

Federal Food, Drug and Cosmetic Act

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CURRENT LEGISLATION

FEDERAL FOOD, DRUG AND COSMETIC ACT.—When great changes are wrought in the economic structure of a nation, of necessity, legislation to meet these changes must be enacted. For the desired balance, our legislative machinery must be geared so that it will move along quickly and efficiently to meet the changes with as little lag as possible. When we find our legislators trailing far behind, not meeting the problems presented by the results of man's progress, we must suffer a period of maladjustment and abuse.

On June 30, 1906, as a result of the efforts of Dr. Harvey Wiley,¹ a food and drug law was enacted prohibiting the shipment in interstate commerce of adulterated and misbranded foods and drugs.² Enacted to meet the needs of the country as they then existed, the Act was soon to find itself inadequate to meet the problems of a people that had progressed beyond the scope of its effectiveness.³ Amended from time to time, in minor respects,⁴ it failed to keep up with the strides made by the various industries and was unable to check certain disreputable methods developed by others.⁵ The vast changes in the fields of cosmetics and advertising left the Food and Drug Administration⁶ with a problem it could not meet under the provisions of the 1906 Act, insofar as the Act gave the Administration jurisdiction over misleading labels only and left unscrupulous advertisers free to make any claims they desired in advertising their products elsewhere.⁷ Hav-

¹ HARVEY W. WILEY, HISTORY OF A CRIME AGAINST THE FOOD LAW (1929) c. I; HYGIEIA, Jan., 1934, p. 6 (the Act followed the campaign waged by Wiley and of great influence were the books, "The Great American Fraud" and "The Jungle").

² 34 STAT. 768 (1906), 21 U. S. C. § 1 (1927).

³ Copeland, *Protection for the Public*, SCIENTIFIC AMERICAN, Feb., 1938, p. 88 (the writer, Senator Copeland, stated, "Modern Commercial practices which Dr. Wiley and his associates could not anticipate, call for new methods of control"). In the Annual Report of the Food and Drug Administration for the Fiscal Year ending June 30, 1933, the Administration said, "if the present law doesn't control all serious abuses * * *, it is to be attributable to the inability * * * to foresee the changes that a quarter century would bring in manufacturing and merchandising technique."

⁴ 37 STAT. 416 (1912), 21 U. S. C. § 10 (1927); 37 STAT. 736 (1913), 21 U. S. C. § 3 (1927); 37 STAT. 732 (1913), 21 U. S. C. § 10 (1927); 41 STAT. 271 (1919), 21 U. S. C. § 10 (1927); 46 STAT. 1019 (1930), 21 U. S. C. A. § 10 (Supp. 1938).

⁵ See note 3, *supra*.

⁶ WEBER, THE FOOD, DRUG, AND INSECTICIDE ADMINISTRATION (1928) (in 1927 the Food & Drug Administration was formed to carry on work of the former Bureau of Chemistry which functioned until 1927, both in the Dept. of Agriculture).

⁷ 34 STAT. 771 (1906), 21 U. S. C. § 9 (1927); VITAL SPEECHES, Apr. 8, 1935, p. 441 (speech by the President, to Congress, in which he said, "It is time to make practical improvements. A measure is needed which will extend the controls formerly applicable only to labels to advertising also * * *"); SCIENTIFIC AMERICAN, Feb., 1938, p. 88 (the writer, Senator Copeland, stated, "When

ing given the term "drug" in the 1906 Act such a restricted definition, it was found that adulterated and misbranded cosmetics could be sold to an unsuspecting public without having to fear any reprisals from the Food and Drug Administration.⁸

Every branch of the food and drug industry was making great strides forward so that it became increasingly difficult to adapt the old law to these changed circumstances. During the twenty-seven years between the passage of the "Wiley" bill and the introduction of the "Copeland" measure in 1933,⁹ only one thing remained constant, and that was the ignorance of the public as to the food they were eating and the drugs and cosmetics they were using.¹⁰

I.

Cognizant of the urgent need for new legislation on food and drugs, and motivated mainly by the desire to include advertising control within the contemplated legislation,¹¹ a bill was drafted in the Department of Agriculture and submitted to Senator Copeland¹² who introduced the measure in the Senate on June 12, 1933.¹³ Two noteworthy changes attempted by this bill were the inclusion of provisions prohibiting the dissemination of any false advertising in interstate commerce for the purpose of inducing the purchase of food, drugs or cosmetics¹⁴ and the inclusion for the first time of cosmetics within its regulatory provisions.¹⁵ The scope of the bill was greatly enlarged, giving more control over all the trades concerned. Opposition to the measure was quick to arise.¹⁶ The various trades that

law enacted (*sic*) labels were important but now advertising is more important in selling goods"; CONG. DIG., March, 1934, p. 72.

