

THE ADMINISTRATION OF THE FEDERAL FOOD AND DRUGS ACT*

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I

Three factors combine to make the enforcement of the Federal Food and Drugs Act of 1906 an administrative problem of peculiar difficulty. These factors are, first, the nature of the offenses defined by the Act; second, the character of the industries affected; and, finally, the limitations inherent in all federal action under the commerce clause. A brief, preliminary consideration of the effect of each of these three factors may throw light on the development of the administrative machinery set up under that Act.

The Act forbids interstate commerce in adulterated and misbranded food and drugs. It provides criminal penalties for violation and also authorizes the seizure of offending products.¹ In the case of standard drugs, the United States Pharmacopoeia and the National Formulary were resorted to by Congress for the purpose of establishing standards of purity and quality which the drug manufacturers were enjoined to follow—unless they declared standards of their own on the labels of their products. In that event, their own standards afforded the criteria to which they were obliged to conform.² In the case of foods, standards were not available, and in their stead, the draftsmen of the Act resorted to generalities proscribing the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products.³ Misbranding was confined chiefly to

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¹ Section 2 of the Act imposes for a first offense a fine not exceeding \$200; for each subsequent offense, a fine not exceeding \$300 or imprisonment not exceeding one year or both, in the discretion of the court. 34 Stat. 768 (1906), 21 U. S. C. A. §2. Somewhat higher penalties are provided for manufacture in the District of Columbia and the territories. *Ibid.* The seizure provisions are contained in §10. 34 STAT. 771 (1906), 21 U. S. C. A. §14.

² F. & D. Act, §7, 34 STAT. 769 (1906), 21 U. S. C. A. §8.

³ *Id.*

the making of false or misleading statements regarding a food or drug on the package or label thereof.⁴ The sale of an imitation was forbidden, but this was accompanied by provisos which relieved mixtures or compounds not in themselves harmful when sold under "their own distinctive names" or when labeled with the word "compound," "imitation" or "blend," from the operation of both the misbranding and adulteration provisions of the Act.⁵ Aside from the latter, the only affirmative labeling requirements were the disclosure of the presence and quantity of enumerated narcotic drugs⁶ and the declaration of the net weight of foods when sold in package form.⁷

It is obvious, of course, that the detection of offenses of this character calls for scientific work of a high order. Difficulty of detection is, however, all too commonly encountered in law enforcement. But the Food and Drugs Act does not make plain what constitutes an offense. What amount of moisture in oats or fresh water in oysters constitutes adulteration? Some is present in all.⁸ When does "whiskey" become "imitation whiskey," to take as an example a problem which once perplexed the Bureau of Chemistry and whose ghost is beginning to walk. Ultimately the answers to these questions must be resolved by the courts, but obviously they must first be determined by the enforcement officials as a preliminary to action.

The magnitude of the food and drug industries, estimated recently as producing goods valued at twenty billion, furnishes an enforcement problem whose seriousness is greatly intensified by the fact that these industries are decentralized, not only as to distribution, which is inevitable, but as to production as well. The emergence of large corporations engaged in processing and distribution is a relatively recent and limited phenomenon; and even this tendency has not materially simplified the problem of enforcement, for the production units are still small and scattered. Fruits and vegetables are usually canned near the source of supply. The same label may be affixed to the products of a hundred canneries. Uniformity as to product and conditions of manufacture can, at best, be only approximate.

To this difficulty must be added the related one which springs from the diversity of products affected. A single drug house publishes a catalog containing fifteen

⁴The misbranding provisions of the original Act are contained in §8. 34 STAT. 771 (1906). They are set forth with amendments in 21 U. S. C. A. §§9, 10.

⁵This immunity does not extend to the presence of added poisonous or deleterious ingredients. See F. & D. Act, §9, 21 U. S. C. A. §10.

⁶The list of drugs comprises "morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide or any derivative or preparation of any such substances contained therein." F. & D. Act, §8, 21 U. S. C. A. § 10. The enumeration has been found not to be sufficiently comprehensive.

⁷F. & D. Act, §8, 21 U. S. C. A. §7. Provision is made for reasonable variations, tolerances, and exemptions as to small packages, to be established by rules and regulations. This clause was recently construed by the United States Supreme Court in *United States v. Shreveport Grain & Elevator Co.*, 287 U. S. 77 (1932).

⁸These questions were recently litigated in *United States v. 800 Sacks Barley Mixed Oats*, 64 F. (2d) 678 (C. C. A. 5th, 1933) and, to cite but one of numerous cases involving this form of oyster adulteration, *United States v. Housman Oyster Co.*, Not. Judg. 19307 (S. D. N. Y., 1932).

hundred pages. Most large food corporations produce more than "57 varieties," including the company which fixed that phrase in the national consciousness.

The third factor, the limitations of federal control, is magnified in importance by the second. The Food and Drugs Act, except in so far as its provisions relate to the District of Columbia and the territories, is based on the power of Congress over interstate and foreign commerce. Only those products entering such commerce are within its purview. The necessity for proof of interstate shipment precludes concentration of enforcement activities at the source. The "original package" doctrine draws an often indistinct line beyond which federal enforcement may not go in the state of distribution. Only in the case of imports is federal control relatively simple.⁹

II

Research in food adulteration had been undertaken by Dr. Harvey W. Wiley, Chief of the Chemical Division of the Department of Agriculture, as early as 1883.¹⁰ The revelations were alarming. These studies, coupled with his unremitting efforts on behalf of pure food legislation, rendered it inevitable that the work of enforcement should be vested by the Food and Drugs Act in that Department. The Bureau of Chemistry, into which the Chemical Division had been transformed, continued in this rôle until July 1, 1927. Its activities were not, of course, confined to this work, and the desirability of divorcing its agricultural research from its regulatory activities led to the creation then of the Bureau of Chemistry and Soils to undertake the former and the Food, Drug, and Insecticide Administration to carry on the latter.¹¹ The Appropriation Act for the Department of Agriculture for 1930 provided funds for the *Food and Drug Administration*, thereby shortening the name of the regulatory branch without affecting the scope of its activities.¹²

⁹ Section 11 provides that the Secretary of the Treasury shall deliver to the Secretary of Agriculture samples of foods and drugs being imported upon the giving of notice to the consignee. The article shall be refused admission if found upon examination to be adulterated or misbranded. Such articles must be destroyed or re-exported within three months, although delivery to the consignee pending examination may be made on the execution of a penal bond. 21 U. S. C. A. §15.

It should be noted that this section contemplates administrative and not judicial action for its enforcement.

¹⁰ See WEBER, *FOOD, DRUG, AND INSECTICIDE ADMINISTRATION* (1928) 2.

¹¹ Department of Agriculture Act of Jan. 18, 1927, 44 STAT. 1002-1003. The basis for this distinction is described in the Report of the Chief of the Bureau of Chemistry as follows:

"Research and regulatory work demand the attention of officials of entirely different qualifications. The regulatory chemist, because of the detriment of delayed decisions to industry and commerce, is obliged to form his conclusions quickly, although in some cases these decisions may be wrong. The research chemist, on the other hand, must form his conclusions with more deliberation because of the necessity of verifying his work by all the possible checks at his disposal. The regulatory chemist, owing to the demands of law enforcement, limits his attention to the small percentage of products which constitute infractions of certain State or Federal enactments and ignores the vastly larger percentage of products which meet the requirements of those acts. The research chemist, on the other hand, is concerned more with the rendering of service to industries whose products are of the latter class." REP. CH. BUR. CHEM. (1927) 3.

