

# How Chemists Pushed for Consumer Protection: The Food and Drugs Act of 1906

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## Introduction

The Food and Drugs Act of 1906 brought about a radical shift in the way Americans regarded some of the most fundamental commodities of life itself, like the foods we eat and the drugs we take to restore our health. Today we take the quality and veracity of these products for granted and justifiably complain if they have been compromised. Our expectations have been elevated over the past century by revisions in law and regulation; by shifts—sometimes of a tectonic nature—in the science and technology that apply to our food, drugs, and other consumer products; and by the individuals, organizations, commercial institutions, and media that drive, monitor, commend, and criticize the regulatory systems in place. But to appreciate how America first embraced the regulation of basic consumer products on a national scale, one needs to start with some of the most important people behind the effort—chemists.

## The USDA Bureau of Chemistry

Chemistry helped us understand the foods we ate and the drugs we took even before 1906. In August 1862 Commissioner of Agriculture Isaac Newton appointed Charles M. Wetherill to undertake the duties of Department of Agriculture chemist, just three months after the creation of the department itself. Those duties began with inquiries into grape varieties for sugar content and other qualities. The commercial rationale behind this investigation was made clear in Wetherill's first report in January 1863: "From small beginnings the culture of the wine grape has become a source of great national wealth, with abundant promise for the future." But another important role of chemistry was in discerning fakery in the drug supply and in foods. Even before the creation of the Department of Agriculture, an 1846 publication, Lewis Caleb Beck's *Adulterations of Various Substances Used in Medicine and the Arts*, provided documentation needed to support the 1848 federal law controlling imported drugs.

Problems in the food supply, more of honesty than production, were at the heart of efforts to initiate a comprehensive federal law to bring the food and drug supply under control. Thomas Antisell, Wetherill's successor, had investigated and called attention to adulteration of food and fertilizers by 1869. The third chemist of the Department of Agriculture, Peter Collier, remarked in his report of 1879: "Where life and health are at stake no specious arguments should prevent the speedy punishment of those unscrupulous men who are willing, for the sake of gain, to endanger the health of unsuspecting purchasers." Indeed, Collier recommended passage of a national food and drug law, and the first such bill was introduced during his tenure. A hundred bills would be introduced at regular intervals over the next quarter-century.

No figure played a greater role in securing a national law than Collier's successor, the fourth chemist of the department, Harvey Washington Wiley. Wiley arrived in 1883, after serving nine

years as professor of chemistry at Purdue, during which time he was also the ex officio state chemist of Indiana. He built his reputation in analytical chemistry in general and sugar chemistry in particular. His investigations and scientific interests after arriving in Washington can be seen in such works as the voluminous Bulletin 13 of the Department of Agriculture's Division (and eventually, Bureau) of Chemistry, *Foods and Food Adulterants*, published in 10 parts from 1887 to 1902, and his textbook *Foods and Their Adulteration*, which went through three editions from 1907 to 1917.



### **The Poison Squad**

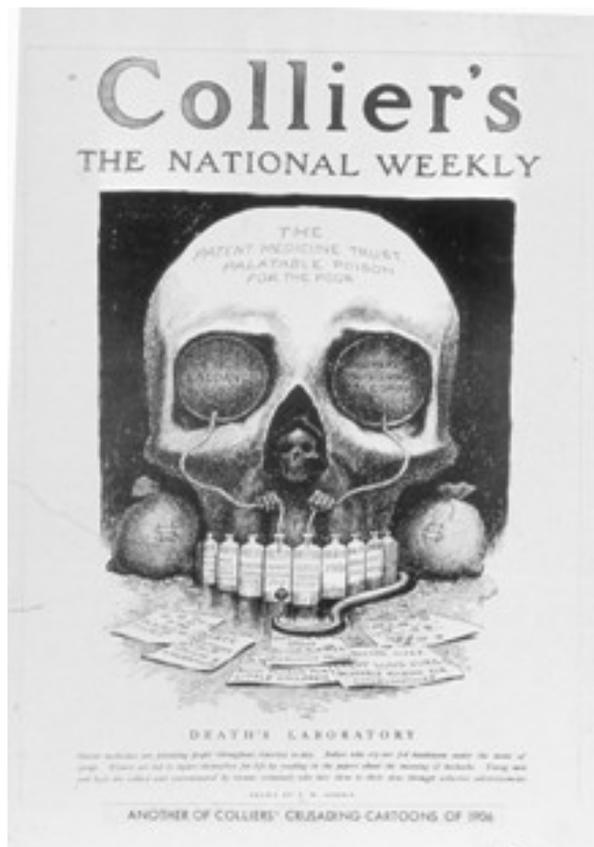
In December 1902 Wiley (standing, third from left) began assembling a group of volunteers whose carefully controlled diet included measured amounts of various food preservatives, such as borax, benzoates, and formaldehyde, and the effects were noted. A reporter dubbed the intrepid diners the “Poison Squad.” The results of the study, which continued for several years, were published as *Influence of Food Preservatives and Artificial Colors On Digestion and Health, Bureau of Chemistry Bulletin 84.*]

