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Executive Summary

There is strong evidence that the spectacular growth in the size of the federal government is a result of its expansion following one crisis or another, either real or imagined. After the crisis it gains new powers that become the norm for the next stage of growth. The Food and Drug Administration provides a particularly apt example of this increase in powers as a response to a series of crises, each of which has increased the regulatory authority of the agency. The Food and Drug Administration, which did not even exist before the twentieth century, now possesses massive regulatory powers over products that account for no less than twenty-five cents of every dollar spent by the American consumer, totaling well over $1 trillion annually. Historical investigation shows that the agency has been able to take advantage of several perceived crises, the combined effect of which was to increase its authority to determine what Americans ingest to the point where today, at least in the case of drugs, it is the agency—and not the consumer—that determines when and what is available. A regulatory agency originally established to ensure that consumers would be provided with full and accurate information on the drugs available to them has become one that determines which drugs are available, when they might be administered, and who may ingest them. This essay traces this growth in terms of the legislative reaction to three crises, the diphtheria antitoxin crisis of 1901, the sulfanilamide crisis of 1937, and the thalidomide crisis of 1960.

Medical Disasters and the Growth of the FDA[1]

Ronald Hamowy

Between 1901 and 2009 federal government expenditures increased from $535 million to $2,563 billion, a nineteen-fold increase in constant dollars. During that period, outlays rose from 2.87 percent to 28.07 percent of the gross domestic product. Economic historians have posited a number of theories to explain this truly spectacular growth in the government's size, among them that the increasing complexities of modern society have made greater central direction essential.[2] While this explanation strikes many as intuitively correct, it defies what we know about the nature of complex institutions, namely that the more complicated the social arrangement, the less likely that it will be amenable to conscious direction. Modern societies are so complex, comprising many millions of independent social interactions each seeking independent ends, that a central scheme of control is far beyond the capacities of even the most knowledgeable mind or group of minds.

By far the most convincing explanation for the growth of government in the last century is that put forward by Robert Higgs, who argues that bursts of government expansion accompany ostensible national crises, which the public are led to believe require the institution of emergency measures that involve a wider scope of government authority. Once having acquired these more extensive powers, however, bureaucracies are loath to surrender any of their newly acquired budgets and regulatory authority and remain at their post-crisis level.[3] While it is true, as Higgs notes, that these emergencies usually take the form of wars and business depressions, an examination of the U.S. government's history shows that lesser crises operate in the same way with respect to particular federal agencies. This paper will examine the creation and expanding power of the Food and Drug Administration[4] as a response to three specific "crises": the diphtheria antitoxin crisis of 1901, the elixir sulfanilamide crisis of 1937, and the thalidomide crisis of 1960.

The Food and Drug Administration is a particularly apt example of a regulatory agency possessed of far-reaching powers. It is charged by the federal government with responsibility to oversee the purity of most of the nation's food and cosmetics and the purity and effectiveness of the whole range of therapeutic agents sold in the United States. Its 2009 budget was nearly $2.4 billion, but the agency's potential effect on the country's economy and welfare is far greater than might be assumed from this figure. Products accounting for no less than twenty-five cents of every dollar spent by American consumers—including all foodstuffs (excepting meat and poultry) and all human and animal drugs and therapeutic devices—are under the FDA's jurisdiction, totaling well over $1 trillion annually. The FDA's mandate is immense inasmuch as it is empowered to determine which drugs are available to American consumers; it thus ultimately has the power of life and death over hundreds of thousands of people suffering from fatal illnesses. We must all, at one point or another, rely on the FDA's permission to obtain and ingest what might prove a lifesaving medication prescribed by our physician, without which we might well die. The agency was originally created and was able to accumulate such enormous powers for the most part through a series of perceived crises, each of which has led to increases in its authority.

The Diphtheria Antitoxin Crisis of 1901

Pressure for passage of a pure food and drugs law grew in intensity in the last decades of the nineteenth century. The ongoing campaign was spearheaded by the leaders of the temperance movement, particularly the Women's Christian Temperance Union (founded in 1874) and by sanitarians, who argued that a large proportion of our food was impure and a danger to health and that our medications, consisting in the main of alcohol and narcotics, were poisoning us. These social reformers were joined by a number of alarmists and muckraking journalists who were convinced that the American food supply was being poisoned by unscrupulous manufacturers and distributors. In addition, a large number of businessmen and farmers actively supported enactment of pure food and drug legislation. Despite their claims that what motivated these reformers was an unselfish concern for the nation's health, the efforts of many of those seeking regulation were driven by the desire to limit or eliminate competition. This also held true of those who opposed passage of regulatory controls. Between 1879 and 1906, when the Pure Food and Drug Act was finally enacted, no less than 190 bills were brought before Congress, all of which (except perhaps for a half dozen, which proved of little consequence) were defeated through the efforts of the manufacturers and sellers of drugs and foodstuffs.

While a stalemated Congress was unable to pass a national pure food bill, it did enact legislation that regulated the sale of serums and toxins that came into interstate or foreign commerce. Congress passed the law, which empowered the U.S. Public Health Service to license all producers of biological products applicable to human disease destined for interstate commerce, in June 1902. Like so much regulatory legislation, Congress was moved to act by a deplorable episode that took place immediately before it took up the issue. Unfortunately, the tragedy would not have been avoided had the new law already existed.