¹² 46 STAT. 423 (1930). In addition to the Food and Drugs Act, the Administration is charged with the enforcement of the following statutes: The Caustic Poison Act, 44 STAT. 1406 (1927); the Insecticide

The geographical decentralization of the food and drug trade has dictated a degree of decentralization in the organization of the Administration. The country is divided into three districts: the Eastern, with headquarters at New York City; the Central, with headquarters at Chicago; and the Western, with headquarters at San Francisco.¹³ Within each district are several inspection stations and laboratories,¹⁴ the duties of which include the collection and analysis of samples of articles subject to the regulatory acts enforced by the Administration, and other investigational and administrative work in connection therewith. Each of the inspection stations has a station chief in charge, and inspectors, chemists and a clerical force. In the Administration's 1929 Report, it is stated that the "field laboratories as a whole have been equipped so that samples of all kinds of products can be analyzed in any one of a number of laboratories. Inspectors have been trained to sample any or all of the commodities covered by the six laws assigned to the administration." Immediate supervision over the inspection station is exercised by the chief of the district within which it is located. Above the district chiefs in the hierarchy is the Chief of the Food and Drug Administration, with offices at Washington.¹⁵ Ultimate authority is in the Secretary of Agriculture, as head of his Department.

The members of the Administration are appointed by the Secretary of Agriculture, under civil service regulations—a six months' temporary appointment, which becomes permanent at the termination of the probationary period. The power to remove also is vested in the Secretary of Agriculture, restricted by civil service rules to removal only for cause. The small size of the personnel has made careful selection possible and contributed to the development of an admirable *esprit de corps*. Resort to disciplinary action has seldom been required.

Act, 36 STAT. 331 (1910); The Milk Act, 44 STAT. 1101 (1927); the Naval Stores Act, 42 STAT. 1435 (1923); and the Tea Act, 29 STAT. 604 (1897); 35 STAT. 163 (1908).

The Tea Act was administered by the Secretary of the Treasury until July 1, 1920, when its enforcement was transferred from the Customs Division of the Department of the Treasury to the Bureau of Chemistry of the Department of Agriculture. 41 STAT. 712 (1920).

¹³ The Eastern district comprises the New England States, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, West Virginia, North Carolina, South Carolina, Georgia, and Florida; the Central district, Ohio, Kentucky, Tennessee, Alabama, Mississippi, Louisiana, Indiana, Missouri, Michigan, Minnesota, Wisconsin, North Dakota, South Dakota, Iowa, Illinois, Kansas, Arkansas, Oklahoma, Texas, and Nebraska; and the Western district, Montana, Wyoming, Idaho, Nevada, Utah, Colorado, New Mexico, Arizona, Washington, Oregon, and California.

¹⁴ Inspection stations and laboratories for the Eastern district are located at Baltimore, Boston, New York City, Philadelphia, Rouse's Point, N. Y., San Juan, P. R., and Savannah; for the Central district, at Chicago, Cincinnati, Kansas City, Mo., Minneapolis, New Orleans, and St. Louis; and for the Western district at Denver, Los Angeles, Seattle, and San Francisco.

There is a complete outline of the personnel of the Administration as of the date of writing in WEBER, *THE FOOD, DRUG, AND INSECTICIDE ADMINISTRATION, ITS HISTORY, ACTIVITIES AND ORGANIZATION* (1928). This work, No. 50 of the Service Monographs of the United States Government published by the Institute for Government Research, contains the most comprehensive study available of the organization of the Administration.

¹⁵ The Washington offices of the Food and Drug Administration include the following subdivisions: Interstate Supervision, Import Supervision, State and City Coöperation, Food Control, Microanalytical Laboratory, Color Certification, Drug Control, Special Collaborative Investigations, Insecticide Control and Naval Stores Control. See inside cover of DEPT. AGR. MISC. CIRC. No. 48 (1930).

III

The Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce are charged by the statute with the duty of promulgating rules and regulations for the enforcement of the Act.¹⁶ After the enactment of the law of June 30, 1906, a committee of three was chosen, one member appointed by each of the three secretaries, for the purpose of drawing up rules and regulations.¹⁷ Hearings were held by the committee in order to make certain that the rules promulgated might not burden unnecessarily the industries affected. The rules and regulations formulated by the committee were issued over the signatures of the three secretaries on October 17, 1906, as a circular of the Department of Agriculture.¹⁸ They have been revised from time to time as the Act has been interpreted by court decisions and as experience has shown to be necessary and are now in the tenth revision.¹⁹

These rules and regulations have the force of law so long as they are administrative of the law and do not attempt to add to its terms.²⁰ Supplementary to them as guides to the public and to food and drug manufacturers are the notices of the judgments reached in all cases which are published after their termination,²¹ and food inspection decisions issued from time to time over the signature of the Secretary of Agriculture prescribing standards which the Administration feels should govern in the determination of questions of purity and quality. The position of the Department with respect to these decisions was formulated in 1906 as follows:

The opinions or decisions of this Department do not add anything to the rules and regulations nor take anything away from them. They therefore are not to be considered in the light of rules and regulations. On the other hand, the decisions and opinions referred to express the attitude of this Department in relation to the interpretation of the law and the rules and regulations, and they are published for the information of the officials of the Department who may be charged with the execution of the law and especially to acquaint manufacturers, jobbers, and dealers with the attitude of this Department in these matters. They are therefore issued more in an advisory than in a mandatory spirit. It is clear that if the manufacturers, jobbers, and dealers interpret the rules and regulations in the same manner as they are interpreted by this Department, and follow that interpretation in their

¹⁶ See F. & D. Act, §3, 21 U. S. C. A. §3.

¹⁷ The committee consisted of H. W. Wiley, Chief of the Bureau of Chemistry; S. N. D. North, Director of the Census Bureau of the Department of Commerce and Labor; and James L. Gerry, Chief of the Division of Customs of the Treasury Department. YEARBOOK, DEPT. AGR. (1907) 70. There is an account of the work of this committee in WILEY, HISTORY OF A CRIME AGAINST THE FOOD LAW (1929) 78 *et seq.*

¹⁸ Circular No. 21. See YEARBOOK, DEPT. AGR. (1907) 70.

¹⁹ Regulations for the Enforcement of the Federal Food and Drugs Act (Tenth Revision, 1930). Service and Regulatory Announcements, Food and Drug No. 1. These regulations are identical in substance with those of the Ninth Revision.

²⁰ United States v. Antikamnia Chemical Co., 231 U. S. 654 (1914). In one instance a member dissented; the regulation as to the use of saccharin in foods was signed by the Secretary of Agriculture and the Secretary of Commerce and Labor, the Secretary of the Treasury dissenting. It was thereupon issued as a *food inspection decision*, (FOOD INS. DEC. 142 (1912), over the signature of Secretary of Agriculture, thereby becoming merely a departmental guide.

²¹ Section 11 of the Act requires the publication of these notices. 19,900 had been published as of April 14, 1933.

business transactions, no prosecution will lie against them. . . . It may often occur that the opinion of this Department is not that of the manufacturer, jobber, or dealer. In this case there is no obligation resting upon the manufacturer, jobber, or dealer to follow the line of procedure marked out or indicated by the opinion of this Department. Each one is entitled to his own opinion and interpretation and to assume the responsibility of acting in harmony therewith. . . .²²

The Department began in 1914 the publication of both the notices of judgment and the food inspection decisions in a single series of pamphlets captioned "Service and Regulatory Announcements." The last food inspection decision was issued June 10, 1927; "Definitions and Standards for Food Products," and "Regulatory Announcements" are now published in their stead. The change is for all practical purposes one of terminology only.