Much as Beck's book had done for the 1848 law, Wiley's research helped form the technical framework to justify passing a comprehensive national food and drug law. Of course, the introduction of so many bills over so long a period testifies to both the earnestness and the intransigence of both sides, those who would reform the marketplace and those who resisted. Mere technical documentation that a big problem existed would not be enough to win the day. Technical documentation had not won Congress's support for the 1848 drug law—that required fingering bad drug imports as the cause of heavy noncombat losses by U.S. troops in the U.S.-Mexican war. Something more was obviously needed to regulate the domestic market as well.

The context for change in the food and drug marketplace emerged with the growth of progressivism in America from the late 1880s on. This movement originated in the upper Midwest but soon appeared on the national stage in the presidential election of 1900. Social, economic, and political reforms in the Progressive Era were characterized by a growing concern for the disadvantaged (expressed in the rise of settlement houses) and for fair competition (trust busting), among other issues. President Theodore Roosevelt had a moderately sympathetic ear for reform and reformers, even if they derived from muckraking journalism.

## Muckrakers

Two works in this genre were immensely important in helping the public focus on the hazards and horrors of food and drugs in America. *Collier's* magazine ran a 10-part feature from October 1905 to February 1906 by Samuel Hopkins Adams. The series, entitled “The Great American Fraud,” excoriated the patent-medicine industry for strong arming, deceiving, addicting, poisoning, and killing the public with their outrageous cure alls for everything from babies’ teething to old age. An even greater public outrage followed publication in 1906 of Upton Sinclair’s *The Jungle*, a well researched novel about immigrant life in Chicago and work in the meat-packing industry. A White House–authorized investigation confirmed the grisly conditions related in Sinclair’s work.

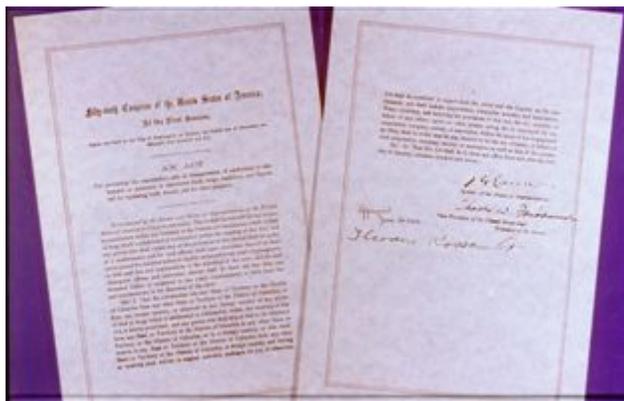


*This cartoon heralded Samuel Hopkins Adams' exposé of the patent medicine industry.*

However, passage of a food and drug law owed just as much to the tenacity of Harvey Wiley. He sustained the pressure for change; brought together interests like the General Federation of Women's Clubs, state food and drug officials, and national health professional organizations, such as the American Pharmaceutical Association and the American Medical Association, to champion these bills; and helped create a public attuned to the dangers of the marketplace.

The Food and Drugs Act was signed by Roosevelt on 30 June 1906, the same day he signed the Meat Inspection Act. Some observers looking back at 1906 have dismissed the Food and Drugs

Act as a mere labeling law containing more inspiration than substance, but it brought the Bureau of Chemistry, predecessor of the Food and Drug Administration (FDA), into the plants where these commodities were produced—checking for signs of deception or just ineptitude, sampling products on the open market, and taking legal action against violative products—thousands upon thousands of times in the first years the new law was in effect. The very act of passing the law convinced many companies to end the sort of practices that necessitated its creation.



*The 1906 Food and Drugs Act also became known as the Wiley Act for the chief chemist's long-standing efforts to secure a law.*

### **Labeling Requirements under the Wiley Act**

The law prohibited adulterated and misbranded food and drugs for human or animal use in interstate commerce, subject to a fine of up to \$200 (and up to \$300 for subsequent offenses) or a jail term of up to one year, or both. Drugs had to be sold according to the standard of purity, strength, and quality set by the *United States Pharmacopoeia* or the *National Formulary*, unless the label stated how the product differed from that standard. The presence and amount of 11 dangerous ingredients, including heroin, morphine, cocaine, and alcohol, had to be labeled on all drugs and foods. A drug label, moreover, could not be false or misleading in any particular. The law forbade adding substances to food so as to conceal inferiority, to substitute for something else, or to make the food injurious to health, and it was forbidden to market a food that was filthy or decomposed. If the ingredients of a food were labeled, that statement had to be accurate.