⁸ 34 STAT. 769 (1906), 21 U. S. C. § 8 (1927); LITERARY DIGEST, Nov. 18, 1933, p. 6 ("the Act makes no mention of cosmetics which has developed into one of the nation's largest industries").

⁹ S. 1944, 73d Cong., 1st Sess. (1933).

¹⁰ CHASE AND SCHLINK, YOUR MONEY'S WORTH (1927); LAMB, AMERICAN CHAMBER OF HORRORS (1936); KALLET AND SCHLINK, 100,000,000 GUINEA PIGS (1933). These authors attempted, quite successfully, to shed some light upon the abuses being practiced. Some credit for the newly enacted law must be given to them for their efforts.

¹¹ See note 7, *supra*.

¹² CONG. DIG., March, 1934.

¹³ See note 9, *supra*.

¹⁴ *Id.* §§ 9, 17(a) (in 17(b), penal provisions for violations were provided and in 19(a) and 19(b) provisions for the issuance of injunctions were made).

¹⁵ *Id.* §§ 2(c), 5.

¹⁶ PRINTER'S INK, Dec. 14, 1933, p. 6 (the bill is clearly confiscatory); LITERARY DIGEST, Nov. 18, 1933, p. 6 (industry claims that the advertising powers mean dictatorial censorship); PRINTER'S INK, Dec. 14, 1933, p. 85 (at the hearings on the bill on Dec. 7-8 in the Senate Office Building at Washington, members of the various industries gave their opinion of the bill, varying from flat opposition to the measure, to bitter attacks on specific parts while favoring a small change).

would have been vitally affected by the proposed law immediately expressed their dissatisfaction with the bill. It was argued that new legislation was not necessary in that the old law could have been readily revised. It was suggested that the control of advertising be left to the Federal Trade Commission¹⁷ and that any other changes desired, as in the case of cosmetics, be made upon the old Act, keeping the rest of the enactment unaffected.¹⁸ The vital objection to this suggestion was that the F. T. C. was not then in a position to deal effectively with false and misleading advertising. While false and misleading advertising was held to be a form of unfair competition, thus giving the F. T. C. jurisdiction over the case,¹⁹ yet, in such suit, it was essential to prove that a competitor of the one guilty of such false advertising had been damaged by such act.²⁰ It can readily be seen that the F. T. C. was not in a position to protect the consumer but only competitors and the public incidentally. It soon became apparent that some sort of food and drug legislation was to be enacted and this led to a new attack in the form of other pure food and drug acts dictated by the trade interests and submitted to Congress in the hope that they would at least divert attention from the feared "Copeland" measure or its successors.²¹ One of these opposition bills retained intact the same penalty provided in the old law disregarding the fact that one of the reasons for enacting a new law was to increase the penalties so as to make the Act more effective.²² Another measure, introduced in the Seventy-fourth Congress in 1935 by James A. Mead,²³ sought to give the F. T. C. power to prevent false advertisements in the same manner as that whereby it was empowered to prevent unfair methods of competition in commerce. The bill failed to include criminal provision for the violations of the advertising sec-

¹⁷ FEDERAL TRADE COMMISSION ACT, 38 STAT. 717 (1914), 15 U. S. C. § 41 (1927).

¹⁸ BUSINESS WEEK, Nov. 28, 1936, p. 19 (the first line of industry's defense was the argument that the entire fabric of the 1906 Act should not be swept into the discard by the new legislation); (1932) 32 COL. L. REV. 720; COMMONWEALTH, July 8, 1938, p. 290.

¹⁹ Handler, *False and Misleading Advertising* (1929) 39 YALE L. J. 22, 42.

²⁰ F. T. C. v. Raladam Co., 283 U. S. 643, 51 Sup. Ct. 587 (1931) (the Supreme Court held it was necessary to show that competitors were being harmed and that methods complained of were unfair and that it was in the public's interest for the F. T. C. to interfere); (1931) 31 COL. L. REV. 526; (1929) 42 HARV. L. REV. 693.