In 1907, the Secretary of Agriculture appointed a Board of Food and Drug Inspection, the duties of which were to consider the questions arising in the early days of the enforcement of the new Food and Drugs Act upon which the decision of the Secretary of Agriculture was necessary, and to conduct hearings upon alleged violations of the law. They also considered and supervised the voluminous correspondence occasioned by the new law, most of which involved interpretations. The Board was necessarily merely advisory in character, and its action required the approval of the Secretary of Agriculture. In 1915 this Board was abolished.

The Food Standards Committee, which is still functioning, was appointed in 1914, following a conference called by the Secretary of Agriculture in 1912. This committee of nine members appointed by the Secretary of Agriculture—three from the federal Food and Drug Administration, three from the Association of American Dairy, Food and Drug Officials, and three from the Association of Official Agricultural Chemists—has for its purpose the formulation of standards to be adopted by both federal and state agencies with a view to attaining uniformity in action.²³ The committee meets at irregular intervals, and hearings are held at which manufacturers and other interested parties may present their views on matters under consideration. When the standards are prepared, they are submitted to the various states for adoption; and following the approval of the states, they are issued over the signature of the Secretary of Agriculture as a regulatory announcement.

Through the Office of Coöperation, also established in 1914, the collaboration of the state with federal food and drug enforcement has been greatly furthered.²⁴ State

²² FOOD INS. DEC. 44 (1906).

²³ Following the enactment of the federal legislation in 1906, state legislation, similar in most respects to the federal statute, was enacted very generally. For a description of this legislation, see THORNTON, *THE LAW OF PURE FOOD AND DRUGS, NATIONAL AND STATE* (1912).

²⁴ "The Bureau of Chemistry's Office of State Control [now the Office of Coöperation of the Food and Drug Administration] is essentially a State agency in a Federal bureau. It is a special agent for the State or municipal official. It acts as a clearing house for all matters dealing with food and drug control, so that all the officials of the country may be kept informed upon all that is in progress throughout the country. It furnishes regularly information and assistance to State and municipal officials. The result is that Federal, State and municipal officials are able to supplement each other more effectively than was

and city enforcement officials are commissioned by the Secretary of Agriculture and, when a violation of the law is discovered, may cause proceedings to be instituted under the federal law if federal action is indicated. At the same time, federal officials upon the discovery of illegality may turn over the case for state action. Especially is this done in instances in which evidence of the interstate character of the shipment is not conclusive. State prosecution is relied upon also in a great many cases in which proceedings might be brought under either federal or state law, as a method of stretching to the greatest possible extreme the limited amount of money at the disposal of the federal agency.

Through these two agencies, the Food Standards Committee and the Office of Coöperation, "independent and conflicting action by independent groups of officials is, to a large extent, voluntarily obviated."²⁵

IV

The fact that, subject to judicial sanction, the determination of what conduct constitutes an offense under the Act lies in considerable measure in the judgment of the Administration gives to its decisions of policy an exceptional significance. Primarily this responsibility rests upon the Chief of the Administration; ultimately, upon the Secretary of Agriculture. It is difficult to determine to what extent the Secretary of Agriculture exercises his potential power of control of the Food and Drug Administration. Whether any Secretary has ever refused to sanction a prosecution recommended by a subordinate official cannot be ascertained. During the first year or so of the enforcement of the Act the hearings afforded to persons accused of violation were sometimes conducted by the Secretary himself.²⁶ This seems not to be the case today.

As to control of administrative action through indirect means, here again what goes on "behind the scenes" seldom becomes public knowledge except when internal disagreement assumes large proportions. The classic instance of dissension is that of Dr. Harvey W. Wiley, the then Chief of the Bureau of Chemistry and one of the draftsmen of the Act, with Secretary of Agriculture James Wilson and President Theodore Roosevelt, a struggle which lasted for several years and which culminated in Dr. Wiley's resignation in 1912.

When some manufacturers sought relaxation of Dr. Wiley's crusade against preservatives in foods, they found him adamant and relentless in his attitude. Control of his zeal was had indirectly through executive appointment of boards and committees. At the instance of President Roosevelt, the Secretary of Agriculture appointed a Board of Food and Drug Inspection to pass upon all the decisions of the possible early in the law's enforcement." Alsberg, *Ten Years of the Food and Drugs Act*, REP. SEC. AGR. (1917) 210, 211.

²⁵ Alsberg, *supra* note 24, at 211. See also Conover, *National, State and Local Coöperation in Food and Drug Control* (1928) 22 AM. POL. SCI. REV. 910, 923 *et seq.*

²⁶ See Bigelow, *DETAIL OF THE ENFORCEMENT OF THE FOOD AND DRUGS ACT*, YEARBOOK, DEPT. AGR. (1907), at 327.

Bureau of Chemistry and to conduct the hearings of alleged violators of the law. The committee consisted of Dr. Wiley and an Assistant Chief Chemist (who took no orders from the Chief) and the Solicitor of the Department of Agriculture. Since any action of the board required a majority vote, the other two members could effectually nullify Dr. Wiley's authority.

The creation of another board came about also as the result of the opposition of certain manufacturers to the ideas of Dr. Wiley, especially as to the use of chemical preservatives. It, too, was appointed by the Secretary of Agriculture acting under orders from President Roosevelt. By means of the Referee Board of Consulting Scientific Experts (usually referred to as the Remsen Board, taking its name from its chairman) even more complete control of Dr. Wiley was effected. The ostensible purpose, at least, of the Board was "to give the Secretary the benefit of the disinterested and unbiased advice of eminent and expert chemists when a serious conflict of opinion should arise as to the deleteriousness of any particular article or substance added to foods."²⁷ The recommendations of the Remsen Board were accepted by the Secretary of Agriculture and used by him in the preparation of departmental guides for enforcement of the Act. On the basis of its recommendations, food inspection decisions allowing the use of small quantities of benzoate of soda, sulphur dioxide, and alum were promulgated.²⁸ Dr. Wiley's opposition to the use of these substances ended only with his death.²⁹

The Secretary of Agriculture has, of course, ample opportunity to influence the enforcement of the Act through his control over the issuance of regulatory announcements defining the Administration's attitude. Dr. Wiley has said that Secretary Wilson refused to permit the publication and issuance of certain monographs and studies on foods and drugs, and charged further that the Secretary forbade the publication of a bulletin on benzoic acid which through error was printed but which the Secretary refused to allow to be reprinted.³⁰

More recently, a regulatory announcement issued by the Secretary of Agriculture completely reversed the policy of the Food and Drug Administration with respect to the use of corn sugar in foods. Early food inspection decisions required that foods containing corn starch be so labeled,³¹ and the term "sugar" was restricted to sucrose.³² Legislation designed to permit the freer use of corn sugar has been before Congress on more than one occasion but has consistently failed to pass. A

²⁷ Weber, *op. cit.*, *supra* note 15, at 18-19. The legality of the Referee Board never came before the courts. It was disputed vigorously in the press of the day, see *e.g.*, *Fight on Dr. Wiley and Pure Food Law* (1922) 22 *WORLD'S WORK* 14787; Dunn, *Dr. Wiley and Pure Food* (1911) 22 *WORLD'S WORK* 14958. However, it was upheld in an opinion of the Attorney-General. 27 *OP. ATTY. GEN.* 300 (1909).