Wiley himself, while appreciating the challenges of agricultural production and food manufacturing, had a rather limited tolerance for the addition to food of chemical preservatives and other substances, such as sodium benzoate, caffeine, sulfur dioxide, saccharin, and nitrogen peroxide (in bleached flour). He clashed with Secretary of Agriculture James Wilson and President Roosevelt over several actions and policies, and in 1907 Wilson, much to Wiley's chagrin, created a Board of Food and Drug Inspection to help administer the law, consisting of Frederick L. Dunlap, a University of Michigan chemist; the solicitor of the Department of Agriculture; and Wiley as chair. Soon thereafter Roosevelt, following a disagreement with the chief chemist over the value of saccharin, assembled a Referee Board of Consulting Scientific Experts to review Wiley's decisions. The board was made up of an illustrious group of chemists: Ira Remsen of Johns Hopkins, the chair; Russell Chittenden of Yale; John H. Long of Northwestern; Christian Herter of Columbia; and Alonzo E. Taylor of California. Though some expected Wiley to resign over this latest effort to dilute his authority, he remained with the

bureau until 1912.

The bureau organized laboratories and inspection posts in Washington and around the country to enforce the new law. Divisions devoted to drugs and to food soon emerged in Washington, with several laboratories in each. The Division of Drugs, for example, had laboratories devoted to synthetic products, essential oils, pharmacology, and drug inspection. Twenty-eight inspectors reported for field service in June 1907, a number that grew to 39 the following year, and they were assigned to about 20 branch laboratories scattered around the country, in addition to other strategic locations. The initial group of inspectors came from many different backgrounds. Some were chemists, though law, pharmacy, medicine, and other callings were represented, too. A member of the Coast Guard, rewarded for performing heroic service with the choice of any position in the federal government he wanted, elected to become a food and drug inspector.



*The Food Inspection Laboratory, like its counterpart in the Division of Drugs, carried out analyses of seized food products.*

The penalties meted out for offenses under the Food and Drugs Act, often not much more than \$50, were inconsequential to many firms, as related in one chief chemist's report: "Not infrequently firms are encountered which repeatedly violate the law, paying the fines imposed . . . , but apparently regarding these penalties as in the nature of a license fee for doing an illegitimate business."

But the bureau nevertheless enforced the law vigorously, moving especially against manufacturers or industries that had ongoing problems conforming to the law. For example, adulteration of olive oil with cheaper vegetable oil was a common problem. So was the practice of inadequately reconditioning certain imported goods, such as cacao beans, lentils, and selected crude drugs, to meet legal requirements; the bureau eventually required destruction or export of such products as a routine measure. Products prone to bacterial contamination, such as crabmeat and butter, also received frequent citations. The government published over 31,000 different notices of actions taken against violative products under the 1906 Act, and it won the vast majority of contested cases.



*Inspector John Earnshaw is shown inspecting an oyster processing plant around 1910.*

### **The Sherley Amendment**

One prominent case the bureau did not win concerned enforcement of the prohibition of false or misleading drug labels. In 1911 the Supreme Court ruled that the Food and Drugs Act did not apply to false therapeutic claims, in part because of the court's belief that medical knowledge itself was more often than not less than certain and thus not subject to government regulation. President William Howard Taft protested that this ruling threw in doubt over 150 cases against patent medicines, "involving some of the rankest frauds by which the American people were ever deceived." Congress attempted to remedy this the following year by passing the Sherley Amendment, which made it illegal to sell drugs that the manufacturer knew to be worthless. But establishing fraudulence in court could be difficult, and consequently many egregious nostrums that claimed to cure diabetes, cancer, and other serious illnesses remained on the market.

The Food and Drugs Act was a substantial leap for consumer protection across the country, making entire industries accountable for their actions for the first time. But this pinnacle of Progressive Era legislation had weaknesses beyond the difficulty of securing decisions against outrageous nostrums. Cosmetics and medical devices could be subject to proceedings by the U.S. Post Office if they used the mails under false or fraudulent pretenses, or by the Federal Trade Commission if advertising were employed in a way that put other firms at an unfair disadvantage. But neither type of commodity was covered in the systematic way that food and drugs were under the 1906 law. While established compendia could be invoked when pressing actions against drugs for violating official standards of identity, no such enforceable standards existed for foods. Two firms might have very different ideas of what peanut butter or jelly or even bread was supposed to be.

Ingredient listing of products was, with the exception of those 11 stipulated in the law, voluntary. And though the inspectors frequently visited manufacturing establishments to ensure compliance with the law, this was a right assumed by the bureau; the 1906 act did not address factory inspections explicitly. Finally, there was nothing, other than its own ingenuity, to keep a firm from introducing a product on the market. There was no legal mechanism to block the marketing

of a drug, for example; no requirement that it be safe, much less that it actually work (the Sherley Amendment notwithstanding).