²¹ A few of these measures follow: H. R. 6376, 73d Cong., 2d Sess. (1935) (introduced by Loring M. Black); H. R. 7964, 73d Cong., 2d Sess. (1934) (introduced by Virginia E. Jenckes); S. 2858, 73d Cong., 2d Sess. (1934) (introduced by Pat McCarran); H. R. 6906 and H. R. 3972, 74th Cong., 1st Sess. (1935) (introduced by James A. Mead); see also BUSINESS WEEK, Jan. 19, 1935 ("business attacks Copeland's measure by bills of its own").

²² H. R. 6376, 73d Cong., 2d Sess. (1934) (this measure was introduced by Black of N. Y.).

²³ H. R. 6906, 74th Cong., 1st Sess. (1935) (Section 5 of the bill contains advertising provisions. By Section 5(b) of the bill, the Sec. of Agriculture was required to furnish to the F. T. C. any scientific information as to foods, etc., as it should require).

tions. The object of this proposed enactment was clear. Its advertising sections would have given the trade interests more latitude than they were then enjoying under the possible restraints of the F. T. C. While Mead's bill was being introduced in the House of Representatives, Senator Wheeler of Virginia introduced a bill²⁴ seeking to amend the F. T. C. Act of 1914²⁵ so as to give the Commission jurisdiction over "unfair methods of competition in or affecting commerce and unfair or deceptive acts and practices in commerce." This amendment was aimed exclusively against the necessity of showing competition in order to give the F. T. C. power to interfere. The bill met with little success but on March 29, 1937, it was passed in the Senate²⁶ and sent to the House Committee on Interstate and Foreign Commerce. The bill made no provisions for the control of advertising insofar as foods and drugs were concerned. At this time, the Committee, with Lea as chairman, was also considering Copeland's measure which gave the control of advertising to the Food and Drug Administration.²⁷ Now, for the first time since the introduction of the Copeland measure, the issues as to the control of false advertising were brought clearly to the fore. The Senate bill was amended by the addition of various provisions controlling the dissemination of false advertisements as to food, drugs, devices and cosmetics and provided for criminal penalties for the violation of the provisions.²⁸

Consumer interests denounced Lea's attempt to weaken the proposed Food and Drug Act.²⁹ Congressman Mapes and others objected to the additions as made in the proposed "Lea" bill, contending that the F. T. C. was not properly equipped to carry out these provisions and that the Food and Drug Administration was the logical place in which to vest such control. The fact was stressed that the F. T. C. lacked the scientific training and equipment essential to deal successfully with the problem of false advertising as relating to food and drugs.³⁰ However, on January 12, 1938, the bill passed the House,³¹ the Senate requested a conference, which was had, and on February 14, 1938 the

²⁴ S. 944, 74th Cong., 1st Sess. (1935) (this was the original bill which sought to amend the F. T. C. Act).

²⁵ See note 17, *supra*.

²⁶ S. 1077, 75th Cong., 1st Sess. (1937); see 81 CONG. REC. 2931 (1937).

²⁷ S. 5, 75th Cong., 1st Sess. (1937), 81 CONG. REC. 2096 (1937).

²⁸ 81 CONG. REC. 9411 (1937); H. R. REP. No. 1613, 75th Cong., 1st Sess. (1937); see note 26, *supra*.

²⁹ BUSINESS WEEK, June 12, 1937 (Lea accused of bias towards the trade interests).

³⁰ 83 CONG. REC. 393 (1938) ("* * * the F. T. C. will have to set up a new division or refer the technical questions to the experts in the Food & Drug Dept." "Some of us on the committee, believe it would be unfortunate to put this power in the hands of the F. T. C. instead of in the F. and D. A."); 83 CONG. REC. 400 (1938); 83 CONG. REC. 3288 (1938) (by Copeland, "If the F. T. C. is given authority * * * it will be necessary for it to duplicate the staff now existing in the F. and D. A. * * * years will be required to assemble an efficiently functioning staff").

³¹ 83 CONG. REC. 424 (1938).

House accepted the conference report.³² On March 14, 1938, Cope-land made his last effort to oppose the adoption of the conference report. Again and again, he showed how the penalties provided for in the proposed F. T. C. bill were ineffective and difficult of application so that the old cease and desist method would be reverted to by the Commission, thus perpetuating the same ineffective control existing under the F. T. C. Act of 1914.³³ Having finished, the Senate proceeded to adopt the conference report.³⁴ On March 21, 1938, the President signed the "Wheeler-Lea Bill"³⁵ and the fight over the control of advertising was a closed chapter, the F. T. C. emerging victorious. The way was now clear for the passage of the Food and Drug Act, minus the advertising provisions. On June 25, 1938, the President affixed his signature to the Federal Food and Drug Act,³⁶ thus ending five long years of bitter struggle.