²⁸ See *FOOD INS. DECS.* 76, 89, 101, 104.

²⁹ On the subject of appointment of the Board of Food and Drug Inspection and the Referee Board, see *Fight on Dr. Wiley and Pure Food Law*, *supra* note 27; Bjorkman, *Our Debt to Dr. Wiley* (Jan. 1910) 19 *WORLD'S WORK* 12443; WILEY, *AN AUTOBIOGRAPHY* (1930) 237 *et seq.*; WILEY, *HISTORY OF A CRIME* (1929) *passim*; 43 *CONG. REC.* 1360 (1909).

³⁰ WILEY, *HISTORY OF A CRIME* (1929) 62.

³¹ *REG. ANN.* 4 (1914).

³² *FOOD INS. DEC.* 66 (1907).

bill to permit its use in bakery and confectionery products was killed by a filibuster in the Senate, after having first been passed in the Senate and then amended in the House.³³ In 1930, a bill to define and set standards for fruit preserves, jams, jellies, etc., which was introduced in Congress provided that these products should contain a certain quantity of fruit and a set percentage of "any kind of refiner's sugar."³⁴ The bill was opposed by the Chief of the Food and Drug Administration on the ground that it permitted the manufacturer to use corn sugar without indicating its presence on the label of the product and on the broader ground that the public should be apprised of the contents of the food they buy. The Chief appeared at the hearing before the House Committee to which the bill was referred and offered amendments to overcome his objection.³⁵ The bill, opposed by some manufacturers and approved by others, was never reported out of committee, so that the position of corn sugar remained *in statu quo*.

On December 26, 1930, over the signature of the then Secretary of Agriculture, the following regulatory announcement was issued:

Corn sugar (dextrose) when sold in packages must be labelled as such; when sold in bulk must be declared as such; but the use of pure, refined corn sugar as an ingredient in the packing, preparation, or processing of any article of food in which sugar is a recognized element need not be declared upon the label of any such product. . . . The term "sugar," with or without the parenthetical expression "sucrose" as used in the definitions to designate the sweetening agent in manufactured food products, is to be interpreted, wherever necessary to effect the purpose of the foregoing decision, as including dextrose (pure, refined corn sugar).³⁶

In the absence of some quarrel of the magnitude of Dr. Wiley's, the reasons behind the change of policy in regard to dextrose will probably never be made public.

V

Congress has, of course, no direct control over the activities of the Administration aside from its power to amend the Act. However, several very effective means of indirect control are at its disposal. The appropriations granted to the Department of Agriculture for the use of the Food and Drug Administration may greatly influence the scope of enforcement.³⁷ The Administration has frequently commented

³³ 69th Cong., 1st Sess., S. 481 (1926). See 67 CONG. REC. 3011; 11317; 11332; 11463; 11511; 11512; 12102; 12305; 12361; 12473; 12478 (1926).

³⁴ 71st Cong., 2nd Sess., H. RES. 9760 (1930).

³⁵ Hearings before the House Committee on Agriculture on H. R. 9760, 71st Cong., 2nd Sess. (1930) 28 (Standards for Fruit Jams, Fruit Preserves, Fruit Jellies, and Apple Butter).

³⁶ Service and Regulatory Announcement, F. D. 2, REV. 1, Supp. 3.

³⁷ Beginning in 1909, which is the first year in which the appropriations were made specifically for the purpose of enforcing the Food and Drugs Act and not embodied in the general appropriation for the Bureau of Chemistry, the amounts granted by Congress have been:

1909\$ 685,460.00	1912\$ 625,000.00	1915\$ 635,161.00
1910 702,340.00	1913 675,000.00	1916 632,951.00
1911 610,110.00	1914 644,301.00	1917 623,521.00

upon the inadequacy of available funds; and its "project system" of enforcement, discussed below, is in some measure the result of an effort to obtain the greatest results possible with the limited means at hand.³⁸ The increase in the number of prosecutions carried on in 1932 has been attributed by the Chief of the Administration directly to the increased budget for that year.

Congressional investigations of the enforcement of the Food and Drugs Act have been largely tempests in teapots from which little if any action or alteration has resulted. In 1910, resolutions were adopted, requesting from the Secretaries of Commerce and Labor, Agriculture, and the Treasury, and the Attorney-General, information as to whether the enforcement of the Food and Drugs Act had been suspended or specific persons exempted from its provisions.³⁹ The Secretary of Agriculture replied that no order had been issued suspending the operation of the Act and that no individual had been granted immunity. The other replies were of the same tenor.⁴⁰

The House hearings on the Expenditures in Agriculture Department in 1911 developed into a general investigation of the intradepartmental operation of the Bureau of Chemistry, then charged with the enforcement of the act. An unofficial Senate hearing on the administration of the Act in 1930 resulted in no changes.⁴¹

Needless to say, individual congressmen frequently confer with the officials of the Administration in Washington on behalf of aggrieved constituents, a process which results more generally in the enlightenment of the congressman than in benefit to the complainant. Occasionally, where regional interests are involved, representations will be made to the Secretary of Agriculture himself. Representatives from the northwestern states have been especially active in recent years on behalf of the fruit growers of that section who felt the burden of the Administration's regulations against the lead and arsenic residues of insecticides remaining on sprayed fruits.

VI

The "project" system of enforcement in use for many years is a system of organization of effort. With the realization that it is for all practical purposes impossible to put an end to all adulteration and misbranding of foods and drugs in interstate commerce, the activities of the Administration are centered upon those articles in widest use and most apt to affect great numbers of people—in other words,

1918	\$ 589,801.00	1923	\$ 704,401.00	1928	\$ 938,000.00
1919	620,221.00	1924	716,260.00	1929	1,030,000.00
1920	579,361.00	1925	788,860.00	1930	1,125,000.00
1921	671,401.00	1926	785,408.00	1931	1,315,865.00
1922	671,401.00	1927	918,780.00		

³⁸ See e.g. REP. F. D. AND I. ADM. (1930) *passim*; Hearings on the Administration of the Federal Food and Drugs Act, 71st Cong., 2nd Sess. (1930) 212.

³⁹ 61st Cong., 1st Sess., H. RES., 66-69 (1909).

⁴⁰ 45 CONG. REC. 412 (1910).

⁴¹ An account and an interpretation of this hearing (which lasted from February 12, 1930 to June 30, 1930) may be found in *History of the Ergot Investigation* (1930) 95 AM. MED. ASSN. J. 722.

upon staple products.⁴² The Administration proceeds upon the theory that most manufacturers are doing a legitimate business and wish to remain within the law. Ordinarily, an isolated violation of the law, unless flagrant and obviously premeditated, is not proceeded against until the violator has been given warning and an opportunity to bring his product into conformity with the law.⁴³ But when advisory methods fail and more severe treatment is required, resort to the courts must be had.

Upon the basis of factory inspections and analysis when necessary, the Administration determines what particular food and drug products are being adulterated or misbranded and what types of violations may be expected during the ensuing year. The comparatively small section of an industry which is doing a questionable business is thereby segregated from the other sections. Thus the field of possible activity is narrowed with respect both to kinds of commodities and to manufacturers of those commodities and the activities of the Administration are directed toward controlling the smaller field rather than proceeding haphazardly against the mass of products in interstate commerce. Plans for the enforcement of the law in a uniform manner throughout the country are formulated at the beginning of each year. The system is kept flexible, however, so that in the event of an emergency such as an outbreak of food poisonings, the forces may be directed toward investigation of the problems connected therewith.

