of the delegations had two or more mem-

bers I was overwhelmed with requests for additional copies. As my supply was limited, I was unfortunately unable to comply. I know you will all be gratified, as I was, at this great interest in the Latin-American Food Code.

Dr. Grau reported to the Conference on the progress of the Latin-American Food Code and mentioned that The Food Law Institute had been most helpful in securing the views of United States industrial, technical and university personnel with respect to its provisions.

At present the FAO Secretariat is distributing to all FAO or WHO member nations those chapters of the Latin-American Food Code which cover the subject matter of the standards drawn up for the European Code, that is, general rules, sampling and edible fungi. This step is being taken without prejudice to any action which may be taken relative to the Latin-American Food Code as a whole by the governments of that group. The Secretariat is getting in touch with these governments to find out what additional action, if any, they may wish to take. These steps are being taken in preparation for the first session of the FAO-WHO *Codex Alimentarius* Commission which will be held in Rome, June 27-July 3, 1963.

Most Important Recent Development in the Food Law Field

The Joint FAO-WHO Conference on Food Standards, referred to above, held under the auspices of the Food and Agriculture Organization and the World Health Organization of the United Nations was undoubtedly the most important recent development in the food law field. The Conference was held on the recommendation of the FAO Conference and the WHO Executive Board to consider a Joint FAO-WHO Program on Food Standards. Representatives from some 45 member countries of FAO and/or WHO attended together with observers from some 24 international governmental and nongovernmental organizations. The countries of the American continent were represented by delegations from Argentina, Brazil, Canada, Chile, Cuba, Dominican Republic, El Salvador, Ecuador, Mexico, United States of America and Venezuela.

Dr. Pierre Dorolle and Dr. Norman Wright, Deputy Directors-General respectively of WHO and FAO gave a warm welcome to the delegates. Josue de Castro of Brazil nominated Dr. E. Feisst, Vice President du Comite National Suisse des Codex Alimentarius, as Chairman. The nomination was promptly seconded by the Austrian and Netherlands delegations and Dr. Feisst was thereupon elected

by acclamation. John L. Harvey, United States Deputy Commissioner of Food and Drugs and Dr. Thianar N'Doye, Director du Service d'Alimentation et de Nutrition Apliquee, Ministere de la Sante et des Affairs Sociales, Senegal, were thereupon elected Vice-Chairmen. J. H. V. Davies of the British Delegation and Gerard Weill of the French Delegation were appointed rapporteurs.

Codex Alimentarius Commission Proposal Endorsed

The Conference then proceeded to endorse the proposals for a Joint FAO-WHO *Codex Alimentarius* Commission as the best means of bringing about the adoption of international food standards which would promote international trade in food, facilitate harmonization of standards, protect the consumer's health and assure fair practices in the food trade.

The Conference next considered the guidelines for the work of the *Codex Alimentarius* Commission. This was by far the most important work of the Conference and the delegates were absorbed in consideration of the various problems involved during most of the time of the meeting. The guidelines adopted afford all nations an opportunity to take appropriate steps to present their views in connection with any standard proposed or considered by the *Codex Alimentarius* Commission. While this will not operate to automatically prevent the adoption of a standard which operates as a barrier to free trade, it will afford an opportunity for full publicity relative to all reasons which were considered in relation to the standard. If the delegates from the various nations to the *Codex Alimentarius* Commission are instructed by their governments to work toward a harmonization of food standards, then food standards which operate as unjustified trade barriers should be kept at a minimum, if not prevented altogether. However, the delegates will have to be alert to such dangers if we are to secure sound food standards which will promote international trade in food.

We must give a great deal of credit for the outcome of the Conference, in establishing these sound guidelines to the Joint FAO-WHO Secretariat and to the rapporteurs. Their continued diligence and good humor under trying circumstances was an example for all.

M. G. Candau and B. R. Sen, the Directors-General, respectively, of WHO and FAO, graciously tendered a reception to the assembled delegates and the staff of their secretariat on the evening of October 3.

This affair enabled everyone to mingle on an informal basis and it contributed to the successful outcome of the Conference.