Diphtheria, a toxin produced by a particularly virulent bacterium, was, in the first decades of the century, the leading cause of death among teenagers, with an incidence in the U.S. of about two hundred thousand cases per year and a death toll of about fifteen thousand. Protection was afforded by inoculation with diphtheria antitoxin, which was prepared by injecting horses with increasingly larger doses of the diphtheria bacterium and collecting the resulting serum.[5] On October 26, 1901, a five-year-old girl died in St. Louis's city hospital from tetanus. The child had been admitted several days earlier and administered two shots of diphtheria antitoxin, which came from the city health department. Over the next few weeks several other children who had been inoculated with diphtheria antitoxin also died of tetanus, pointing to the fact that the antitoxin that was administered to them was contaminated. Despite attempts to cleanse the city's supply of diphtheria antitoxin, four more children were reported to have died of the same cause on November 1. At this point the St. Louis Board of Health launched an inquiry into the city's method of preparing and testing serum, which showed it to be completely inadequate. The inquiry uncovered the fact that one of the horses used in preparing the antitoxin had contracted tetanus; however, no attempt to stop collecting blood from this horse was made. Almost no serum was in fact tested, laboratory bottles were improperly identified and mislabeled, and, even more startling, those in charge of serum production were fully aware of having distributed diphtheria antitoxin that was contaminated. While the investigation was proceeding, another eight children died as a result of being administered contaminated serum.

At about the same time, a similar incident occurred in Camden, New Jersey, where in the fall of 1901 almost a hundred cases of post-vaccination tetanus occurred following the administration of smallpox vaccine. These cases of tetanus resulted in the death of nine children. An investigatory com-

mittee from the Philadelphia College of Physicians suggested that the source of the tetanus infections was the administration of impure smallpox vaccine manufactured by H. K. Mulford, a commercial biologicals producer.[6] However, further examination of the evidence suggested that the vaccine was not at fault.[7] Despite these findings, the public attributed the Camden deaths to causes similar to those that had been responsible for the St. Louis fatalities.

The effect of these revelations was that people throughout the country became distrustful of all biologic agents, and many refused to allow physicians to administer these products to their children. Desperate to restore the reputation of the nation's medical practitioners and especially the various state and city boards of health (among them those that had passed on the safety of the various tainted antitoxins), in the spring of 1902 the Medical Society of the District of Columbia proposed legislation along the lines eventually passed by Congress. The bill empowered a newly created board to issue regulations for licensing establishments throughout the nation that were engaged in preparing and selling biologic substances destined for interstate or foreign commerce. The new Public Health Service was authorized to inspect all establishments that had been licensed, and all substances covered by the act were required to carry an expiry date. President Theodore Roosevelt signed the Biologics Control Act into law on July 1, 1902.[8]

It is of some significance that the provisions of the 1902 law would have done nothing to prevent the tragedies that occurred in St. Louis and Camden. In both cases, competent governmental authorities inspected the biologic agents and labeled them as pure, and they were administered under the direction of licensed professionals. In addition, local and state boards of health had the power to seize impure vaccines and antitoxins and to destroy them. Finally, tort law was sufficiently strict with respect to drugs and foodstuffs to deal with instances of this sort, placing the manufacturer or vendor under an affirmative obligation to guarantee that the products sold were, under normal circumstances, not harmful to the user's life and health. It is also worth noting that the smallpox cases that occurred in the Camden area, despite the perceptions of the press and public, were, as far as could be determined, not brought about by impurities in the smallpox vaccine administered.

Despite these facts and undeterred by passage of the Biologics Control Act of 1902, the press and those organizations agitating for a national pure food and drugs act seized upon these two events as proof that government supervision of the food and drug supply was essential if the nation were to be protected. One man particularly was untiring in his lobbying efforts. When the Pure Food and Drug Act was finally enacted in 1906, its passage through Congress could with some justification be credited to Harvey Washington Wiley who, between 1883 and 1912, held the post of chief chemist at the Bureau of Chemistry at the Department of Agriculture, the federal government division charged with certifying the purity of the nation's food supply and the forerunner of the Food and Drug Administration. Wiley was a graduate of Hanover College in Indiana and the Indiana Medical College, where he took his degree in 1871.[9] In 1874 he was appointed professor of chemistry at the newly opened Purdue University and while associated with the University devoted a good deal of time in Germany studying the principles of food analysis. In 1882, during Chester Arthur's administration, George Loring, who was then the U.S. Commissioner of Agriculture, offered Wiley the position of chief chemist.[10] Wiley's major interest when first arriving in Washington appears to have centered on the domestic sugar industry.[11] He was a strong supporter of placing bounties on the production of sugar and high tariffs on imported sugar. However, he soon added to this concern for America's inefficient sugar producers' fears that America's food supply contained adulterants that were poisoning the public.[12]

Toward this end he began a series of experiments on certain foods to test their purity, the first of which was commercial maple syrup, which he found was commonly "adulterated" by the admixture of glu-

cose and sugar syrup! Over the course of the next few years, the Bureau of Chemistry issued a series of bulletins dedicated to specific foods, each of which contained a detailed study on how the food was adulterated and with what other substances. These technical studies were rewritten in 1890 in a report aimed at a lay audience and published under the title *A Popular Treatise on the Extent and Character of Food Adulteration,* which concluded that almost every article of food was in some way or another impure and that this fact deprived the farmer of his livelihood, damaged our export market, and compromised the morals of the American public.[13] At no point was it claimed that these investigations uncovered any adulteration that seriously compromised the health of consumers. Despite this, the report noted that the American food supply contained "to an alarming extent, poisonous adulterations that have, in many cases, not only impaired the health of the consumer, but frequently caused death" and urged that pressure for both state and federal pure food and drug laws should continue with even greater vigor.[14]