In the actual enforcement the problem of detection is complicated by the limitations of federal authority. The first step in the procedure for the punishment of suspected violations is the collection of samples,⁴⁴ a matter in itself somewhat complex. The specimens must be taken in such a manner that the interstate character of the shipment which was sampled can be shown, and detailed instructions are issued describing all the various pieces of information which must be obtained in order properly to prove interstate shipment.⁴⁵

The sample, with all the accompanying data as to mode and place of collection, interstate shipment, etc., is forwarded to the nearest inspection station, where it is

⁴² See REP. CH. CHEM., Dept. Agr. (1924) 18. The Administration has said:

" . . . the entire personnel and appropriation granted for the law-enforcement work could be utilized annually in a meticulous supervision of the interstate and import traffic in one or two staple commodities. It has been estimated, for example, that a thorough sampling and analysis of every interstate shipment of two such staple commodities as flour and butter would more than absorb the entire annual appropriation for the enforcement of the law. . . ." REP. F. D. AND I. ADM. (1930) 3.

⁴³ "It is believed that more effective compliance with the law may be obtained by showing reputable manufacturers how to bring their products into conformity with its terms than by imposing fines or effecting seizures and confiscations after the violation has been committed. Its policy, therefore, is to pursue educational methods as a preliminary to legal action where this can be done without jeopardizing the public interest or legitimate competitive conditions." REP. F. D. AND I. ADM. (1926) 20.

⁴⁴ Three specimens are taken. "Upon request one subdivision [of the sample] if available shall be delivered to the party or parties interested." Reg. 3.

⁴⁵ See MANUAL OF PROCEDURE FOR GUIDANCE OF CITY AND STATE HEALTH, FOOD AND DRUG OFFICIALS (Dept. Agr. 1919). Although this pamphlet is issued primarily for the use of coöperative officials, the sampling procedure is the same.

analyzed.⁴⁶ If the analysis shows adulteration or misbranding within the Administration's understanding of those terms, and if the station chief considers the case appropriate for prosecution proceedings, the results of the analysis, together with the recommendation for criminal prosecution, are sent by the station chief to the district chief. The district chief considers the recommendation and, if he approves, instructs the inspection station to cite the manufacturer or shipper or dealer from whom the sample was procured to a hearing at the station headquarters. At the same time the district chief submits a statement of the action taken to the Chief of the Administration in Washington.

Section 4 of the Act requires a hearing as a prerequisite to action by the Administration where criminal prosecution is contemplated. It is not, however, a prerequisite to independent action by a district attorney,⁴⁷ nor is it required in the case of seizure proceedings⁴⁸ where time may frequently be of the essence. The hearing is not a judicial proceeding⁴⁹ and is for the "purpose of affording the manufacturer, shipper, or dealer an opportunity to show that an error has been made in either the collection or analysis of the sample or the interpretation of the results. He may also produce evidence of a guaranty from the person from whom he obtained the consignment of which the sample is a part."⁵⁰

On the date set for hearing, the person cited may report in person or by attorney for an oral hearing, or he may present his statement in writing as to why the government should not take further action, or, if he choose, he may remain silent. There is no method of compelling his attendance or the transmittal of written statements. If the person cited appears for an oral hearing, the proceedings are conducted by a member of the Administration, usually the station chief. After the hearing, if there has been one, or after the date set for the hearing if the person cited has chosen to remain silent, the station chief sends to the district chief a recommendation as to the proper course to be pursued. If there was a hearing, the station chief's summary of the findings is forwarded with the recommendation. The district chief may indorse the station chief's recommendation or he may modify it. In either event he sends

⁴⁶ Bigelow, *supra* note 26, at 321 *et seq.*, and Dept. Agr. Misc. Pub. No. 48 (Supp. 1930) have been largely relied upon for the following account of procedure. See also Wharton, *Requirements of the Federal Food and Drug Act*, 20 AM. FOOD J. 461 (1925); Dunbar, *Enforcement of Food and Drugs Act*, 110 OIL, PAINT AND DRUG REPORTER (Nov. 1, 1926) 22.

⁴⁷ *United States v. Morgan*, 222 U. S. 274 (1911).

⁴⁸ This has been the practice since the beginning. See Bigelow, *supra* note 26, at 328. The courts have sustained the practice. *United States v. Seventy-Five Boxes of Alleged Pepper*, 198 Fed. 934 (D. C. N. J. 1912); *United States v. W. T. Rawleigh*, 57 F. (2d) 505 (C. C. A. 10th, 1932).

⁴⁹ ". . . But the hearing is not judicial. There is no provision for compelling the presence of the party from whom the sample was received; if he voluntarily attends he is not in jeopardy; an adverse finding is not binding against him; and a decision in his favor is not an acquittal which prevents a subsequent hearing before the Department, or a trial in court.

"The provision as to hearing is administrative, creating a condition where the district attorney is compelled to prosecute without delay." *United States v. Morgan*, *supra* note 47 at 281. Notice and hearing are not conditions precedent to prosecution. *Id.*

⁵⁰ Bigelow, *supra* note 26, at 327.

all the papers in the case to the office of the Chief of the Administration, with his statement of what he deems the proper action to be taken.

The Chief or Assistant Chief may decide on the next step. As a rule, however, he refers the matter to the laboratory at the central headquarters in Washington which specializes in the product under consideration. If the specialist agrees with the district chief's recommendation for prosecution the case is turned over to the Chief or Assistant Chief with an endorsement of the recommendation. If one of these officials agrees with the recommendation for prosecution, all the papers in the case are examined by the Administration's solicitor in the office of the Solicitor of the Department of Agriculture who decides whether the evidence at hand is sufficient to support criminal prosecution; and if he and the solicitor concur in the Administration's recommendation, he prepares the papers necessary to be transmitted to the Department of Justice.

Where seizure proceedings are contemplated, a more direct procedure is followed. In an instance of a violation of novel impression, the station chief reports the facts and the results of analysis and examination to the central Administration in Washington and institutes seizure proceedings only upon the authorization of the office of the Chief of the Administration. The action in this case, however, serves as a departmental precedent; and if permission to seize has been granted and the seizure has resulted in a decree for condemnation of the offending article, the station chief may proceed on his own initiative against similar articles found in interstate commerce thereafter. As remarked above, no hearing is held.

VII

The procedure thus far considered takes place within the Department of Agriculture, chiefly in the Food and Drug Administration. After collection of specimens, analysis, hearing and recommendations by the various officials concerned, the papers necessary for the Government's case, prepared by the solicitor of the Department of Agriculture, are transmitted to the Department of Justice, from which department the records are sent to the United States Attorney for the district in which the case is to be tried.⁵¹ He may institute criminal proceedings either by indictment or, since violations of the Act fall within the category of "petty offenses," by information.⁵² The proceedings in prosecutions for violations of the Act are those of any federal criminal trial. Members of the Food and Drug Administration staff usually appear as witnesses at the trial. In cases involving therapeutic claims, it is usual to supplement their testimony with that of physicians of standing in the community. In an important case, it may be necessary to call upon physicians and scientists of national reputation to serve as expert witnesses.