II.

While regrettable that the control of advertising should have been taken from the Food and Drug Administration, the new Act may be considered a step forward. With its increased enforcement provisions and its extended scope, the Food and Drug Administration may now cope more readily with any problem that may arise. In essence, the Act prohibits the introduction into interstate commerce of adulterated or misbranded foods, drugs, devices, or cosmetics.

The Act is divided into nine parts. Sub-chapter 2 is devoted to definitions of terms used in the Act while the sections following specify the prohibited acts and penalties. Then follow separate sections devoted to foods, drugs and devices, cosmetics, general administrative provisions, imports and exports and ending with a section of miscellaneous provisions. A comparatively involved law, it makes the following outstanding changes:

(a) All cosmetics, except toilet soap, are now within the purview of the Act.³⁷

(b) Devices, defined as instruments, apparatus, and contrivances * * *, intended for use in the diagnosis, cure * * *

³² 83 CONG. REC. 1142 (1938).

³³ 83 CONG. REC. 3287 *et seq.* (1938) ("the offenses of adulteration, misbranding and false advertising are inextricably interwoven and present a single unified administrative problem"); HENDERSON, *THE FEDERAL TRADE COMMISSION* (1924); H. R. REP. No. 1613, 75th Cong., 1st Sess. (1937) (Congressmen Mapes and Chapman condemn the measure).

³⁴ 83 CONG. REC. 3293 (1938).

³⁵ PUB. L. No. 447, 75th Cong., 3d Sess. (March 21, 1938), 52 STAT. 111, 15 U. S. C. A. c. 2 (Supp. 1938). This Law is discussed in *Legis.* (1939) 39 COL. L. REV. 259.

³⁶ PUB. L. No. 717, 75th Cong., 3d Sess. (June 25, 1938), 52 STAT. 1040, 21 U. S. C. A. c. 9 (Supp. 1938).

³⁷ *Id.* § 321(i).

of disease in man * * * or to effect the structure of any function of the body of man * * *, are now included within the Act.³⁸

(c) All penalties have been increased.³⁹

(d) Injunctions may be used to restrain certain violations of the Act.⁴⁰

(e) The Secretary of Agriculture is empowered to promulgate regulations establishing a reasonable definition and standard of identity and quality for food.⁴¹

(f) Labels on products are to contain certain specified information.⁴²

(g) In certain specified cases, requires a manufacturer to hold a permit issuable by the Secretary of Agriculture, as a condition precedent to his trading in interstate commerce and provides for the inspection of such manufacturing plants and all other manufacturing plants within the purview of the Act.⁴³

(h) Labeling on drugs must contain adequate directions for use, must warn that it may be habit-forming, if such be the case, and if the drug is liable to deterioration, must bear certain statements as may be required by the Secretary.⁴⁴

(i) Traffic in new drugs is prohibited unless certain specified prerequisites are performed, insuring the fact that such drugs will be safe to use.⁴⁵

For the purpose of brevity and clarity, the Act will be considered under four main classifications.

Adulteration, Under the Act.

Foods: Under the previous Act, a food was considered adulterated if it contained any *added* poisonous substance.⁴⁶ If the product contained any poisonous qualities, naturally present, it was not adul-

³⁸ *Id.* § 321 (h).

³⁹ *Id.* §§ 333.

⁴⁰ *Id.* §§ 332.

⁴¹ *Id.* § 341.

⁴² *Id.* §§ 343, 352, 362.

⁴³ *Id.* §§ 344, 374.

⁴⁴ *Id.* § 352 (f), (d), (h).

⁴⁵ *Id.* § 355.

⁴⁶ 34 STAT. 769 (1906), 21 U. S. C. § 8 (1927) (a food, deemed adulterated, "if it contain any *added poisonous* or other deleterious ingredient * * *") (Italics ours.) GREELEY, FOOD AND DRUG ACT OF 1906 (1907).

terated within the meaning of the Act. Provision is now made for cases where the poison may be naturally present in the food, holding such food is adulterated if the quantity of such substance naturally present renders it injurious to health.⁴⁷ Whenever the addition of any poisonous substance is essential and cannot be avoided, the Secretary of Agriculture is empowered to promulgate regulations limiting the quantity of such added poison.⁴⁸ The Secretary is also to list coal-tar colors suitable for use in foods, and the use of any coal-tar color not certified is prohibited.⁴⁹ Deception through additions, substitutions, or omissions of substances in foods so as to make it appear better or of greater value than it is, is banned.⁵⁰ Confectionery containing non-nutritive substances such as the toys found in "trick-candy," or alcohol in excess of a certain specified amount, is to be deemed adulterated.⁵¹