Between Wiley's aggressive efforts, the lobbying of temperance groups, the pressures placed on Congress by certain drug and food manufacturers opposed to the competition of cheaper products, and the fears occasioned by the diphtheria antitoxin crisis of 1901, Congress passed the Pure Food and Drug Act in 1906. On June 29, both the House and the Senate passed the bill in its final form, and on the following day President Roosevelt, in a ceremony at the Capitol, signed a number of measures, including a food and drug act, into law. The act prohibited the manufacture and sale of adulterated and misbranded foods, drugs, and liquors and regulated traffic in such products. It forbade introducing them into interstate or foreign commerce or from buying them for resale. The secretaries of the Treasury, of Agriculture, and of Commerce and Labor were empowered to devise the rules and regulations for enforcing the act while the authority to police the industry was given to Wiley's Bureau of Chemistry. The bureau was empowered to examine specimens of foods and drugs and to determine which had been misbranded or adulterated. Proprietary medicines were required to "bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin," and derivatives of these substances present.[15] Violators were subject to fines not exceeding two hundred dollars for the first offense; subsequent offenses could result in a three hundred-dollar fine or imprisonment for up to one year or both. The law also provided that the government could seize and destroy adulterated goods. All the groups that had worked with such effort for its passage warmly received the act, which the press quickly dubbed "the Wiley law." The American Pharmaceutical Association and the American Medical Association were especially delighted with the labeling provisions as they related to over-the-counter medications.

Thus did the events in St. Louis five years earlier galvanize Congress into finally enacting national legislation to regulate the purity of the nation's food and drug supply, which was already regulated by the various states and which, in the main, met existing standards of purity and cleanliness.

The Sulfanilamide Crisis of 1937

Prior to 1938 all non-narcotic drugs could legally be sold without prescription, that is, as over-the-counter remedies not requiring the mediation of a physician for their sale. As a consequence, drug advertising was directed primarily at the consumer. However, in 1937 events once again intervened that led to Congress enacting far stricter regulations.

In the mid-1930s, German and French bacteriologists had discovered the truly dramatic effects of sulfanilamide, which was an extremely powerful antibacterial and one of the first anti-infective agents to be prepared synthetically. The drug soon became enormously popular and by 1937 was routinely used to combat streptococcal infections, the majority of which occurred in children. It was marketed in powder and tablet form, but these proved difficult to administer to the very young given its unpleasant taste. As a result in 1937 the S. E. Massengill Company of Bristol, Tennessee, intro-

duced the medication in liquid form in response to growing demand, especially from the firm's Southern customers.[16] The company, which had been founded in 1897, was directed by Dr. Samuel Evans Massengill and had an excellent reputation for producing only the highest quality pharmaceuticals. The firm's chief chemist was Harold Cole Watkins, who, in attempting to prepare a liquid form of sulfanilamide had discovered that the drug would dissolve in diethylene glycol, a compound with a somewhat sweet taste similar to raspberries. When the mixture was tested for taste, appearance, and fragrance, it was found to be acceptable. Amazingly, Watkins did not bother to test for toxicity, either in humans or animals. In early September, over six hundred cases, some 240 gallons, of the elixir were compounded and shipped throughout the country from the company's main plant in Bristol and from its branch plant in Kansas City.

On October 11, American Medical Association officials in Chicago were informed that six deaths had occurred in Tulsa, Oklahoma, following the administration of Elixir Sulfanilamide-Massengill.[17] The AMA's Council on Pharmacy and Chemistry had not received a sample of the product for testing nor had Massengill informed the AMA of its drug's composition. The AMA requested a sample of the medicine from Tulsa and proceeded to contact Massengill for more information on the product. It then began a series of tests. Meanwhile the number of deaths mounted and a number of fatalities were reported from East St. Louis, Illinois. At the same time, the national press and radio were informed and made every effort to alert the public to the danger of the medicine. When the Massengill Company learned of the medication's poisonous effects, it immediately telegraphed more than a thousand salesmen, druggists, and doctors. Rather than admit culpability for the deaths that had occurred, however, the telegrams simply requested that any preparations of elixir sulfanilamide be returned to the Massengill offices immediately.

It was only at this point, on October 14, that the FDA heard about the incident from a physician in New York who was associated with another pharmaceutical company. As a result, FDA inspectors were dispatched from Kansas City to Tulsa to investigate. On October 16, five days after the AMA had been notified of the deaths and their probable cause, an FDA investigator telegraphed the AMA from Tulsa that nine persons had died after having taken the preparation. This was the first date on which official notice of the problem occurred. Having been informed of Massengill's attempts to recall all the elixir sulfanilamide outstanding, the FDA urged the Massengill Company to send a follow-up telegram, warning of the immediate dangers that might follow from ingesting the drug, and insisted that the telegram contain the caution "Product may be dangerous to life." The fact was that diethylene glycol, a chemical customarily employed as an antifreeze, was a deadly poison and known to be such by the FDA.[18] However, Massengill made no presale examination of the drug's safety nor was it customary for the FDA to conduct such tests, although to do so was within their warrant. It is true that once informed of its toxicity, the FDA, along with state and local officials, made every effort to track down the shipments and were eventually successful, but not before 107 people, many of them children, had died as a result of ingesting the drug. Since passage of the 1906 act, the Massengill Company had had an excellent record with the FDA. Only three cases had been brought against the company, all three during the 1930s. The first involved fluid extract of colchicum, which was found to be slightly over strength when compared with the standard shown in the National Formulary. The second, tincture of aconite, was found to be somewhat under strength. Finally, in reference to a shipment of elixir terpin hydrate and codeine, it was held that a disparity existed in the quantities of both ingredients between what was stated on the product's label and its actual contents. These violations resulted in two small fines, $250 and $150.