⁵¹ It has been pointed out by the Assistant Chief of the Administration that there is a review by at least six responsible officers before a case is actually placed before the federal courts for prosecution. Dunbar, *supra* note 46, at 22. This process was severely criticized by Dr. Wiley, who said that the law provides that the Secretary of Agriculture shall decide what action to take, and that there is too much "red tape" in the enforcement of the Food and Drugs Act. Wiley, *Maladministration of the Food and Drugs Act*, 110 OIL, PAINT AND DRUG REPORTER (Nov. 22, 1926) 23.

⁵² *United States v. J. Lindsay Wells Co.*, 186 Fed. 248 (W. D. Tenn. 1910).

The alternative to criminal proceedings under the Act, seizure for confiscation by a process of libel for condemnation, authorized by Section 10, is resorted to only in certain classes of cases. These have been outlined by the Administration as follows:

Seizure actions are instituted in four classes of violations:

(1) In the case of food products containing added poisonous or other added deleterious ingredients which may be harmful to health; (2) in the case of food products consisting in whole or in part of filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, or a product of a diseased animal, or one that has died otherwise than by slaughter; (3) in the case of food or drug products so grossly adulterated or misbranded with false claims that their distribution constitutes a serious imposition upon the public; (4) in the case of deliberate frauds in the shipment of adulterated and misbranded food products which seriously demoralize legitimate trade practices. Unless a violation falls clearly within one of these four classes, seizure action is not taken but the party responsible for the violation may be prosecuted.⁵³

Seizure usually precedes the issuance of the libel, but authority is divided whether this is requisite.⁵⁴ Any party having an interest in the libeled goods may intervene as claimant. The procedure followed must conform "as near as may be" to the admiralty practice in libel,⁵⁵ except that the right of trial by jury of any issue of fact is given both parties. The burden of proof is on the Government, but since the proceeding is not criminal in character, proof need not be "beyond a reasonable doubt," and the Government as well as the claimant enjoys the right of appeal.⁵⁶ Products which are condemned as violative of the Act may be ordered destroyed by the court, or, upon the filing of a bond by the claimant conditioned upon the goods being reconditioned so as to meet the provisions of the law, they may be released. The proper disposition to be made is a matter for the discretion of the court.⁵⁷

⁵³ REP. CH. BUR. CHEM. (1926) 19.

⁵⁴ That seizure is not a prerequisite to libel, *United States v. Capon Water Co.*, 30 F. (2d) 300 (D. C. Pa., 1929). *Contra*: *United States v. Two Barrels of Dessicated Eggs*, 185 Fed. 302 (D. C. Minn., 1911); *United States v. Eight Packages and Casks of Drugs*, 5 F. (2d) 971 (D. C. Ohio, 1910). The last case also held that verification is necessary. To the contrary is *United States v. Eighteen Cases of Tuna Fish*, 5 F. (2d) 979 (W. D. Va., 1925) where it is said, at 981: "As has been said, the words 'as near as may be' permit the exercise of a reasonable discretion, and as the delays involved in laying before the court affidavits by persons having first-hand knowledge of the facts may frequently be fatal to the efficacy of the proceeding, I believe it permissible and judicious to order the issue of monitions and attachments on informations which are wholly unsupported by oath or affirmation."

⁵⁵ "Section 10 of the act is of very doubtful meaning in several respects; and which of several practices in admiralty was in the mind of the draftsman will, I believe, always be in doubt." McDowell, J., in *United States v. Eighteen Cases of Tuna Fish*, *supra* note 54, at 981.

Speaking of the words "as near as may be" in connection with their use in the Federal Conformity Act, 17 Stat. 197 (1872), Professor Dobie has characterized them as "the sand in the gearbox, the fly in the ointment, the nigger in the woodpile." Dobie, *Frictional Points of Conflict Between State and Federal Courts*, 19 VA. L. REV. 485, 487 (1933). The same characterization may be made of their use in §10 of the Food and Drugs Act.

⁵⁶ *Four Hundred and Forty-three Cans of Frozen Egg Product v. United States*, 226 U. S. 172 (1912).

⁵⁷ *United States v. Two Cans of Sweet Birch, etc.*, 268 Fed. 866 (S. D. N. Y. 1920). In this case, release was denied; the articles were not deleterious but were of low quality and the claimant was a former offender.

Since 1913, the policy has been followed of sending the Department of Agriculture's solicitors to aid in the prosecution of cases brought under the Act. The technical nature of the proof necessary to establish violations renders the assistance of specialists in this type of litigation of great value. Generally, their cooperation has been welcomed, but some United States District Attorneys do not seem to have looked with favor upon the practice. The Administration has never been convinced of the authority of its solicitor to insist upon such participation.⁵⁸

An indirect consequence of the smallness of the penalties provided by the Act is that the local prosecuting officials and trial judges tend to minimize the importance of food and drug cases which, as to first offenses, can result in no more than a \$200 fine. Yet their technical character frequently requires thorough preparation, considerable expense in securing expert witnesses, and a full presentation of the Government's case. Such consideration was especially difficult to obtain when the criminal dockets of the federal courts were crowded with cases arising under the Volstead Act.

A source of some conflict between the Departments of Justice and Agriculture lies in the fact that the former determines when an appeal shall be taken, and in some instances it has refused to proceed further in cases where the Food and Drug Administration believed such action to be important. Thus, the Administration favored review of the Bred-Spred case⁵⁹ in order to have an authoritative determination of the "distinctive name" proviso of the statute, and of the Lee's "Save the Baby" decision⁶⁰ for a ruling on the applicability of the Sherley Amendment, which covers statements of therapeutic claims, to circulars packed with the carton but not physically a part of the label; but the Department of Justice thought otherwise.⁶¹

VIII

The necessity of judicial action for enforcement of the Act in each contested case⁶² is an important limitation upon the activities of the Administration. Yet probably the establishment of a commission to take *quasi-judicial* action in the first instance, subject only to judicial review, is not a practicable alternative. To require hearings in Washington for the minor violations occurring throughout the country would subject defendants to an intolerable burden. Nevertheless, the requirement of a court trial in each contested case has undoubtedly handicapped enforcement.

The generality of the definitions of offenses in the Act is, as has been observed, a source of much difficulty. Each case must stand upon its own factual situation. Interpretation of these definitions by the court is required in virtually every case, although there are instances to be found in which the question of adulteration or

⁵⁸ Hearings before the Committee on Agriculture, *supra* note 35, at 199 on H. R. 9760.

⁵⁹ United States v. Ten Cases, More or Less, Bred-Spred, 49 F. (2d) 87 (C. C. A. 8th, 1931).

⁶⁰ United States v. Certain Bottles of Lee's Save the Baby, 37 F. (2d) 137 (D. C. Conn., 1929).

⁶¹ See REP. CH. F. & D. ADM. (1931) 4.