I was privileged to address the Conference, as President of The Food Law Institute, and pointed out that if more varied, more nutritious and more plentiful diets were to be made available to the peoples of the world, all unjustified barriers to international trade must be eliminated from the world's food laws. I expressed the hope that the guidelines established by the Conference would result in standards that would wipe out barriers to free trade among the nations.

My report on the Conference, together with the guidelines is set forth in the January, 1963 issue of the FOOD DRUG COSMETIC LAW JOURNAL.

Preparation for the Meeting

Most of the steps to be taken in preparation for the meeting of the *Codex Alimentarius* Commission will fall upon the Secretariat. However, the governments must take appropriate steps to select the members of their delegations to attend in their behalf. Governments have also been urged to make available their 1963 contributions as soon as possible.

The Secretariat is proceeding to distribute to all FAO-WHO member nations approved texts of material completed by the European Council of the *Codex* (these cover general rules, sampling and edible fungi) and those chapters of the Latin-American Food Code which cover the same subject matter. They will also supply governments with positive lists together with specifications of identity and purity for colors, preservatives, and antioxidents, as well as emulsifiers, based on work carried out under the Joint FAO-WHO Program on Food Additives. The standards for milk and milk products, and fresh fruit and vegetables will be supplied to those governments which have not already received them. With respect to the other products to be given priority, pursuant to the action of the Conference, it is planned to submit to the Commission, as a basis for discussion, a resume on each of these groups of products summarizing the principal national standards involved and containing, where possible, a draft international standard.

It is planned to hold two associated meetings just prior to the meeting of the *Codex Alimentarius* Commission. From June 17-22, 1963, the Sixth Session of the Code of Principles Committee (now the joint FAO-WHO specialist body on milk and milk products) will

consider and possibly approve standards for cheeses, methods of sampling and analysis, and so forth. From June 24-26, 1963, the Second Joint FAO-WHO Conference on Food Additives will review the work done, determine areas of future work, and proceed to evaluate the contribution of the FAO-WHO program on food additives to the work of the *Codex Alimentarius* Commission.

That Commission will hold its meeting from June 27-July 3, 1963. The tentative agenda provides for the Commission to adopt rules of procedure, elect officers, review existing food standards work at the government level, allocate new work and to discuss with a view of acceptance—the following completed texts:

General Rules

Sampling

Edible fungi

Permitted lists and specifications of identity and purity for:

Colors

Preservatives and antioxidants

Emulsifiers

The foregoing history of developments to date and of plans for the future shows that there is ground for hope that a sound harmonization of international food standards may be achieved.

Finally, I would report to the Section the following draft:

RECOMMENDATION

The Inter-American Bar Association, after careful consideration of this subject recommends to all American countries that their Delegations to the Joint FAO/WHO *Codex Alimentarius* Commission be instructed to work for the sound harmonization of international food standards and to protest the adoption of any food standard which would operate as unjustified barrier to free trade between nations. **[The End]**

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

June Food Seizures Report.—Over 736 tons (1,472,765 pounds) of adulterated food were seized in 31 actions during the month of May. Nearly one-half of this total came in the danger to health group; 307 tons of soybeans containing poisonous crotalaria seeds were in this category.

Of the unfit foods seized, 232 tons were contaminated by rodents and insects before or during shipment and 150 tons were contaminated in storage after receipt in fit condition. Thirty-five tons were seized on charges that they were processed under insanitary conditions. An additional 13 tons consisted of decomposed frozen and canned items.

Fifteen seizures were made on "pocketbook protection" charges.

Drug and Device Seizures.—A total of 28 products were seized on the following charges: misbranding with false and misleading therapeutic claims—9; marketing of new drugs without prior safety clearance—3; prophylactics, falling below purported quality by containing holes—9; cathartic pills and an antibiotic below USP standards—2; and failure to bear adequate labeling information, warnings or directions for use—5.

Cosmetic Seizures.—A deodorant was seized because the information required by law was inconspicuously placed on the label, and toothpicks were charged to contain poisonous oil of cinnamon or cinnamic aldehyde.

Hazardous Substances.—Four products—an airplane fuel (2 actions), a highly flammable water repellent, and a product claimed to give traction on icy surfaces were seized because of failure to bear precautionary labeling required by the Federal Hazardous Substances Labeling Act.