Estimates that the consumption of all 240 manufactured gallons of elixir sulfanilamide would have resulted in some 4,000 deaths and that the nation was thus indebted to the FDA for having

saved almost 3,900 lives is absurd. Much has been made of the fact that it was only because of a minor technicality that the FDA became involved in the incident. Elixir sulfanilamide was, technically, mislabeled. Inasmuch as it contained no alcohol, it could not properly be called an "elixir." Had it been labeled a "solution" instead, it is argued, the agency could have done nothing to track down and confiscate what medication remained in the public's hands. This is simply not true. The FDA, had it so chosen, could have used the same rationale to enter the case as it later employed to bring criminal charges against the owner of the Massengill Company, a rationale more than adequate to support its attempts to ferret out what medication remained unaccounted for. Indeed, the Massengill Company strongly supported a total recall of all the remaining elixir, and both state and local authorities actively participated in searching for that portion unaccounted for.[19] But even if the FDA had chosen not to participate in the search and seizure, to imply that the public would have been helpless while this lethal material continued to circulate and that no authority or organization would have attempted to locate and confiscate the outstanding elixir is preposterous. Nor was it the case that, in the absence of an FDA prosecution, the public would have been helpless to punish the offenders. By common law, the sale of a medication was regarded as a contract that, in the case of medicines and foods, contained an implied warranty of quality. Should that warranty not be met, the seller could be judged to have engaged in fraud and was subject to an action of tort.[20]

In the end, the Massengill Company is reputed to have paid out over half a million dollars in wrongful death suits. In addition, the FDA brought criminal charges against S. E. Massengill. The rationale for FDA action was that their elixir sulfanilamide was adulterated. It was the agency's contention that the drug "fell below the professed standard under which it was sold" inasmuch as the medication claimed to offer the same therapeutic results as did sulfanilamide, whereas "its principal action was that of an acute poison."[21] In September 1938 Dr. Massengill's attorneys filed a demurrer, but his plea was overruled. Inasmuch as the FDA did not seek imprisonment,[22] Massengill pled guilty to most of the charges and he was fined $150 on each of 164 counts, a total of $24,600, the largest fine ever assessed under the Pure Food and Drug Act. Watkins, the chemist whose incompetence was directly responsible for having determined the ingredients of the poisoned medication, committed suicide before Dr. Massengill's trial began.

The Food and Drug Administration, as expected, capitalized on the event to link the disaster to the absence of a new food and drug bill, and this view soon became the orthodox one, constantly repeated in the press. Walter G. Campbell, director of the FDA, in the very first public statement the agency made suggested that it was catastrophes of this nature that pointed to the need for passage of a reinvigorated version of a bill then before Congress for the future licensing of all drug manufacturers. Most supporters of a new measure did not seem to notice that the FDA had assumed jurisdiction over the events connected with Elixir Sulfanilamide-Massengill under the provisions of the 1906 act, nor did it strike anyone as odd that, were the FDA's comments taken at face value, even the bill that was then stalled in Congress would have proved inadequate in dealing with the crisis. Indeed, the FDA, with a field force of 239 inspectors and chemists, did not learn about the incident until three days after the AMA was made aware of the problem and more than five weeks after Massengill had made its first shipments to its customers, and then only by virtue of the fact that a physician associated with another drug manufacturer telephoned the FDA offices.

The demand for passage of a revised FDA bill soon became enormous. The AMA, women's groups, and the American Pharmaceutical Association were joined by the national press in a calling for action and the FDA publicized the disaster and its own heroic efforts in its literature and its bulletins. The FDA was even able to get two motion pictures about the events surrounding Elixir Sulfanilamide-Mas-

sengill produced in which the agency's inspectors were depicted as heroes. In both *Permit to Kill* and *G-Men of Science* Walter Campbell appeared and, as had J. Edgar Hoover in any number of G-man movies, spoke of the need for an ever-vigilant food and drug police—the very last thing the FDA had proved itself to be—and for strict new legislation.[23] Despite the tragic deaths of so many people, the agency viewed the incident as somewhat of a victory and were particularly pleased—the word used by one historian is "jubilant"—that the offending medicine had been produced in the Tennessee constituency of Representative Carroll Reece, who was a fierce opponent of the bill then before Congress to expand the FDA's authority.[24] All this favorable publicity for a new act was not lost on Congress. On November 16, Royal Copeland of New York brought up the Massengill incident in the Senate and was followed the next day by Virgil Chapman of Kentucky in the House. Both legislators introduced resolutions in their respective chambers calling on the Department of Agriculture to report on the tragedy. The resolutions were passed unanimously, and a thirty-four-page summary of the events was duly presented to Congress on November 20.[25]

Agitation for a new and stronger law regulating the manufacture and sale of food and drugs had preceded the Massengill crisis by several years. The election of Franklin Roosevelt in 1932 led the FDA to make a determined effort to strengthen its enforcement powers beyond those provided in the 1906 act. With the New Deal, the Democrats replaced the Republicans as the principal party embracing massive government intervention in the economy. Walter Campbell, who had become director of the FDA (under its earlier designation) in 1921,[26] was one of the first to try to capitalize on Roosevelt's election by lobbying to expand the FDA's powers, and in this he was encouraged by the new assistant secretary of agriculture, Rexford Tugwell. Indeed, it is Tugwell, one historian notes, who must be awarded the credit for initiating the movement to revise the 1906 act.[27] Tugwell was an enthusiastic proponent of economic planning. One-time professor of economics at Columbia University and a member of Roosevelt's Brain Trust, he had spent two months in the Soviet Union in 1927 and was enthusiastic about what he had seen there.[28] Early in his career as a high-ranking member of the Roosevelt administration, he is reputed to have maintained that "property rights and financial rights will be subordinated to human rights."[29] Tugwell sympathized with the need to broaden the agency's authority and quickly obtained approval for a revision of the 1906 act from President Roosevelt.