Drugs: If the drug purports to be or is represented as one for which a standard has been established, it must meet such standard or be deemed adulterated, unless the difference in strength, quality, or purity from such standard is plainly stated on the label. If the drug is not within the class of drugs for which a standard has been established, it is to be barred if it falls below the standard it purports to represent or possess.⁵² A drug containing a non-certified coal-tar color, or any filthy or decomposed substance, or any substance mixed with the drug so as to reduce its quality or strength, is to be deemed adulterated.⁵³

Cosmetics: A cosmetic containing any poisonous substance which may render it injurious to users under the conditions prescribed in the labeling or under such conditions of use as may be customary or usual, is to be deemed adulterated.⁵⁴ This provision

⁴⁷ 52 STAT. 1046, 21 U. S. C. A. § 342(a) (1) (Supp. 1938) (a food deemed adulterated "if it bears or contains *any poisonous* or * * *." Note the elimination of the word "added"). (Italics ours.)

⁴⁸ *Id.* § 346(a). The old Act failed to make any such provision so that small quantities of poison were being used in cases where it was not absolutely essential. In determining the amount of poison to be tolerated, the Secretary is to take into consideration the effect of the poison on the public and the necessity for its addition to the food.

⁴⁹ *Id.* §§ 342(c), 346(b).

⁵⁰ *Id.* § 342(b) (this provision was also in the old Act, 34 STAT. 769 (1906), 21 U. S. C. § 8 (1927)).

⁵¹ *Id.* § 342(d) (the section expressly states that "this paragraph shall not apply * * * to any chewing gum by reason of its containing harmless non-nutritive masticatory substances").

⁵² *Id.* § 351(b), (c). The 1906 enactment provided for a standard for drugs but failed to make a similar provision for foods. See 34 STAT. 769 (1906), 21 U. S. C. § 8 (1927).

⁵³ *Id.* § 351(a), (d) (similar provisions are made for foods in § 342(a) and (c), and for cosmetics in § 361(b) and (e)).

⁵⁴ *Id.* § 361(a); see note 8, *supra*.

is inapplicable to coal-tar dyes, the labels of which clearly set forth certain specified warnings.⁵⁵

Misbranding, Under the Act.

Foods: A food, the labeling of which is false or misleading in any particular, is to be deemed misbranded.⁵⁶ A loophole in the old enactment was the so-called "distinctive names" provision.⁵⁷ Under this section one could sell an otherwise adulterated product under a "distinctive name" and so stay beyond the prohibition of the Act. A manufacturer could advertise as a pure fruit jam, a compound containing only 30% fruit and could then sell it to the public under the "distinctive name" popularized by his advertising. Under the present Act, if the food purports to be one for which a standard has been set, it must meet such standard or be deemed misbranded.⁵⁸ If it does not purport to be any such food for which a standard has been established, then its label must bear the common name of the food⁵⁹ or, if it is fabricated from two or more ingredients, the common or usual name of each ingredient must be placed on the label.⁶⁰ Thus, in our example, assuming a standard has been established for jams requiring 80% fruit and 20% fill, the product, selling as a jam, must meet such standard. If a standard has not been established for jams, then our manufacturers must either claim that his product is a jam and so open the door to a misbranding suit, or must specify on his label that it is composed of 30% fruit and 70% fill, and so adequately warn any purchaser of its true nature. Today, if our product is an imitation of another food, the label must so specify⁶¹ and a food may not be offered for sale under the name of another food.⁶²

⁵⁵ *Ibid.*; LAMB, *op. cit. supra* note 10, at 15 *et seq.*, wherein the author cites various cases in which users of certain cosmetics suffered loss of money, health and life because of the deadly nature of such products being sold free from any governmental control.

⁵⁶ *Id.* § 343(a) (a similar provision is found in § 352(a) applicable to drugs and § 362(a) applicable to cosmetics). The 1906 Act had a similar provision, 34 STAT. 771 (1906), 21 U. S. C. § 10 (1927).

⁵⁷ 34 STAT. 771 (1906), 21 U. S. C. § 10 (1927). Mixtures or compounds which would have been required to bear the legend "compound, imitation, or blend" could be sold under a "distinctive name" (a special name given to a product, fanciful or otherwise) without such description. Manufacturers could popularize and sell an inferior product under a "distinctive name" and thus defeat the purpose of the Act in that the purchaser would not be in a position to know that he was buying an inferior product.

