Food and Drug Enforcers in the 1920s: Restraining and Educating Business

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"The hardest task for both industry and . . . [the Food and Drug Administration]," a law professor asserted a decade ago, "is *simultaneously* to be adversarial and cooperative" [16]. During the prosperity decade of the 1920s, with business at a lofty level in the structure and esteem of American society, cooperation between regulated and regulators markedly expanded, although continuing enforcement of the Food and Drugs Act of 1906 sparked considerable controversy.

In the first phase of enforcing the law, from 1907 to 1912, under the redoubtable Harvey Washington Wiley, controversy had predominated. Securing the law had been a long and complex process [5, 49]. Some branches of business had supported the campaign with the hope of using such a law as a weapon against competitors [44, 49]. Others desiring a law--a coalition of state chemists, women's club members, muckraking journalists, physicians, and agrarian state legislators--were motivated by consumerist objectives, to protect the public health and purse from abuses in the production of foods and drugs [49]. Wiley, chief chemist of the Department of Agriculture, played the role of broker among the diverse array of pro-law factions. An astute compromiser prior to victory, Wiley's basic convictions emerged as his Bureau of Chemistry, given authority to recommend actions under the law, began its task. He has been called a "hide-bound crusader" who insisted on "chemical fundamentalism" [1, 15]. His own "Poison Squad" experiments had persuaded him that chemical preservatives in foods, indeed, almost all commercial tamperings with nature, were hazardous to health and should be taboo. He intended to enforce the law with utmost rigor [5, 49]. When an early member of Wiley's staff protested that a proposed action was not authorized by the law, the chief chemist replied: "But we must read it into the law!" [29] Such impetuousness disturbed Wiley's superiors, who came also to distrust his science. Both Secretary of Agriculture James Wilson, who viewed his own chief mission as the protection of agricultural markets [23], and President Theodore Roosevelt, who feared political repercussions from questionable policies, created machinery to curb Wiley's independent decision-making [5].

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These high-level battles dominated the headlines as well as Wiley's time and concern. He paid scant attention to workaday administration [5]. The chief "was somewhat distant to us," recalled one of the early inspectors; "he was an image more than a man" [30]. The inspectors, hired to collect samples of foods and drugs entering interstate commerce, were given minimal training, and no structured plan of action was initially devised [18, 1907 report, p. 5; 1921 report, p. 457]. "When we first started," remembered Walter G. Campbell, whom Wiley appointed chief inspector, "it was a sort of gum shoe method, because we could bring down game no matter where we aimed" [11]. Experience and emergencies revealed where the greatest problems lay [48]. Foods mentioned most frequently in the Bureau's early annual reports were milk, eggs, vinegar, oysters, tomato products, stock feed, olive and salad oils, and canned vegetables. As to drugs, outrageous patent medicines received the main emphasis.

Even in these early days, Bureau of Chemistry officials began to educate industry as they policed it. The chemical reagents they depended on for their analyses, Bureau scientists discovered, showed deficiencies, and these were pointed out to their manufacturers who were then cooperative in making "marked improvements" [18, 1904 report, p. 99; 1910 report, p. 158; 1911 report, p. 223]. Hearings with producers of synthetic drugs revealed that shortcomings seldom resulted from "willful intent" but rather from "lax or faulty control" systems; manufacturers took the lessons to heart and sought to enhance their procedures [18, 1912 report, pp. 273-74]. The law did not give the Bureau direct authority over santitation in processing plants, but inspectors like W. R. M. Wharton realized how poor sanitation could lead to illegal products, and he made that lesson clear to manufacturers [19, 32 (May 1948), pp. 107-108]. To educate industry in better methods of cold-storage and transportation of eggs, poultry, and fish, Wiley set up in Philadelphia a Food Research Laboratory directed by Mary E. Pennington [38].

Bacteriology as applied to food processing and pharmacology as related to drug production were still in their early days when the 1906 law began to be enforced. Until the 1930s, Louis Lasagna has said, the American drug industry was "a pygmy"; even at the end of the '30s, Macy's department store in New York City had an annual sales volume larger than that of any American ethical drug manufacturer [26]. Pharmaceutical research was minimal, and industry scientists were scorned by academicians [35]. Food processing was more firmly established at the start of the century, accounting for a fifth of the nation's total manufacturing, but the real heyday of canning was still two decades away [37]. In 1905, per capita production of canned fruits and vegetables was 9.7 cans; in 1925 it reached 24.9 cans [13].