With the backing of the Roosevelt administration and particularly of Secretary Tugwell, Campbell was hopeful that he could quickly prevail on Congress to increase his agency's authority. During hearings on expanding the agency's powers, Campbell had cemented the FDA's relationship with Senator Copeland, Democrat of New York, who had shown sympathy with the agency's battle for stronger powers. Copeland, a homeopathic physician and one-time commissioner of health of New York City, had been invited to sit with the Senate Committee on Agriculture and Forestry, which then had jurisdiction over the FDA. He did much to deflect any questions that might have put the agency in a bad light. Indeed, during the hearings the press had begun referring to him as "counsel for the defense."[30]

The FDA's governing officials determined to take advantage of growing public discontent with the 1906 act to prevail on Congress to scrap the Pure Food and Drug Act and substitute an entirely new statute. When news reached the nation's food and drug manufacturers that the FDA would seek a completely new law, many manufacturers became convinced that it would contain so many restrictions that anything even vaguely resembling a free market would disappear. This was especially true of drug manufacturers, a good number of whom feared that the new act's provisions would force them out of business. In the event, their fears proved justified.

In late May 1933 Senator Copeland, who had now become the FDA's greatest champion, introduced a draft measure in the Senate known as the Tugwell bill. The bill was intended to replace the

1906 act and was crafted in Tugwell's offices in the Department of Agriculture.[31] Under its terms the FDA would no longer have to prove fraudulent intent in order to take legal action against a proprietary remedy. A medication could be held to be misbranded if its labeling made any therapeutic claim whatever, even if the claim were only implied, that was contrary to the general agreement of medical opinion. Additionally labels were required to specify that their contents were palliatives and not cures, unless evidence existed that proved that the medication could indeed cure. Finally, all ingredients, not solely a group of specified narcotics, must be disclosed, and medicines containing certain narcotic or hypnotic substances were required to carry the following notice: "Warning–May be habit forming." For the first time medical devices were brought under the purview of the bill and were subject to provisions similar to those applied to drugs.

Following news of the sulfanilamide disaster, it became obvious that the Copeland bill in its most recent form would have had no effect on the events leading up to the tragedy, and as a result on December 1, 1937, Copeland introduced a supplementary bill, not meant to replace the earlier measure but to be acted on independently.[32] The bill had reference to all new drugs and provided that manufacturers were required to furnish the Secretary of Agriculture with: records of all the tests regarding a drug's safety that had been conducted; a complete list of the drug's ingredients; a description of how the drug was to be manufactured, processed, and packaged; and specimens of all projected labels the drug would carry. In addition, if requested, the manufacturer would be obligated to supply samples of the drug to the FDA. The secretary would then either certify the drug as safe for sale to the public or, if no certificate were issued, provide the reasons detailing why it was refused.

The FDA found a number of allies in its campaign for increased powers in the national women's organizations, whose support once again was to prove crucial in eventual passage of a new law. The American Association of University Women, the American Home Economics Association, the National Congress of Parents and Teachers, the National Women's Trade Union League, and the National Board of the YWCA, among others, together with the same constellation of groups that had worked so tirelessly for the 1906 law, all endorsed the Copeland bill much as women's groups had supported passage of the earlier act. As had been the case prior to passage of the 1906 law, a substantial proportion of the women who sought passage of the Copeland bill welcomed a greater role for government in private life and looked on massive social engineering as the only effective method for social betterment. The American Home Economics Association, for example, was identified with the whole range of Progressive Era legislation, very much along the lines of the General Federation of Women's Clubs, including labor legislation limiting hours of work and minimum pay, child labor laws, women's suffrage, tighter controls on pornography, prostitution, and drug use, and a host of government programs to "improve American health and hygiene practices." Other women's groups joined them in enthusiastically endorsing similar reforms.

The conference report, reconciling the Senate and House version of a new bill, was issued on June 11 and was quickly ratified by both the House and Senate. President Roosevelt signed the bill into law on June 25, 1938. The Federal Food, Drug, and Cosmetic Act prohibited the introduction into interstate commerce of "any food, drug, device, or cosmetic, that is adulterated or misbranded."[33] The overwhelming portion of the bill then proceeded to deal with what constituted a misbranded or adulterated product, with a chapter of the act devoted to each category. For the first time the government extended its regulatory control to cosmetics and therapeutic devices and required that new drugs be shown to be safe before they could be marketed. It empowered the Secretary of Agriculture to fix tolerance levels for poisonous substances whose use was unavoidable. In addition it authorized factory inspections and authorized the Secretary of Agriculture to set standards of identity, quality, and the fill of all foods

in containers. It permitted multiple seizures in misbranding cases where the Secretary, "without hearings by him or any other officer or employee of the Department," determined that an article was "dangerous to health" or where the label was "fraudulent or, in a material respect misleading." Finally, to the existing penalties of seizure and prosecution, the act added the use of court injunctions.

Henceforth almost all new drugs would be available to consumers only through the mediation of a physician.[34] In the FDA's *Annual Report* for 1939, the first following full operation of the new law, the agency admitted that it had reached "an administrative conclusion of some moment." In attempting to comply with the law's requirement that all drugs be adequately labeled, the agency admitted that there was no way to label certain drugs such that they did not constitute a danger to health except to allow their use only by prescription. "Many drugs of great value to the physician are dangerous in the hands of those unskilled in the use of drugs. The statute obviously was not intended to deprive the medical profession of potent but valuable medicaments."[35] The category of drugs judged dangerous to health except by prescription grew at an enormous rate. Indeed, the twenty years following passage of the 1938 act witnessed a therapeutic revolution that saw the emergence of a host of new and efficacious drugs.[36]

No sooner had the 1938 act been signed into law than the FDA, armed with its new powers, ruled that sulfanilamide, in whatever form, could not be sold without a prescription. A few days later it made similar rulings regarding several other commonly used drugs. After having established its "prescription only" requirements in December, the FDA then determined that its regulations were still loose enough to permit some over-the-counter sales. Indeed, it soon became aware that announcing a drug that was ostensibly available only through a physician's prescription was a sure method of encouraging its general sale. As a result, in February 1939 Commissioner Campbell circulated another letter to drug manufacturers urging a more conspicuous and stronger warning. In the fall of 1940 the agency hit upon the idea of instructing firms selling prescription-only drugs to remove from their labels any information whatever that might guide lay users. Instructions regarding a drug's use were limited to leaflets targeted at physicians only. Far from making all medications safer for the public, the FDA had now managed to make some as unsafe as was possible. Instructions for the use of prescription medications that passed from one user, who had perhaps obtained the medicine through a physician, to another were henceforth limited to what the first user could recall respecting the drug's purpose. And drugs that remained in patients' medicine chests, unused for months or perhaps years, would now be employed at the direction of the original user's memory alone.