Voluntary Actions by Industry.—Over 151,000 pounds of adulterated food were voluntarily removed from human consumption by the food industries in the past month to protect the public from unfit products. Two of the largest of these voluntary actions involved extensively fire damaged lots; one of 49,110 pounds of pressed cocoa cake, and another of 25,000 pounds of various food items including fish and meat. Among other food destructions were 185 bags of mustard seed and bran which were dumped and bulldozed under when it became evident that rodent-contamination had penetrated to the contents of the bags.

The retail selling price of the drugs and devices voluntarily removed from commercial channels amounted to $37,276. A pharmacy in New York State dumped $21,000 worth of prescription and over-the-counter drugs which had been exposed to water and chemical vapors from extinguishers used in a fire which ravaged the store.

Other merchandise destroyed included repacked physicians' samples, sub-potent vitamins, outdated vaccine and an outdated veterinary antibiotic, unlabeled drugs, products misbranded by false and misleading therapeutic claims, penicillin past its expiration

date, a night cream containing a coal-tar color no longer permitted, various drugs which failed to bear mandatory labeling, and new drugs not approved by FDA as safe and effective.

Plant Improvements. — Food, drug and cosmetic industries invested more than $560,000 to maintain and improve sanitary conditions. A grocery company in Alabama spent $200,000 on a new steel and concrete warehouse building. A new freezer and automatic packaging equipment for use in its frozen sliced sweet potato operation was installed by a Louisiana firm at a cost of $100,000. A New York dairy plant reported expenditures of $150,000 for new blenders and scales to insure uniform, up-to-standard fat content in its creamed cottage cheese products. A Kansas flour mill replaced some of its old wooden equipment, and installed a pneumatic conveyor system and a new type of electrostatic purifier at a cost of $50,000. A Missouri drug firm improved its manufacturing facilities by spending $30,000 on the construction of new areas for tablet mixing and punching, and a sterile fill room for the preparation of injectables. Work has begun on a control laboratory in that firm also. Almost $13,000 on clean-up operations to upgrade sanitation was invested by an Alabama cookie company. A New York bakery replaced its wooden equipment and conveyor system with two new metal systems, aluminum trays, and a tile floor at a cost of $8,620.

Drug Research Plans Reviewed by FDA.—Drug sponsors who wish to start or continue trial of drugs on humans are required to report to FDA concerning the composition and production of the drugs, the previously completed research on animals, and their program for testing on humans, including the names, qualifications, and facilities of the investigators. June 7, 1963, was the deadline for the submission of plans by the drug companies. The plans must be filed for review by the FDA under the Kefauver-Harris Drug Amendments enacted by congress last year.

About 1,000 plans were received by the Division of New Drugs, Bureau of Medicine, of the Food and Drug Administration which has primary responsibility for monitoring each new drug from the animal test stages through clinical trials and on to the market. The division is composed of five branches:

1. The Investigational Drug Branch investigates each of the plans for tests on humans. It evaluates the animal tests, as well as the manufacturing methods and controls, and the qualifications and facilities of the investigators. It determines whether tests on humans are justified and whether the plans of investigations contain the type of information needed to evaluate the drugs for safety and effectiveness. Progress reports on drug investigations are monitored and appropriate recommendations to modify or cancel the studies are made.

2. In the Medical Evaluations Branch data developed through animal and clinical tests which are submitted to FDA in a New Drug Application are evaluated. The drug must be approved as safe and effective before it can legally be marketed for general use.

3. The New Drug Status Branch advises manufacturers and others about the application of the law to chemicals newly proposed for drug use and to new uses or dosage forms for drugs already on the market.

4. The Surveillance Branch checks to see that the approved new drugs are being marketed according to approved applications. Reports on adverse reactions required by the Kefauver-Harris Drug Amendments are received by this branch.

5. The Control Evaluation Branch evaluated the adequacy of manufacturing controls, methods and facilities proposed by manufacturers of new drugs to establish the identity, strength, quantity and purity of the drugs.