⁵⁸ 52 STAT. 1047, 21 U. S. C. A. § 343(g) (Supp. 1938) (a sub-standard food may be sold if its label bears a statement stating that it falls below the standard).

⁵⁹ *Id.* § 343(i).

⁶⁰ *Ibid.* If compliance with this section is impracticable, exemptions may be established by the Secretary.

⁶¹ *Id.* § 343(c). A drug is deemed to be misbranded under § 352(i) if it is an imitation of another drug. It would seem that the statement that it is an imitation will not save it from a misbranding charge.

⁶² *Id.* § 343(b). A similar provision is found in § 352(i) for drugs.

The Secretary of Agriculture is now empowered to establish a reasonable definition and standard of identity and quality for foods and/or a reasonable standard of fill for containers,⁶³ with certain exceptions noted.⁶⁴ If a food is represented to be a food for which such a standard has been set, it must conform to it or be deemed misbranded, and the label must contain the names of any optional ingredients, required by regulations to be established by the Secretary of Agriculture.⁶⁵ If the food falls below the standard of quality or fill established by the Act, it will not be deemed misbranded if the label clearly sets forth such fact.⁶⁶

In the past, labels were not required to be informative. A manufacturer was merely warned not to print misleading labels.⁶⁷ Today, he must supply certain information. Every label must bear the name and place of business of the manufacturer, packer, or distributor, the weight, measure or numerical count of the contents,⁶⁸ and a food purporting to be for a special dietary case must bear certain information as the Secretary of Agriculture may require.⁶⁹ If the product contains any artificial flavoring, coloring, or chemical preservatives, the label must so state,⁷⁰ and in all cases where any information is required, it must appear prominently on the label.⁷¹ To prevent the common practice of deceiving the public as to quantity, a section has been added which considers as misbranded, an article sold in a container which is so made, formed, or filled, as to be misleading.⁷²

Drugs: If the drug contains any designated habit-forming substance, its label must bear the name and quantity of such drug and the statement, "Warning—May be habit forming." Labels must bear adequate directions for use and adequate warnings against use by children where its use may be dangerous to health, and must warn against unsafe dosage. If the drug be subject to deterioration, it must be

⁶³ *Id.* § 341. This represents one of the major improvements of the new Act over the 1906 enactment, which did not provide for any standard for food. In 1930 the old Act was amended so as to set up a standard of quality, condition and/or fill for canned foods. See 46 STAT. 1019 (1930), 21 U. S. C. A. § 10 (Supp. 1938). This amendment is repealed with the rest of the 1906 Act.

⁶⁴ *Id.* § 341 (fresh or dried fruits or vegetables and butter are excepted).

⁶⁵ See note 58, *supra*.

⁶⁶ *Ibid.*

⁶⁷ Allen, *Pure Food Legislation*, POPULAR SCIENCE MONTHLY, July, 1906, p. 52 *et seq.* ("Food and Drug adulteration has grown because interests have been permitted to violate certain principles of identification in the sale of their products").

⁶⁸ 52 STAT. 1047, 21 U. S. C. A. § 343(e) (Supp. 1938). The Secretary may permit exemptions. A similar requirement is made for drugs in § 352(b) and for cosmetics in § 362(b).

⁶⁹ *Id.* § 343(j).

⁷⁰ *Id.* § 343(k) (exemptions to be permitted).

⁷¹ *Id.* § 343(f) (a similar provision is found in § 352(c) for drugs and § 362(c) for cosmetics).

⁷² *Id.* § 343(d) (a similar provision is found in § 352(i) for drugs and in § 362(d) for cosmetics).

packed in such a way and its label must bear such precautionary statements, as the Secretary of Agriculture shall require. If the drug is dangerous to health when used in the dosage or with the frequency or duration prescribed in the labeling, it is deemed misbranded. Making adequate provision for drugs dispensed on a written prescription signed by a licensed physician, dentist or veterinarian, the Act provides that if such drug bears the name of the dispenser and physician and place of business of the dispenser plus the date and serial number of such prescription, it need not comply with the weight and name sections of the statute, and if the prescription is marked non-refillable, it need not comply with the section requiring the warning "habit-forming".⁷³

Enforcement.