The Thalidomide Crisis of 1960

In 1951 Congress enacted the Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act of 1938. Prior to the amendment's passage, drug companies themselves could, in the main, determine whether a physician's order was necessary for the sale of a drug. The 1951 bill, known as the Prescription Drug Amendment, established two classes of drugs: those that were available directly to consumers and sold over-the-counter, and a second set, prescription drugs, available only through a physician's mediation, among them those that were habit-forming, subject to the FDA's new drug application approval process, or were regarded by the FDA as unsafe for use except under a doctor's supervision. With passage of the Durham-Humphrey Amendment, the FDA determined to crush public access to most medications without a prescription. In 1954 it devoted no less than one-third of the total appropriation earmarked for drug regulation to ensuring control over restricted drugs.[37] Over the course of slightly more than a decade, the FDA had moved from preventing fraud by guaranteeing the safety of drugs sold, to supervising the sale of medicines to consumers blind to their own welfare and incapable of making decisions regard-

ing their own health. The next step was to insure not only the safety of medicines consumed by ignorant consumers but also to guarantee their efficacy.

In 1960 the FDA found itself confronted with another drug disaster as horrendous as had occurred in 1937 when elixir sulfanilamide had been responsible for the deaths of over a hundred people, and, just as in 1937, the agency was able to capitalize on the tragedy to obtain legislation expanding its authority. In 1953 Ciba, a Swiss drug company, initially synthesized a new drug, thalidomide, which, after extensive testing, appeared to possess no pharmacological effects. At that point Ciba decided to abandon it, and in 1954 turned it over to a German drug manufacturer, Chemie Grünenthal, which showed interest in the substance. Chemie Grünenthal first marketed thalidomide as an anticonvulsant for treating epilepsy but continued to test the product more extensively, in particular in trials for a new allergy treatment. While the drug proved of no value in this regard, it did seem extremely effective as a sedative, which was especially efficacious for those experiencing nausea and morning sickness. It therefore seemed an ideal medication for pregnant women suffering nausea and insomnia. Testing appeared to show it completely safe and having no side effects. Indeed, it was suggested that no lethal dose could be established. It is now known that the first thalidomide baby was born in 1956; however, the causes of the birth defects that were exhibited had not yet been traced to thalidomide, and the drug was still regarded as quite safe for the purposes for which it was prescribed. As a result, in 1957 Chemie Grünenthal began general marketing of the drug, which quickly became extremely popular with pregnant women and was widely prescribed in Germany, Britain, Australia, and Canada.

Chemie Grünenthal attempted to expand its sales of thalidomide into the United States during 1960 and applied to the Food and Drug Administration for approval through its U.S. distributor, William S. Merrill Company. It appears that both the distributor and the FDA considered the approval as routine, and as a result the application was turned over to one of the agency's junior people, Dr. Frances Oldham Kelsey. Concern over some of the routine tests that Chemie Grünenthal had originally conducted on thalidomide and earlier scattered reports that thalidomide might cause neuropathy in some of its users led Dr. Kelsey to delay approval of the application for about a year. It is worth underscoring that neither of these concerns was in any way fatal to thalidomide's application, and had reports that the drug was extremely dangerous when used by pregnant women not intervened, there is no question that the drug would in fact have been approved in the United States as it had been in Europe, Britain, and Canada. The reasons for Dr. Kelsey's delay had nothing whatever to do with birth defects nor with the drug's effect on the human embryo, and the FDA's later claim that her prior work in animal toxicity, including toxic effects in pregnancy, suggested that a delay was warranted is without any foundation whatever.[38]

In mid-1960 an Australian gynecologist in Sydney reported his suspicions that thalidomide was responsible for severe limb and bowel malformations in three children he was treating. By the end of the year a number of observations were reported in Great Britain and in other areas, and evidence began to accumulate that thalidomide was the responsible agent in the increasing number of severe birth defects that were occurring. These reports soon reached the press, and Chemie Grünenthal felt obligated to withdraw the drug from distribution, as did Distillers, its manufacturer in Britain. It was quickly established that thalidomide was teratogenic (dangerous to embryos) when ingested by pregnant women in the first trimester, but not before it had caused many thousands of stillbirths and miscarriages and was responsible for severe birth defects in thousands of others. That its application was withdrawn in the United States,[39] however, has nothing to do with the FDA being more vigilant than its counterparts in other parts of the world. The truth is that thalidomide was not distributed throughout the United States[40] because the agency's approval process was mired in red tape and because a bureau-

crat had determined that it really didn't matter how long it took her to approve a drug that might have relieved hundreds of thousands of pregnant women from serious discomfort. The nation is indeed lucky that Dr. Kelsey decided to temporize, but we can only be thankful that it was not a vaccine for polio that was under consideration. Thalidomide had not undergone reproductive tests before 1961 nor did the FDA require such tests. Indeed, it appears that if such tests had been performed in rats it would not have resulted in any malformed births. At most, tests on rats have shown that litter size was decreased after ingestion of thalidomide.