Except for the Proprietary Association, established by the major makers of so-called patent medicines in 1881, the major trade associations in the food and drug field followed in the wake of the law's enactment: the American Pharmaceutical Manufacturers' Association in 1906, the American Drug Manufacturers Association in 1907, and the National Canners Association, formed by fusion of two regional groups, in 1907 [7, 14]. At the turn of the century, the can opener was deemed an evil symbol, but by the end of the '20s public prejudice against canned goods had been so conquered that the can

opener was called "Boss of the Kitchen" [12; 3 (February 1929, pp. 59-60)]. The American diet during these decades became restructured [28]. Two historians, indeed, have linked canned food to a broader revolution in American life: for Daniel Boorstin "foods . . . preserved out of season" constituted one of the jolts to the traditional sense of comfortable reality that had characterized the earlier rural nation, and for Jackson Lears canned goods were a symbol for the "prepackaged artificiality" of life that brought trauma to middle class Americans at the dawn of the new century [8, 27].

In 1912, Harvey Wiley, weary from his bureaucratic battles and desiring greater income to support his wife and baby son, resigned from government to take a position writing on food and drug matters for *Good Housekeeping* [5; 3 (November 15, 1912), p. 9]. President William Howard Taft replaced him with Carl Alsberg, a pharmacologist from the Department of Agriculture's Bureau of Plant Industry [20]. Alsberg had a less combative personality than Wiley's. While believing in firm enforcement of the law, the new chief was more willing to accommodate industry if he thought it could be done without jeopardizing the public interest. "Education must go hand in hand with federal and state regulation," Alsberg told the American Public Health Association, "in the future development of food control. As in our public schools, the old system of using the rod freely has long since given way to better methods of teaching, so will the use of drastic legal action gradually become less necessary as an enlightened food industry utilizes better methods for manufacturing, handling and preparing foods. But just as the best results are obtained in schools where some form of discipline supplements the best methods of teaching, so the highest results in the production of pure food in those cases where educational methods alone are not effective will be obtained when there is available sufficient legal power and adequate machinery to administer corrective discipline" [1].

Alsberg took this stance, for example, with respect to artificial colors for butter and oleomargarine [22], and the new chief gave more authority to Walter Campbell who replaced the Bureau's somewhat haphazard method of sample collection with a project system [19 (November 1921), pp. 1-2]. This plan set priorities of effort for each year based on carefully determined needs and specified what work should be done by each station and district. In 1927, the Bureau of Chemistry's basic research and its regulatory role were split, the latter given to a new Food, Drug, and Insecticide Administration with Campbell as director [18, 1927 report, pp. 645-48; 1928 report, p. 679].

In his first annual report, Campbell explained the views he had held throughout his service [18, 1928 report, pp. 679-80]. He regarded the laws he had to enforce as "corrective rather than punitive." The Agriculture Department, he stated, "has adopted an advisory-before-the-act attitude by offering constructive suggestions which should enable manufacturers to keep their products in compliance with the law. It has not hesitated, however, to initiate proceedings under the law in those instances where the protection of the consumer or negligence or willfulness on the part of the shipper indicated such action to be proper." "Cooperation rather than conflict with industry," Campbell asserted, ". . . is the key-note of law-enforcement work today" [10]. He cited as examples the sardine canning industry in Maine and tomato

canning across the country. The latter had begun in Wiley's day when the Bureau's B. J. Howard had developed his mold count method of estimating the amount of decomposed tomato in catsup and tomato sauce, and manufacturers were educated in the use of the techniques so as to improve their packing processes [5]. Federal and state officials were still in the '20s holding classes for cannery workers [18, 1928 report, pp. 679-80].

Working together to solve problems brought an *entente cordiale* between regulators and major segments of the regulated industries. Industry's "suspicion and positive enmity in the early days," observed the agency's house organ, *Food and Drug Review*, had changed to an "attitude of appreciation, cordial cooperation and enthusiastic assistance. The food and drug inspector today is not looked upon in most quarters as a detective or policeman, but as a technician who will assist a manufacturer by timely suggestions to produce a legal and therefore a more profitable product" [19 (February 1927), pp. 4-5]. From this atmosphere of harmony the consumer benefited. Although some "dishonest producers" of food products, using ever more devious methods of deceit, persisted, and although general factory sanitation needed sprucing up, "there is no other article of commerce," proclaimed a food and drug official in 1922, "more free from adulteration and misbranding than food" [19 (November 1922), p. 1].