⁶² This requirement is relaxed only with respect to imports. Goods offered for entry but found to violate the law are merely refused entry and destroyed if the owner fails to export or destroy them within 30 days. F. & D. Act §11, 21 U. S. C. A. §15. Regulation 29 deals minutely with import procedure, bonds for release, for reconditioning, etc.

misbranding was determined by analogy to previous cases.⁶³ There have been but relatively few cases involving the interpretation of the Act which have reached the Supreme Court, and the decisions in the lower federal courts are oftentimes conflicting. On some points, the different circuits are at variance;⁶⁴ in at least one instance, the decisions within a single circuit are not uniform.⁶⁵ The determination of the interstate character of a shipment and the application of the "original package" doctrine have increased the scope of judicial control. In general, it may be said, however, that the interpretation of the statute has been in the furtherance of its purposes. An egregious exception was the decision of the Supreme Court that therapeutic claims were not included within the scope of the original provision against misbranding.⁶⁶ This decision led to the enactment, upon the recommendation of President Taft, of the Sherley Amendment prohibiting "false and fraudulent" claims of this character.⁶⁷

The requirement of trial by jury, which was extended to seizure cases probably to obviate the risk of unconstitutionality, has not infrequently hampered the work of the enforcement officials. Of one hundred seventy-four notices of judgment published March 25, 1933, forty-four followed prosecutions. In the four of these in which pleas of not guilty were entered, there were three jury trials. In each of them the verdict was not guilty.

The technical character of the issues submitted to the jury will often make difficult an intelligent determination of the questions raised. What are the proper ingredients of macaroons?⁶⁸ Is caffeine added to a food product a deleterious ingredient?⁶⁹ These are not questions for the "man on the street," yet, when the evidence is conflicting, they must be left to the jury. Again, it is reasonable to assume that local juries will sometimes favor a local defendant. In a proceeding brought in Buffalo for the condemnation of cherries canned in the vicinity, the jury returned a verdict in favor of the claimant. In explanation of its verdict, the jury submitted to the judge the revealing statement which follows:

This jury after long deliberation further desires to state to this court that from the admitted facts in this case, which show that the management of the Westfield Canning Company in conduct and treatment of the cherries in question were either careless, incompetent, or wilfully negligent after knowing that the cherry season of 1924 was an abnormal

⁶³ See, e.g., *United States v. Boeckman*, 176 Fed. 382 (C. C. N. Y. E. D., 1910), which followed *In re Wilson*, 168 Fed. 566 (C. C. D. R. I., 1909).

⁶⁴ For example, in construing the confectionery sub-section of §7, prohibiting the use of certain named substances "or other mineral substances," the doctrine of *eiusdem generis* was applied to restrict the meaning of "other mineral substances" to minerals used to increase bulk and weight at the expense of quality in *French Silver Dragee Co. v. United States*, 179 Fed. 824 (C. C. A. 2d, 1910), and was not so applied in *United States v. Oriental Dragee Co.*, Not. Judg. 176 (D. N. J. 1909).

⁶⁵ The same product with the same label was held misbranded in *United States v. Scanlon*, 180 Fed. 485 (N. D. Ohio, 1908), and not misbranded in *United States v. 68 Cases of Syrup*, 172 Fed. 781 (E. D. Ill. 1909).

⁶⁶ *United States v. Johnson*, 221 U. S. 488 (1911).

⁶⁷ 37 Stat. 416 (1912), 21 U. S. C. A. §10.

⁶⁸ See *F. B. Washburn & Co. v. United States*, 224 Fed. 395 (C. C. A. 1st, 1915).

⁶⁹ See *United States v. Coca Cola Co.*, 241 U. S. 265 (1916).

one, in not taking such special care and precautions that such conditions require, knowingly to market such goods which were far below the standards of other concerns shows gross carelessness and mismanagement.

This jury in consideration of the canning company's stock being held largely by the farmers and fruit growers of the community feels that they would be great sufferers if any adverse conditions affected the company. We, therefore, hope that the stockholders will demand a thorough investigation of the concern and see that this plant is as good and can produce as fine a quality of goods as any in the state and respect the pure food laws.⁷⁰

The establishment of legislative standards in lieu of the administrative standards whose validity may be an issue in any trial would reduce the risk both of adverse interpretation and of misguided jury verdicts. The establishment of such standards has long been urged by the Administration. Once established as reasonable, such standards would no longer be open to question. Except in so far as the original Act incorporated the definitions and standards of the United States Pharmacopoeia and the National Formulary, it provided no legislative standards.⁷¹ Congress has since enacted standards for apples⁷² and butter.⁷³ The McNary-Mapes Amendment providing that any substandard canned food (except canned meats) shall be deemed misbranded unless it bears a label prescribed by the Secretary of Agriculture indicating that it is substandard,⁷⁴ represents, therefore, a departure from past practice.

The Secretary of Agriculture is authorized by this Amendment to promulgate standards for canned foods and to prescribe the labels that must be affixed to canned foods whose quality falls below the prescribed standard. In the discussions in Congress immediately preceding the passage of the original Act in 1906 it was specifically pointed out that the proposed statute neither provided for nor authorized any binding standards but that all enforcement was put in the hands of the courts.⁷⁵ It is very doubtful whether the Act would have passed at that time had the executive been given any great amount of power.⁷⁶ In the first case brought to test the validity

⁷⁰ (1925) 20 AM. FOOD J. 482, quoting from the *Buffalo Morning Express*, Aug. 3, 1925.

⁷¹ The Act, as has been pointed out, did give to the three Secretaries a power to make rules and regulations which, if reasonable and within its terms, have the force and effect of law. See note 20, *supra*. These must be distinguished from the purely administrative standards and definitions promulgated by the Secretary of Agriculture. These have been declared to be determinations of fact upon which the law is made to depend and not law. *United States v. Frank*, 189 Fed. 195 (S. D. Ohio, 1911), quoting with approval a statement similar in tenor by Lurton, J., in *Coopersville Coop. Creamery Co. v. Lemon*, 163 Fed. 145, 147 (C. C. A. 6th, 1908).

⁷² 37 STAT. 250 (1912), 21 U. S. C. A. §20.

⁷³ 42 Stat. 1500 (1923), 21 U. S. C. A. §6.

⁷⁴ 46 Stat. 1019 (1930), 21 U. S. C. A. §10.

⁷⁵ See 40 CONG. REC. 1923; 9495; 9735; 9740 (1906).

⁷⁶ During the consideration in the Senate of an urgent deficiency appropriation bill for the Department of Agriculture, Jan. 25, 1909, Senator Heyburn had the following to say:

"We absolutely refused, in enacting the pure-food law, to consider favorably the proposition of establishing standards by legislation. . . . It is the spirit of the pure-food bill that the courts should determine these questions [of adulteration and misbranding] and that no other definition than that of the courts should constitute a rule of action under the law; . . . It was the essence of that principle in the pure-food law that as much as anything else held it back in Congress for almost a quarter of a century. People would not submit to the principle that we should establish standards by legislation. The people who intelligently considered that measure demanded that each case should stand upon its own facts, and when the Senate expressed its final conclusions the law was so written." 43 CONG. REC. 1360 (1909).

of a standard established under the Amendment, the District Court for the Southern District of Indiana held the standard unconstitutional.⁷⁷ An appeal is pending.

IX

The penalties provided by the statute are not severe,⁷⁸ and their leniency has been a target for criticism.⁷⁹ The Administration itself complained of their inadequacy in the 1931 Report in which it was stated:

Not infrequently firms are encountered which repeatedly violate the law, paying the fines imposed under this section whenever shipments are apprehended by the department and legal proceedings brought, but apparently regarding those penalties as in the nature of a license fee for doing an illegitimate business. While firms of this character do not persist in business indefinitely, a more positive deterrent effect would be insured if more severe financial penalties could be imposed. It is practically impossible to secure jail sentences, authorized in second offenses, where the shipper is a corporation.⁸⁰

The quantity of goods seized is seldom such as to subject the manufacturer to serious loss. The dealer who may not be in a position to know the quality of the goods stocked by him can protect himself from criminal prosecution by securing a guaranty, provided for by Section 9 of the Act, from his seller, which shifts the risk of prosecution to the guarantor.