In order for an act to command the respect and compliance essential to the success of any enactment, it must provide enforcement provisions sufficiently strong to accomplish the desired results. The penalties for violations of the vastly important Food and Drug Act of 1906 were insignificant when compared with the gravity of the offense. Under that Act, a first offender was subject to a \$200 maximum fine and a second offender was subject to a \$300 maximum fine, or imprisonment for the maximum term of one year, or both.⁷⁴ For such a first offender, the possible \$200 fine was small compared with the huge profits to be made dealing in adulterated foods or drugs. Considering the trouble and expense, in order to prosecute such a suit, the small fine was absolutely ridiculous. The new Act successfully attempts to remedy such defect in the old enactment by providing for a maximum fine of \$1,000, or one year imprisonment, or both, for a first offender, and a maximum fine of \$10,000, or imprisonment for not more than three years, or both, for a second offender.⁷⁵ When the violation is with the *intent to defraud or mislead*, the maximum fine is raised to \$10,000 and the possible prison term increased to three years and the offender may be subject to both such fine or imprisonment.⁷⁶ Thus, a first offender who had the necessary *mens rea* is subject to these increased penalties. Facing such an imposing array of penalties, a manufacturer will not so readily violate any pertinent provision of the Act.

The enactment of 1906 was also weak in failing to provide for

⁷³ *Id.* §§ 352(d), (f), (h), (j), and 353(b). In a consideration of this part of the Act, it should be noted that if a drug is represented as an antiseptic, it shall be held as a representation that it is a germicide, and a failure to meet the standards of a germicide, subjects the manufacturer to penalties for violating this Act. See § 321(o).

⁷⁴ 34 STAT. 768 (1906), 21 U. S. C. § 2 (1927).

⁷⁵ 52 STAT. 1043, 21 U. S. C. A. § 333(a) (Supp. 1938).

⁷⁶ *Id.* § 333(b).

any injunction proceeding.⁷⁷ Preventing potential damage, especially when we are dealing with food, drugs or cosmetics, may be more valuable than merely punishing one guilty of an accomplished wrong. With this in view, the district courts of the United States and the United States courts of the Territories have been given jurisdiction, with minor exceptions, to restrain violation of this Act. A violation of the injunction subjects the party to a contempt proceeding.⁷⁸

While the criminal penalty and injunction provisions are valuable weapons, it may also become necessary, at times, to obtain possession of the potentially dangerous product and place it where it can do no harm. As weak as the 1906 Act was, it had a comparatively strong clause providing for the seizure of certain adulterated and misbranded food and drugs.⁷⁹ Under the seizure provisions of the new law, "any food, drug, device or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce," or which may not under the permit system be introduced into interstate commerce or which, if a new drug within meaning of the Act, has not been tested and approved as provided for, "shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found."⁸⁰ Such condemned product may be destroyed or sold for the benefit of the United States if such would not violate the provisions of this Act, or, upon posting of a sufficient bond, the owner of such article, upon condition that such article be brought into compliance with this Act, may obtain such and dispose of it to the public.⁸¹

An important feature of the present law is its attempt to control and check the source of all the potential trouble by providing for the inspection of factories manufacturing products for interstate trade. A refusal to allow such an inspection, at reasonable times, is a violation of this Act.⁸²

Whenever the Secretary finds, after investigation, that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms, be injurious to health, he may then provide for the issuance of temporary permits to such manufacturers, to which he may attach such conditions as he may deem necessary to protect the public health.⁸³ In such cases, the permit is

⁷⁷ The 1933 bill had provisions for injunctions for repetitious violations of the Act. S. 1944, 73d Cong., 1st Sess. (1933) § 19.

⁷⁸ 52 STAT. 1043, 21 U. S. C. A. § 332(a), (b) (Supp. 1938).

⁷⁹ 34 STAT. 771 (1906), 21 U. S. C. § 14 (1927).

⁸⁰ 52 STAT. 1045, 21 U. S. C. A. § 334(a) (Supp. 1938).

⁸¹ *Id.* § 334(d).

⁸² *Id.* § 374. As to the first bill introduced as S. 1944, see note 26, *supra*. Provision was made in § 22 of that bill for voluntary inspection of factories. Those who applied for inspection and met the approval of the Secretary could so state on the labels of their products. These provisions have given way to the one providing for mandatory inspections.