Two examples, one from the food field, the other about drugs, supply substance to support the regulators' generalizations. One evening in January 1920, an Italian housewife in the Bronx became suddenly ill with disturbing symptoms, and the next morning she died, the doctor ascribing death to "uremia, chronic nephritis" [9, 41, 46]. Three days later, the bereaved family prepared supper in the kitchen, the husband, two sons, a daughter, and two of the husband's brothers. They shared the meal of macaroni and a salad made of anchovies, pickled peppers, ripe olives, olive oil, and vinegar. Within three days all the males had died; only the girl of nine survived. Hospital doctors suspected food poisoning and remembered recent news reports of similar tragedies in Ohio and Michigan. Epidemiological surveys and laboratory tests placed the blame on botulism. The jar of ripe olives had been tainted with the deadly toxin.

Bureau of Chemistry investigation established that the midwestern incidents had been caused by olives packed on the same day in the same batch at the same California plant [9]. The processor refused to accept the blame: he charged that an enemy agent during the late war must have poisoned the rubber rings used for sealing the jars. The New York olives, the Bureau discovered, had been packed by one of the most reputable of California food processors, a member of the state legislature. Bureau officials warned the public, removed ripe olives from the marketplace, and sought explanations for the disaster.

Already the Bureau had done some research on botulism, and now this was intensified in collaboration with industry. In 1913 the National Canners Association had created a research committee, hiring to manage it Wiley's second in command, Willard D. Bigelow, long head of the Bureau's food division [33]. During the 1920s, to look ahead, a number of Bureau scientists and inspectors were lured to higher paying jobs in trade associations and

industry, this aspect of the revolving door fostering agency-industry cooperation. Also, Secretary of Commerce Herbert Hoover urged trade association-government bureau collaboration [4, 40]. In 1916 the canners had begun to finance a broad study of food poisoning by a Harvard professor, supervised by a committee of the National Research Council [3 (April 1917), pp. 183-84]. When the ripe olive crisis came, Bigelow hurried to California. Advised by Bureau of Chemistry officials, members of the California Olive Association, the California State Board of Health, and professors from several universities, he created a three-member Botulism Commission of distinguished scientists to save the olive industry and revive flagging consumer confidence in all processed foods [9, 32].

From the targeted research efforts much new knowledge resulted: that *Clostridium botulinum* is telluric, its natural habitat the surface layers of virgin soil all over the world; that a minute trace of the bacillus or its spores getting onto fruit or vegetables or meat as a result of contact with susceptible soil, and then being processed in such a way as to provide an anaerobic core, then heated inadequately, then later eaten without boiling, can quickly kill [31]. A Bureau of Chemistry bacteriologist found the bacillus and its toxin in an old olive dump at the rear of the California plant that had processed the fatal New York olives, and a member of the Botulism Commission found the bacillus in the grove in which those olives were grown [9, 37]. The Commission set processing standards sufficient to kill the spores. In 1921, Carl Alsberg urged the Public Health Service and the National Canners Association to join the Bureau of Chemistry in a major national campaign to educate all those who came in contact with food, whether in store or at home, "as to their responsibilities for the destruction of spoiled food" [37]. The Bureau raised its threshold of alertness as to the risk of botulism in the foods it inspected.

A major field of cooperation between regulators and industry in the '20s concerned medicinal drugs intended for prescription to sick patients, especially pills and tablets [47]. The law set two official standards for such pharmaceutical preparations, the *United States Pharmacopoeia* and the *National Formulary*, and for drugs not included in these volumes required that they meet the standards stated on their labels. In 1912 the Bureau of Chemistry had studied such tablets and pills and found a wide variation between the quantity of active ingredient claimed, be it nitroglycerin, morphine, or nux vomica, and the amount that analysis revealed to be present [18, 1912 report, p. 279]. Court actions followed, and leading manufacturers did not escape.