Once again, however, the FDA was able to turn this tragedy into a victory for itself. Thalidomide, we are told, was halted at our borders by an alert pharmacologist dedicated to seeing to it that all Americans were safe from the dangers that might beset them by untested or inadequately tested drugs. Indeed, Dr. Kelsey, whose delays in approving thalidomide were in fact a function of her own foot dragging, appears not to have been in the least embarrassed by the myth that it was through her efforts alone that the nation was spared a tragedy of the sort that befell Germany and Britain. The historian of drug regulation in America whose work is regarded as definitive has referred to the thalidomide episode as "one of the agency's great triumphs" and notes that "the shrewdness and firmness of an FDA woman physician had kept the United States from sharing in a terrible medical disaster."[41] For her efforts, Dr. Kelsey received the highest civilian award her nation could bestow, the President's Award for Distinguished Federal Civilian Service, from President John F. Kennedy in August 1962.[42]

The events surrounding thalidomide were crucial not only in making the FDA appear to be an agency of government that had spared Americans a major disaster but also in deflecting a series of negative reactions to the FDA's attempts to tighten restrictions on access to drugs. This was a pure power play in which the agency, allied with the American Medical Association, sought to further restrict what they regarded as quack medicines available to the consumer, thus forcing the consumer to consult a trained professional who alone had the power to dispense effective therapeutic agents. This cooperation was sealed at the Congress on Medical Quackery held in Washington in 1961 under the joint sponsorship of both the FDA and the AMA. Of particular concern were medications aimed at conditions that orthodox medicine was then helpless to treat, particularly cancer and arthritis.[43] These medications—in almost all cases—in fact, did no harm. Nor, in most cases, could it be argued that they prevented patients from taking advantage of more efficacious drugs, since none existed. Still, both the FDA and the AMA were infuriated that individuals were allowed to choose their own medications despite the fact that they might not have had therapeutic value.

The move to prohibit the distribution and sale of drugs and medical devices that the FDA had decided were without therapeutic merit had begun in 1910, when Wiley's Bureau of Chemistry attempted to prosecute packages of medicine that bore labels stating that they could cure cancer. The Supreme Court then ruled that therapeutic effectiveness was not covered by the 1906 act.[44] The issue, however, remained uppermost in the minds of FDA bureaucrats who were exasperated that they were unable to deal with the large number of remedies that they regarded as of no value. In 1955 Oveta Culp, the secretary of Health, Education, and Welfare,[45] appointed a Citizens Advisory Committee to investigate quackery in America. As was expected, the committee recommended that the FDA's "educational" efforts be considerably strengthened, both about the hazards of quack medicines and therapeutic devices and about the FDA's role as protector of the nation's drug supply. Partly in response to these recommendations, the FDA organized a Division of Public Information in 1958, which issued a stream of press releases, and in the same year the new secretary of Health, Education, and Welfare, Arthur Flemming, held a number of press conferences on the dangers of questionable nutritional and dietary products.[46]

The 1961 Congress on Medical Quackery did not confine itself to the issue of drugs and devices that were felt to be without value. It also addressed the fact that the chemotherapeutic revolution, which had been under way for a decade, had produced drugs of such potency that were prescription drugs misused or prescribed to certain patients despite their contraindications dire consequences could result. In addition, a certain number of drugs, while effective, had cumulative toxic effects. While such information could not appear on the label of medications resold to the public by prescription, new prescription drugs were required to enclose accompanying material with each package that described the drug's proper purpose and dosage, together with any relevant warnings and contraindications. However, it was sometimes the case that only pharmacists saw this information since it was not routinely distributed to physicians. The FDA was also concerned about drug advertising aimed at physicians, which, the agency argued, did not present "a balanced picture" of the benefits and liabilities of a particular drug. Finally, accusations were made that the price of prescription medications were substantially higher than one would have expected in a competitive environment.

The Kefauver Commission, whose first meeting on prescription drugs occurred at the end of 1959, was especially interested in the prices of drugs and whether the drug industry was in fact competitive. Senator Estes Kefauver from Tennessee had run for the Democratic nomination for president in 1952. He lost the nomination to Adlai Stevenson, but in 1956 was chosen as Stevenson's running mate in a hopeless campaign against President Dwight Eisenhower. In 1959, as chairman of the Senate's Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, he began hearings to investigate the drug industry, which the committee believed was responsible for charging exorbitant prices for drugs of dubious value.[47] As Kefauver himself remarked: "Ethical drug prices are generally unreasonable and excessive. They are unreasonable whether compared to costs, to profits, or to prices in foreign countries."[48] The Kefauver committee meetings seemed endless, its hearings filling volume after volume, in the main directed at the competitive position of firms that comprised the pharmaceutical industry. In April 1961 Kefauver submitted his drug bill to the Senate.[49] S. 1552[50] was introduced primarily to amend and supplement the antitrust laws with respect to the manufacture and distribution of drugs. The bill limited the conditions under which a new drug could be patented and included a provision that patent holders were compelled, after three years, to award licenses to all manufacturers who sought them. The measure further required that all producers of prescription drugs be licensed, required that all advertising and promotional material fully disclose all negative information associated with the drug, called for the inspection of all manufacturing facilities, empowered the Food and Drug Administration to determine the generic name of any drug, and required manufacturers to present evidence not only of the safety but of the efficacy of all medications.[51]

On March 15, 1962, President John F. Kennedy submitted a message to Congress on consumer protection, calling for a huge number of new regulations relating to everything from automobile safety to all-channel television sets. That portion of his remarks that were devoted to drugs, while similar in most particulars to Kefauver's bill, neither mentioned the issue of drug prices, which was of particular concern to Kefauver, nor explicitly endorsed S. 1552, as the senator had requested. "I recommend," Kennedy announced:

