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FOOD AND DRUG LEGISLATION IN THE UNITED STATES: INTRODUCTORY COMMENTS ON ITS HISTORY

by

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THE history of food and drug legislation in this country is a story of reaction to crisis, tragedy, or scandal. Prior to this century it was felt that consumer protection was primarily a matter of local concern, and almost all laws on food and drugs were at the state and local levels. These earlier local laws mainly dealt with particular food products such as milk and meat.¹

Local laws dealing with drug protection were a later development.² Dr. Harvey Young's book, *The Toadstool Millionaires*,³ illustrates the lack of public protection regarding proprietary medicines in the nineteenth century. Dr. Young wrote: "Prior to 1906, the only inhibition upon American patent medicine proprietors, except for an occasional critical article, was self-restraint."⁴

The early state food laws primarily dealt with economic protection; for example, weights and measures.⁵ Later, adulteration began to be covered, then misbranding and labeling.⁶ Finally, and in weaker form, protection was given in this century against false or misleading advertising.⁷ At the beginning of this century, comprehensive food and drug laws began to appear at the federal and state levels. Today, federal statutes provide a wide range of food and drug protection⁸ and every state has, in at least some form, a general food and drug law.⁹

The Food and Drugs Act of 1906,¹⁰ often called the "Wiley Pure Food and Drug Law," was the first comprehensive food and drug law on the federal level.¹¹ Efforts to secure a federal food act had begun in Congress

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¹ See, e.g., Mass. Acts & Resolves 1866, ch. 253 (Meat).

² See Dunn, *Food, Drug and Cosmetic Laws in the United States*, 3 *FOOD DRUG COSM. L.Q.* 308, 309 (1948); Conn. Gen. Stat. ch. 188, § 3129 (1888).

³ H. YOUNG, *THE TOADSTOOL MILLIONAIRES* (1961).

⁴ *Id.* at 247.

⁵ See Dunn, *supra* note 2.

⁶ See, e.g., Criminal Code of Ala. 433 (1896); N.C. Pub. Laws ch. 86, at 216, ch. 369, at 508 (1899).

⁷ See, e.g., N.M. STAT. ANN. § 54-6-3 (1953).

⁸ Part of the wide range of protection is the enforcement available at the federal level. Despite the troubles it has had in recent years, the Federal Food and Drug Administration is one of the top agencies in Washington. The FDA badly needs more financial assistance, additional personnel, and statutory improvements, but it also merits strong public support for its dedication and service to the public, in the face of giant obstacles, over the past 63 years.

⁹ The states now have a variety of general laws, modeled more or less on either the 1906 or 1938 federal statutes. Many of these laws are in need of updating, especially as to drugs. But progress is being made on the legislative and personnel levels. Personnel is a key problem with many states, and also at the local level. Salaries and support are often so weak that good people either do not stay with the service or else lose, through frustration, their zeal for consumer protection.

¹⁰ Food and Drugs Act of 1906, 34 Stat. 768.

¹¹ Miller, *Original Federal Food and Drugs Act of June 30, 1906—Introduction to the Act*,

in 1848, and included a total of 103 bills. The general pattern of the 1906 food and drug law had emerged piecemeal by 1888.¹² The final passage thus required over half a century of time.

The passage of the 1906 legislation not only took much time, but also required the impetus of a small group of journalists whose scorching articles were published in *Colliers Weekly* and the *Ladies' Home Journal*. In addition, the best-selling novel by Upton Sinclair, *The Jungle*,¹³ and the work of Dr. Harvey W. Wiley, an employee of the Department of Agriculture, were instrumental in the enactment of this legislation. The great public clamor that followed these works caught the attention of President Theodore Roosevelt, during whose administration the first two general food statutes, the Food and Drugs Act of 1906 and the Meat Inspection Act of 1906,¹⁴ became law.

The Food and Drugs Act of 1906 was reasonably effective for a time, but it proved insufficient in the long run. For example, in a case in 1911 involving a medicine represented as a cure for cancer, the Supreme Court ruled that the Act did not cover false claims for cures.¹⁵ Because the 1906 Act was not totally effective, efforts began in the early 1930's to secure a stronger act. In 1933, Senator Royal S. Copeland introduced a bill that completely rewrote the 1906 Act. This bill and its successors remained in Congress for five years, and then a tragedy was reported in the national press. Between 75 and 90 people died as a result of taking a drug, "Elixir Sulfanilamide," that used a deadly solvent, diethylene glycol.¹⁶ This tragedy caused such an uproar that Congress became concerned and enacted our present law, the Food, Drug, and Cosmetic Act of 1938.¹⁷

In addition to Senator Copeland, who fought hard for the law but had little to do with its drafting, several people played important roles in securing the new Act. Among these were Rexford G. Tugwell, then Assistant Secretary of Agriculture; Walter G. Campbell of the Food and Drug Administration; President Franklin D. Roosevelt; a group of independent "experts"—Professor David F. Cavers, who was then on the Duke University law faculty, Professor Milton Handler of Columbia University, Mr. Frederick P. Lee, and others.¹⁸ After the passage of the 1938 Act, one of these men, Professor Cavers, wrote: "Perhaps the most striking characteristic of the history of the Food, Drug, and Cosmetic Act is the fact that this measure, which was of consequence to the health and pocket-book of every citizen . . . never became the object of widespread public attention, much less of informed public interest [T]he public at

1 FOOD DRUG COSM. L.Q. 290 (1946); Dunn, *Original Federal Food and Drugs Act of June 30, 1906—Its Legislative History*, 1 FOOD DRUG COSM. L.Q. 297 (1946).