In 1923 a marked expansion of Bureau drug control work occurred, directed by George Hoover, a physician and chemist who had come to the Bureau before the 1906 law was passed [19 (January 1923), p. 4]. Hoover confessed that hitherto drug policies had been random and the Bureau had "not kept up with the growing tendency of the times" [19 (June 1923), pp. A-B]. American drug manufacturing had taken a spurt since war had broken German drug dominance. Now, with new vigor, Bureau scientists checked anesthetics for their purity, performed bioassays of crude drugs and of galenicals made with them, and of glandular products. Pharmaceutical tablets

were reexamined with special emphasis on those intended for use in hypodermic injections. Variations ranged disturbingly far from official or professed standards. Nitroglycerin tablets, for example, deviated from a deficiency of 93 per cent to an excess of 600 per cent [47]. At either extreme, patients might suffer severely. Regulatory actions were launched against the worst abuses. Bureau officials realized they did not know what tolerances the state of manufacturing technology would warrant. In 1924 Hoover spoke at the annual meetings of both the American Drug Manufacturers Association and the American Pharmaceutical Manufacturers' Association. He asked them to gather information on this problem and to take steps to remedy the situation. Each organization selected a contact committee to make studies jointly and to confer with the Bureau [14, 19 (August 1924), pp. 37-39].

The Combined Contact Committee developed monographs on individual tablets, proposing methods of analysis and suggesting feasible tolerances [19 (January 1928), p. 26]. Sometimes the Bureau urged modifications. The final results were published in a notebook, "Pharmaceutical Standards Including Tolerances and Methods of Assay" [25]. The process was extended to a study of ampuls. Both manufacturers and regulators expressed satisfaction at the way collaboration worked to improve the pharmaceutical marketplace and enhance patient care [18, 1926 report, p. 638; 1927 report, p. 667; 1928 report, p. 682]. A trade association resolution termed the process "epoch-making" [19 (July 1929), p. 229]. The contact committee system continued beyond the decade's end [14, 3 (January 1928), p. 26]. Using the new standards agreed upon, the new Food, Drug, and Insecticide Administration wielded its regulatory power to force laggards to conform [18, 1928 report, p. 696]. Dr. Hoover got help from established manufacturers in reporting violations they had discovered and in testifying about the higher trade standards when cases came to court.

Another important result of cooperation was the abandonment by pharmaceutical manufacturers of misleading drug names [47, 19 (March 1927), p. 5]. Many therapeutic products had entered the prescription market called "liver stimulant," "heart remedy," and "indigestion tablets." Under agency urging, drug companies modified their labels and catalogs to designate these medicines by composition rather than by body organ or disease condition. These revisions, the FDIA asserted, had "been of great assistance in connection with the consideration of proprietary preparations of similar compositions, by removing the excuse that similar unwarranted titles . . . [were] being used by pharmaceutical manufacturers."

Relations between regulators and the makers of proprietary medicines during the 1920s underwent a slight warming trend but remained frosty. No cooperative projects developed between bureaucrats and proprietary contact committees. Prior to the 1906 law's enactment, the patent medicine business had been subjected to savage muckraking, and proprietors had been among the most vigorous opponents of a law [49]. With defeat, however, came also opportunity, as the major firms in the Proprietary Association reassessed the situation [45, 50]. The trade association had some 250 members, whereas the nation contained three thousand nostrum-making firms [42 (January 1915), pp. 5-6; 42 (April 1920), pp. 13-14]. They must reform sufficiently to meet the

law's demands, the leading proprietors decided, while letting regulators restrain their smaller competitors. So the Proprietary Association adopted a code [42 (May 1916), pp. 11-12, 17-19; (November 1916), pp. 20-23, 37-39; (August 1917), pp. 7-10; (January 1918), pp. 14-21; (April 1919), pp. 30-31]. No member should market narcotic medicines for children or vend abortifacients or male weakness remedies. Dangerous ingredients should be omitted or kept to a strict minimum. Label claims "must be neither obviously unreasonable or demonstrably false." Even advertising--not controlled by the law--should avoid making curative claims for incurable diseases. In the '20s, indeed, the names of dread diseases disappeared from advertising in the popular magazines, replaced by the hazards of acid indigestion, body odor, halitosis, intestinal fatigue, sneaker smell, and underarm offence [36].