In the case of antibiotics, the Division of Antibiotic Medicine, Bureau of Medicine, and the Division of Antibiotics, Bureau of Biological and Physical Sciences, evaluates the adequacy of plans of investigation.

The Division of Pharmacology of the Bureau of Biological and Physical Sciences also evaluates animal tests which precede trials in humans.

Protection for the Older American.—The month of May was designated Senior Citizens Month by Presidential Proclamation. Three developments in FDA's program are of special interest in this connection.

First, in response to the President's request that all agencies provide information useful to older Americans during the month, a series of three "Consumer Memos" were issued under the general title "Your Money and Your Life." These covered the subjects of "Nutrition Nonsense," "Drug and Cosmetic Quackery" and "Mechanical Quackery" with special reference to false promotions addressed to the Senior Citizen population group.

Second, the Consumer Education Branch has added a specialist whose principal activity will be to develop channels of communications with and information materials for the older population groups. The new employee is Miss Fannie Davis, who has experience with newspapers and public relations.

Third, several seizures of products likely to be purchased by the older Americans were included in routine enforcement activities during the month. Among them was a "high potency vitamin and mineral supplement with digestive enzymes." Also seized as labeling for the article was a supply of testimonial letters and other literature promoting the capsules for those over 50.

Charged misbranded by bottle label and promotional material in that the name of the product and the promotional material suggest it is adequate and effective for the treatment of run-down and weak conditions; lack of energy; inability to withstand the noise of children; tiredness; lack of appetite; loss of enjoyment of life; inability to be the man or woman formerly possible; coated tongue; bleeding gums; tooth decay; brittle bones; constipation; weight loss; poor eyesight; inability to sleep; skin breaking out; nervousness; bad digestion; gas; heart conditions; swoller, inflamed joints; mental depression.

More Pill Peddlers Sentenced.—Court cases charging illegal sales of dangerous drugs were closed in May with fines totaling over $8,500 and sentences totaling over 12 years in jail or other federal custody. These cases involved 11 truck stops, two drug stores and three individual "peddlers."

The drugs most frequently involved were amphetamines, otherwise known as "bennies," "pep pills" and the like. These drugs are peddled at truck stops, gasoline stations, restaurants, bars and other outlets catering to truck drivers, as "stay awake" pills. They are also used to produce an abnormal feeling of exhilaration or alertness. They are dangerous drugs that can legally be sold only upon prescription. Common side effects of the drugs are: excessive nervous stimulation, loss of desire for sleep, impairment of judgment, hallucinations and mental derangement.

One of the drug stores involved was shown to be selling amphetamine drugs to a truck stop peddler. The judge commented, in imposing the fine and two years' probation, that another similar violation would result in imprisonment.

Another drug store was charged with selling amphetamines and a hormone drug without prescription. The individual pharmacists involved each received prison sentences which were suspended. The judge in one instance commented that the defendant should go to prison as an example to other would-be peddlers of dangerous drugs. Another judge, sentencing the other pharmacist involved, commented that the pharmacist owed a higher loyalty to the law than he did to his superior or employer.

A third drug store case, terminated in April but not previously reported, involved refilling, without a doctor's authorization, of prescriptions for tranquilizers, barbiturates and a diuretic drug. In passing sentence, the judge

referred to comments by the defendants that doctors sometimes become annoyed with pharmacists who call for authorization before refilling a prescription. The judge said that this was a hazard of the business and must be accepted as such. The judge pointed out also that the law provides for a more severe penalty in the event of a second offense.

Truth in Packaging Bill Goes to Full Committee.—The Antitrust and Monopoly Subcommittee of the Senate Committee on the Judiciary has approved for full committee consideration, with amendments, S. 387, which would prohibit unfair methods of packaging and labeling consumers' commodities, particularly with reference to quantity of contents and price. The amended bill retains the provision that "any consumer commodity introduced or delivered for introduction into commerce in violation of any regulation promulgated by the Secretary of Health, Education and Welfare under this section while that regulation is in force and in effect shall be deemed to be misbranded within the meaning of chapter III of the Federal Food, Drug and Cosmetic Act," but adds a new proviso that "the provisions of section 303 of that Act [prescribing penalties] shall have no application to any violation of any such regulation."

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