### **The American Chamber of Horrors**

Just as the milieu of progressivism had prepared the way for passage of the long sought food and drug law, so the coming of Franklin Roosevelt to the White House along with the New Deal introduced an ear receptive to proposed remedies for the shortcomings of the 1906 act. To help get its point across to a variety of audiences, including Congress, the White House, the press, radio listeners, and even visitors to the 1933 World's Fair in Chicago, the FDA assembled a collection of sometimes gruesome examples of products that were on the market legally. Among them were Banbar, a remedy for diabetes consisting of an extract of horsetail weed, introduced by a shirt salesman as an injection-free cure for this disease after the discovery of insulin. Although the FDA established in court that diabetics were dying on this nostrum even though insulin was available, the government lost its case because it could not meet the standard of establishing fraud.



*Various versions of the Chamber of Horrors exhibit were shown to a wide array of audiences.*

Another star in this collection of consumer minefields that a press observer aptly christened “the Chamber of Horrors” was Lash Lure, an aniline eyelash and eyebrow dye that a number of women suffered injuries to their eyes, including one confirmed case of permanent blindness in the early 1930s; a picture of one victim, her disfigurement exposed in a poster, was one of the more shocking entries in the chamber. So were X-rays showing children who had ingested trinkets enclosed in food, the prize outlined in the esophagus for all to see. Yet another example of outlandish and dangerous medical technology was the Diana Ideal Womb Supporter, which could puncture the uterus if inserted the wrong way. No federal statute stood between a dangerous drug and its sale directly to the public, as evidenced by the popularity of the diet preparation dinitrophenol in the 1930s. Dinitrophenol so accelerated metabolism, creating grave side effects, including cataracts, that most clinicians skilled in the evaluation of such products had abandoned it. Yet about two dozen brands, heavily promoted in newspapers, magazines, and radio, remained on the market for any lay user interested in losing weight.

Another dangerous drug, which came on the market in October 1937, was not part of the Chamber of Horrors exhibit but was more influential than any exhibited product in demonstrating that the 1906 law needed to be improved. The S. E. Massengill Company of Tennessee introduced a liquid form of the new wonder drug sulfanilamide as an alternative to the large tablets of the original formulation. The chemical chosen to effect this route of administration, diethylene glycol, was never examined for safety, neither in the laboratory nor even in the medical literature. Recourse to either would have revealed that Elixir Sulfanilamide, the name Massengill chose for its preparation, was deadly.

Over 100 people died, including many children, and the FDA staff around the country launched a massive search for any Elixir Sulfanilamide that might remain in warehouses, pharmacies, physician offices, and medicine cabinets of those to whom the drug had been prescribed. The government charged Massengill with the only violation it had committed under the law, selling a misbranded drug in interstate commerce: technically, elixirs had to contain alcohol as a drug vehicle, and Elixir Sulfanilamide had none.

### **The 1938 Food, Drug & Cosmetics Act**

Congress had introduced bills to replace the Food and Drugs Act since 1933, but none had earned enough support by the time of Elixir Sulfanilamide. That therapeutic disaster and the public outrage it engendered pressured Congress to step up efforts to pass a comprehensive law, and on 30 June 1938 President Franklin Roosevelt signed the Food, Drug, and Cosmetic Act. Besides the provision that the FDA approve new drugs before they were marketed, the law brought medical devices and cosmetics under regulation; it required that standards of identity and packaging for foods be implemented; it mandated factory inspections; it instituted tolerances for certain poisonous substances; and it created the framework within which the FDA could require good manufacturing processes. Further, drugs had to carry adequate directions for safe use—though advertising of drugs would fall under the Federal Trade Commission—and fraud no longer had to be established to prove misbranding. The 1938 act has since been amended many times, and the regulation of several products, including medicines of biological origin and radiation-emitting devices, has been added to the FDA's responsibilities. But the Food, Drug, and Cosmetic Act remains today the essential law overseen by the FDA.

Almost 100 years ago, America decided it had had enough of a marketplace where the only rule was caveat emptor. People deserved better than to be treated thoughtlessly by unscrupulous, deceitful, and avaricious peddlers of goods to which no one should be exposed. It did not happen overnight: efforts were constantly thwarted by those who stood to benefit by a marketplace of this nature and by those who were philosophically opposed to the sort of government intervention that these bills required. But the steadfast devotion to change by many, especially Harvey Wiley, won in the end. The Bureau of Chemistry, predecessor of the FDA, enforced its provisions tirelessly and innovatively, drawing upon experts from its own ranks and sometimes from outside to inform its policies and buttress its arguments. Sometimes problems were attacked collaboratively with industry. The law was far from perfect, but it nevertheless represents a revolutionary landmark in the history of consumer protection in America. Its centennial is cause for every citizen to celebrate and to remember.

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