The Proprietary Association's plan succeeded. Few cases were brought against its members by the Bureau of Chemistry [42 (January 1918), pp. 8-10]. Smaller competitors were curbed considerably, even though a Supreme Court decision hampered enforcement. The 1906 law, the Court ruled, was not meant to ban false and misleading therapeutic claims on nostrum labeling [43]. The Sherley Act of 1912, in seeking to plug the loophole, placed upon the Bureau the difficult task of proving curative claims both false and fraudulent [50]. Surveys at the start of the '30s showed that half the money spent by the American public for medications went for secret self-dosage preparations, and 80 per cent of this volume was produced by Proprietary Association members [34, 39]. The United States was the largest exporter of packaged medicines in the world, the makers aided in their marketing by the Department of Commerce [6, 42 (April 1920), pp. 13-14]. Proprietary Association officials basked in the success of their industry and its enhanced prestige. They granted the law's contribution to a greater public confidence in their products [42 (January 1919), pp. 8-10].

Bureaucrats welcomed proprietors to their offices to talk over problems, and proprietors invited bureaucrats to their conventions to address the state of the industry [42 (January 1928). p. 11]. In the mid-'20s, Bureau of Chemistry officials commented on a "changed attitude" among manufacturers, a greater willingness to make changes in labeling in response to criticism [19 (June 1925), pp. 8-9]. Industry "suspicion" had diminished, and in turn regulators sought to maintain "a policy of helpful friendliness" [42 (May 1927), pp. 46, 48]. Proprietary Association leaders, finding officials too "fussy" early in the decade and "not perfect" later on, nonetheless believed that their "bureau contacts" provided one of the trade association's greatest assets to its members [42 (September 1920), pp. 13-14, 23; (May 1925), p. 12]. Bureau officials became more willing to discuss formulas and to evaluate labels before proprietors went into the marketplace [19 (July 1929), pp. 232-33]. The agency also began to make advance announcements of campaigns against specific labeling abuses, giving prudent proprietors time to make changes. Such evidences of "growing cooperation," an official told the Proprietary Association in 1928, greatly gratified him [19 (June 1928), p. 29].

Despite diplomatic words and mutually admired deeds, relations between regulatory officials and proprietors remained tense. Several actions undertaken by regulators to curb abuses upset proprietors especially. They

considered "monstrous" the use of multiple seizures by which a manufacturer's entire operation could be shut down before his guilt was proved in court [42 (November 1926), p. 13; (May 1927), p. 22]. Ripper bills to ban the practice appeared in Congress but did not pass [19 (1931), pp. 342-33]. Proprietors also protested the Bureau's use of claims made in collateral advertising to interpret label claims too vague or ambiguous to take to court [42 (September 1922), pp. 20, 22, 24]. And, as the decade ended and an influenza epidemic raged, proprietors became angry at the Food, Drug, and Insecticide Administration for launching an attack on a wide variety of products, some made by major companies, promoted as effective against the flu [18, 1929 report, pp. 696-99].

As the Great Depression began, ethical restraints in advertising tumbled. Regulators seeking to stem the tide increased the ire of proprietors [50]. "The drug industry is long suffering," an editorialist complained. "It apparently is afflicted with some sort of inferiority complex. It has been law-ridden for ages, and it seemingly knows not how to get rid of its 'old Man of the Sea.' . . . When will the drug trade . . . shake off its fear of over-zealous officials . . . and fight as it could fight for its rights" [17].

A fight lay ahead, indeed, but not one in which the proprietary industry sought to regain freedom lost, rather a fight to prevent the Food and Drug Administration from securing greater regulatory authority over food and drugs, including drugs intended for self-dosage. In the 1920s, as Pendleton Herring explained in a 1935 article, the balance of social forces had shifted away from the weight of consumer interest peaking in 1906 so needful in securing the law [21]. Business ascendancy in the '20s had given it the advantage. Enforcers could find plenty to do "without insisting upon a rigid interpretation of the act." Facing "potentially hostile forces and poorly armed with legal power," officials placed great emphasis on conciliation. The depression, however, and the New Deal were to bring a new change in the balance of social forces. In this new climate, after a five-year tussle, a new law would emerge, a law containing more rigorous restraints on business, the Food, Drug, and Cosmetic Act of 1938 [24].

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