⁸³ *Id.* § 344(a).

a prerequisite to the manufacturer dealing in interstate commerce. The Secretary may suspend such permit if any conditions have been violated, and a refusal to allow an inspection of the plant is sufficient cause for such suspension of the permit.⁸⁴

To provide part of the necessary information in cases that come before the Administration, it is provided that the records of the interstate shipments of foods, drugs, devices or cosmetics, made by an interstate carrier or by others dealing with such articles, are to be kept open to officials of the Administration, under penalty of violating this Act.⁸⁵

A particularly significant section of the Act is the one which authorizes the dissemination, by the Secretary, of information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer.⁸⁶ That this power should have a salutary effect upon manufacturers, who realize the economic value of a good reputation, can not be disputed.

Miscellaneous.

The reported deaths of many persons who had reputedly used a new drug known as "Elixir Sulfanilamide",⁸⁷ brought to light the desirability of some sort of control over all new drugs. Accordingly, a new section⁸⁸ was added to the Act which requires a manufacturer, intending to put a new drug on the market, to file, with the Secretary, an application in which certain required information must be disclosed so as to enable the Secretary to decide whether or not such drug is safe for use. Upon finding it is unsafe for use, he may reject the application, thus preventing its introduction into interstate commerce. An appeal may be had by the applicant from any order of the Secretary refusing to permit the application from becoming final.

The authority to enforce the various provisions of the Act and to promulgate any regulations for the efficient enforcement of this chapter, with minor exceptions, is vested in the Secretary of Agricul-

⁸⁴ *Id.* § 344(b), (c).

⁸⁵ *Id.* § 373. It shall be unlawful for any such carrier or person to fail to permit such access. "Evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained."

⁸⁶ *Id.* § 375(b) (there was no such provision in the old Act).

⁸⁷ *N. Y. Times*, Nov. 26, 1937, p. 42, col. 1 (Secretary of Agriculture Wallace, in his report to Congress made pursuant to Resolutions previously adopted in both houses, cited in this news article, set the number of deaths attributable to this drug at 93); (Winter 1939) *LAW AND CONTEMPORARY PROBLEMS*, p. 20 (Prof. Cavers of Duke University School of Law and Advisor to the Dept. of Agriculture with regard to food and drug legislation, set the figure somewhere between 73 and 90); *CHRISTIAN CENT.*, June 29, 1938, p. 814 ("We owe to those who died after using a lethal 'extract' of Sulphanilamide, the provisions about the introduction of new drugs").

⁸⁸ 52 *STAT.* 1052, 21 *U. S. C. A.* § 355 (Supp. 1938).

ture.⁸⁹ Under the Act, the regulations are subject to judicial review by the circuit court of appeals at the instance of any person who would be adversely affected by such regulation in cases where an actual controversy had arisen.⁹⁰ In this court's review, any findings of the Secretary as to facts, if supported by substantial evidence, is conclusive.⁹¹ Previously, a party adversely affected by any regulation would have had to depend upon the court's relief against such regulation when it was sought to be enforced against him, in which event, as part of the case, the regulation would be subject to the court's review. Today, the judgment of the court, affirming or setting aside any order of the Secretary, is final, subject only to review by the Supreme Court of the United States.⁹²

The new Act, with the exception of a few minor provisions which became effective on the date of its enactment, is to go into effect on June 25, 1939, on which date the old 1906 Act is expressly repealed.⁹³

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THE FEDERAL FIREARMS ACT.—The transition of crime from a chiefly local problem to one of interstate and even international proportion has been taking place since the World War. This gradual change, necessarily resulting in a partial disability of local law enforcement, engendered the clamour for federal crime control. Accordingly, in 1933, the Senate directed the Committee on Commerce to investigate the subjects of kidnapping, "racketeering", and other forms of crime, and to recommend the necessary remedial legislation.¹ To the layman it might seem that the only authority required for the passage of such laws would be the police power but actually, the United States Government is, in this respect, under the very burdensome restraint of the Tenth Amendment.² The national government

⁸⁹ *Id.* § 371(a) (under subd. (e) the Secretary, upon his own initiative or upon the application of any interested industry, is to hold public hearings upon any proposal to issue, amend or repeal any regulation, with certain exceptions noted).

⁹⁰ *Id.* § 371(f) (1).

⁹¹ *Id.* § 371(f) (3).

⁹² *Id.* § 371(f) (4).

⁹³ *Id.* § 292(a). The sections of the Act authorizing the Secretary to promulgate regulations for the new Act, are to go into effect immediately. This will enable the Administration to set the groundwork so that the Act may be put into effect on June 25, 1939, with little disruption.

¹ SEN. RES. No. 74 (May 8, 1933, as amended June 12, 1933).

² U. S. CONST. Amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people").