¹² Dunn, *supra* note 11, at 298.

¹³ U. SINCLAIR, *THE JUNGLE* (1905).

¹⁴ Act of June 30, 1906, ch. 3913, 34 Stat. 674, as amended, 21 U.S.C. §§ 71-99 (1964).

¹⁵ *United States v. Johnson*, 221 U.S. 488 (1911).

¹⁶ The use of this solvent violated the 1906 Act only in the technical sense that the word "elixir" was inappropriate—the solvent was not an elixir, but a solution, and with accurate labeling the product was probably legal.

¹⁷ 21 U.S.C. §§ 301-91 (1964).

¹⁸ Two books also served to draw attention to the problem: A. KALLET & F. SCHLINK, *100,000,000 GUINEA PIGS* (1932); F. SCHLINK & S. CHASE, *YOUR MONEY'S WORTH* (1927).

large . . . knew little or nothing of what was transpiring in Congress."¹⁹

The Food, Drug, and Cosmetic Act of 1938 (often referred to as the Copeland Act) has been amended in important respects on several occasions. The Durham-Humphrey Amendment of 1951²⁰ established the present system in regard to sales of prescription drugs. The crisis that brought this bill to enactment was the sleeping pill problem. More stringent requirements for certain drugs were added by the Drug Abuse Control Amendment of 1965.²¹ Perhaps the most comprehensive addition to the 1938 Act came, however, with the Drug Amendments of 1962.²² This statute deals with controls in manufacturing, records, standardization of drug names, factory inspection, and advertising.

The Color Additive Amendments of 1960²³ provided stronger controls over colors used in foods, drugs, and cosmetics. The Pesticidal Chemicals Act of 1954²⁴ was a monumental piece of legislation, and only recently have we come to realize the full importance of such legislation to the health and well being of the American people. The Food Additives Amendments of 1958,²⁵ which regulate the use of the multitude of additives available for use in food, could not have been conceived in 1906. Yet today, with all the discoveries in science, it is inconceivable that we would not have such a law; its passage is a classic example of law reacting to developments in science. Man's progress in science has brought great benefits to mankind, but also great dangers, and one of the high tasks of the law is to protect the public from these dangers.

There have been other changes in the Federal Food, Drug, and Cosmetic Act, but the foregoing are the major ones. There are, of course, many other federal food and/or drug laws, including the narcotics laws, and some of these have interesting histories.²⁶ A compilation of all of these federal laws, with major regulations, would run around 1,400 pages.²⁷

The Federal Food, Drug, and Cosmetic Act of today is a strong law—for example, it is a criminal law and one of the few that imposes what amounts to absolute liability. Its various provisions, including those of factory inspection, multiple seizure, control of additives and of new drugs, and regulation of drug advertising, provide substantial consumer protection. And it is heartening to observe that this law, under which the president of a drug firm can be fined or even sent to jail for an act he knew nothing of, has the active support of the industry which it regulates.

But what about the future? It is clear that our present laws will not meet the needs of this day. We cannot wait for disaster this time. We must

¹⁹ Cavers, *The Food, Drug, and Cosmetic Act of 1938*, 6 LAW & CONTEMP. PROB. 2, 3 (1939).

²⁰ 21 U.S.C. §§ 333, 353 (1964).

²¹ 18 U.S.C. § 1114 (Supp. I, 1965); 21 U.S.C. §§ 321, 331, 333-34, 352 note, 360-60a, 327 (Supp. I, 1965).

²² 21 U.S.C. §§ 321, 331-32, 348, 351-53, 355, 357-60, 372, 374, 376, 381 (1964).

²³ 21 U.S.C. §§ 321, 331, 333, 342-43, 346, 351-52, 361-62, 371, 376 (1964).

²⁴ 21 U.S.C. §§ 321, 342, 346a-b (1964).

²⁵ 5 U.S.C. § 2205 note (1964); 21 U.S.C. §§ 321, 331, 342, 342 note, 346, 348, 451 note (1964); 42 U.S.C. § 210 (1964).

²⁶ See T. CHRISTOPHER, SPECIAL FEDERAL FOOD AND DRUG LAWS (1954).

²⁷ *Id.*

have more adequate, up-to-date statutes and more complete high quality enforcement to provide the needed consumer protection in the food and drug areas. We are entering an era of acute sensitivity to consumer protection, and we doubtless shall see substantial improvements in the next decade. We will require protection from narcotics, air and stream pollution, traffic congestion, and loan sharks. But food and medicine are what all Americans use, and the laws and enforcement regarding these are in the forefront in importance for consumer protection.