It is difficult to estimate the value of the publicity afforded prosecutions and seizures under the Act through the publication of notices of judgments. These are seldom noted by periodicals of general circulation, but trade journals tend to inform their readers of such actions. The liability to seizure of goods known to have been held in violation of the Act renders wholesalers and retailers chary of stocking them. Where the manufacturer has its own channels of distribution, this sanction is, of course, unavailing.

The fact that offending products may be seized simultaneously in various parts of the country has given rise to a problem of considerable difficulty. It has been held that the institution of multiple seizure proceedings in various parts of the country against the same product may be enjoined, on the theory that irreparable injury may be done to manufacturers of the product while the cases are being litigated.⁸¹ In line with this decision is the holding of a Circuit Court of Appeals

⁷⁷ *Morgan v. Nolan*, 3 F. Supp. 143 (S. D. Ind. 1933).

⁷⁸ The penalty imposed by §2 for a first offense is a fine not exceeding \$200; for each subsequent offense, a fine not exceeding \$300 or imprisonment not exceeding one year or both, in the discretion of the court. Somewhat higher penalties are imposed by §1 for manufacture in the District of Columbia and in the territories. The average fine under both sections in successful prosecutions from Jan. 1, 1907 through June 30, 1931 was less than sixty-six dollars. There seem to have been only two jail sentences ever imposed. See Note (1932) 32 COL. L. REV. 721, 734 *et seq.*

⁷⁹ See KALLET & SCHLINK, "100,000,000 GUINEA PIGS" (1933) 213-219.

⁸⁰ REP. CH. F. & D. ADM. (1931) 4.

⁸¹ *National Remedy Co. v. Hyde*, 50 F. (2d) 1066 (C. A. D. C., 1931). The court stated, p. 1068: "Inasmuch as every district attorney to whom the Department makes certification must institute appropriate proceedings, by indictment or libel for condemnation, or both, it is evident that, even though the findings of the Department are merely administrative, nevertheless, if such certification should be made to the district attorney in every district where a product might be found, the manufacturer would be

that where seizure proceedings brought against an article as misbranded under the Insecticide Act have resulted in judgment adverse to the Government, the Government will thereafter be estopped to institute similar proceedings against a different shipment. The court used the following language:

If the government is not bound by an adverse judgment, neither is the appellant. Hence, without modifying its formula or changing its labels, it could, notwithstanding the decree herein, ship its preparation into other territory, and indeed into the same territory, with the hope of a more favorable result elsewhere, or next time should the government bring other libels. And, instead of "peace and repose of society," the result would be chaos and endless turmoil.⁸²

Although this decision was reached under the Insecticide Act, the terms of that statute as to misbranding are similar to those of the Food and Drugs Act,⁸³ and it would seem that the principle of estoppel would apply as well under one law as the other. The result seems to be that the Government must prove each case of misbranding, so long as the judgments are favorable to it, while the first ruling for the defendant will automatically bar any further proceedings against an article so long as its formula and label remain the same.

Directly contrary to this case is the holding of a district court in a case which involved a subsequent seizure of a proprietary medicine under the Food and Drugs Act. The court decided that the prior decree for the defendant might be shown as conducing to an application of the doctrine of *stare decisis* but that it was not *res adjudicata*.⁸⁴ Since there is no Supreme Court ruling on the question, which of these two latter decisions will be followed is a matter of surmise.

It seems clear, however, that a single seizure proceeding will not be enjoined.⁸⁵ The validity of the seizure may be tested in the libel proceeding, and consequently the remedy at law is adequate. Where, however, the case involves the import of goods alleged to offend the Act, an injunction seems appropriate since the denial of entry is a matter for administrative discretion. Of course, relief will be granted only when such discretion is palpably abused.⁸⁶ The remedy of injunction would also

crippled or ruined long before the final adjudication in the court could be had. Such a result, we think, was not contemplated by Congress, except possibly in unusual cases where drastic action would be necessary for the immediate protection of the public. Is this a case of that character? We think not."

⁸² *Geo. H. Lee Co. v. United States*, 41 F. (2d) 460-462 (C. C. A. 9th, 1930).

⁸³ Compare §8 of the Insecticide Act, 36 STAT. 331 (1910), with §8 of the Food and Drugs Act, 21 U. S. C. A. §10.

⁸⁴ *United States v. Certain Bottles of Lee's Save the Baby*, *supra* note 60.

⁸⁵ *Shawnee Milling Co. v. Temple*, 179 Fed. 517 (S. D. Iowa, 1910). The court said that injunction will lie to restrain the enforcement of a criminal or penal statute only when the statute is unconstitutional or otherwise invalid, and property rights are invaded in the attempt to enforce it or when often repeated attempts to enforce it create a multiplicity of actions. The court found that property rights were invaded, but held the statute constitutional as being a valid exercise of the federal power to regulate commerce. The question as to whether the product was adulterated under that statute was held to be for the jury.

⁸⁶ *Ambruster v. Mellon*, 41 F. (2d) 430, 432 (C. A. D. C., 1930). The court in this case refused to review the Administration's decision on the ground that the exercise of its authority had not been shown to have been "capriciously or arbitrarily" abused.

seem appropriate to restrain the establishment of legislative standards such as those contemplated by the McNary-Mapes Amendment.⁸⁷

X

It is without the scope of this paper to consider the adequacy of the substantive provisions of the Act and the proposals which are current for its amendment. These are discussed elsewhere in this issue.⁸⁸ That amendatory legislation is needed is manifest. The Chief of the Administration has stated that the Food and Drugs Act is now enforced even more strictly than during Dr. Wiley's era,⁸⁹ yet it is a far cry from the following publicly-expressed and enthusiastic appraisal of the Act, in 1907:

It is without exception the most complete, overwhelming and bloodless victory that legislation has ever accomplished. Whether the consciousness of guilt, the desire for reformation, the appreciation of anticipated benefits or fear of prosecution has produced this consequence, is an open question, but whichever motive has been the dominant one, the evils which induced the legislation have been already practically removed and while, of course, the future is bound to bring about some instances of statutory violation, yet, in the main, the purposes of the Act have been already realized,⁹⁰

to the statement of the Chief in his report for 1932:

Some . . . comments and inquiries reveal that a considerable portion of the public is perhaps expecting greater protection through the enforcement of the pure food and drug law than the legal authority conferred by that legislation will permit. . . . If the public is depending on the act for protection in instances where it has no protective provisions, it is worth while to inform consumers of the law's limitations so that they may not suffer through a false sense of security.⁹¹

⁸⁷ An injunction against such a standard was granted in *Morgan v. Nolan*, *supra* note 77.

⁸⁸ See Fisher, *The Proposed Food and Drugs Act: A Legal Critique*, *infra* p. 74; Burton, *What the Food Manufacturer Thinks of S. 1944*, *infra* p. 120; Kallet, *A Consumer Looks at the Food and Drugs Bill*, *infra*, p. 126.

⁸⁹ Hearings, *supra* note 38, at 343.

⁹⁰ Reed, *Some Aspects of the Federal Food and Drug Act*, ILL. STATE BAR. ASSN. (1907) 99, 102.

⁹¹ REP. CH. F. & D. ADM. (1932) 11.