> legislation to strengthen and broaden existing laws in the food-and-drug field to provide consumers with better, safer, and less expensive drugs by authorizing the Department of Health, Education, and Welfare to–
>
> (a) Require a showing that new drugs and therapeutic devices are effective for their intended use–as well as safe–before they are placed on the market;

> (b) Withdraw approval of any such drug or device when there is substantial doubt as to its safety or efficacy and require manufacturers to report any information bearing on its safety or efficacy;
>
> (c) Require drug and therapeutic device manufacturers to maintain facilities and controls that will assure the reliability of their product;
>
> (d) Require batch-by-batch testing and certification of all antibiotics;
>
> (e) Assign simple common names to drugs;
>
> (f) Establish an enforceable system of preventing the illicit distribution of habit-forming barbiturates and amphetamines;
>
> (g) Require cosmetics to be tested and proved safe before they are marketed; and
>
> (h) Institute more effective inspection to determine whether food, drug, cosmetics, and therapeutic devices are being manufactured and marketed in accordance with the law.[52]

While the Kefauver bill had passed his own subcommittee, the full Committee on the Judiciary referred the measure for consideration to another of its subcommittees, the Subcommittee on Patents and Trademarks, chaired by John McClellan, Democrat of Arkansas. Kefauver was convinced that this would have the effect of killing his bill, but instead the McClellan committee excised the measure's provisions for compulsory licensing and, in that form, reported it to the Committee on the Judiciary. Coincidentally, reports of the thalidomide disaster focused the nation's and Congress's attention on the issue of drug safety and greatly increased the likelihood that some drug bill would be enacted during that session of Congress. Indeed, the administration, apparently fearful that its poor record on health care legislation would work against the president in light of the failure of his Medicare proposals, endorsed Kefauver's measure in a letter to the chairman of the Senate Judiciary Committee, James Eastland from Mississippi.

In addition to having indicated support for the Kefauver bill in the Senate, on April 23 Kennedy sent his own drug bill to the House. Representative Oren Harris, chairman of the House Committee on Interstate and Foreign Commerce, introduced the bill on May 2, 1962, and covered the various specifics raised in the President's message.[53] Several weeks later Harris's committee conducted hearings on the bill, and in September the measure passed the House. Both the Kefauver and the Harris bills, which closely reflected the wishes of the Food and Drug Administration and the president, cemented the agency's approach to food, drugs, cosmetics, and medical devices: that it is the function of government, and not each consumer, to specify exactly what level of safety each of us should demand in these products, regardless of the disparate circumstances in which each of us might find ourselves. To this was now added the notion that the federal bureaucracy should determine for us the amount of risk we each should take with a particular product. It had been determined that a panel of functionaries was more competent than were adults to make these decisions. In this respect, 180,000,000 Americans were no more able to care for their own welfare than were their pets. It was therefore especially appropriate that, in testifying in support of the Harris bill, Abraham Ribicoff, the Secretary of Health, Education, and Welfare, noted that the new law "will, for the first time, give men, women, and children the same safeguards against worthless drugs that Congress has been giving hogs, sheep, and cattle since 1913."

While a series of amendments incorporating the FDA's objectives were pending before Congress prior to the thalidomide incident, the events associated with the tragedy increased the agency's confidence that a stronger bill with a more complex approval process would pass even though it likely meant that fewer new drugs would be developed. Senator Kefauver must have struck the agency as a perfect sponsor for such legislation since he had

often voiced the belief that a good deal of drug innovation was socially wasteful. As one economist has characterized Kefauver's view:

> The waste was said to arise from product differentiation expenditures in an imperfectly competitive market permeated by physician ignorance; product differentiation expenditures were incorporated in prices which therefore did not reflect the "true value" of the drug to the consumer. It was argued that only in hindsight would doctors or patients discover that claims for new drugs were exaggerated; consumers would have been better off if they had used lower-priced old drugs (especially unpatented old drugs and most especially non-branded unpatented old drugs) instead of the new drugs.[54]

The Kefauver bill in its final form differed substantially from the measure as it was introduced sixteen months earlier.[55] It had undergone a number of changes, both at the hands of the McClellan subcommittee and in the Eastland Committee on the Judiciary, many of which the Food and Drug Administration crafted. It had passed the Senate several weeks before the Harris bill passed the House, and the two measures were then sent to a conference committee. Finally, the Kefauver-Harris amendments were signed into law on October 10, 1962.[56] The changes Congress made in 1962 to the 1938 Food, Drug, and Cosmetic Act contained several significant provisions that extended the FDA's power. All drug manufacturers were required to register their establishments with the agency and to undergo a thorough inspection at least once every two years. In addition, the new act required that all pertinent records be kept and made available for inspection. More important, all reports on drugs that suggested any adverse effects were to be promptly transmitted to the FDA. In what must have been a particularly sweet victory for the agency, all authority over the advertising of prescription drugs was transferred from the Federal Trade Commission to the FDA. All advertising copy henceforth had to contain a full disclosure of adverse effects and contraindications. Trials on human subjects could not be undertaken without informed patient consent. Finally, and of greatest import, manufacturers were required to prove, by substantial evidence, not only the safety but the effectiveness of all new drugs, and all time constraints associated with the approval process were removed.

Conclusion

As a result of legislative reaction to three crises—the diphtheria antitoxin crisis of 1901, the sulfanilamde crisis of 1937, and the thalidomide crisis of 1960—the FDA was able to increase its authority to determine what Americans ingest to the point where today, at least in the case of drugs, it is the agency, and not the consumer, that determines what is available and when. It exercises regulatory powers over products that account for approximately twenty-five cents of every dollar spent by the American consumer. While it is doubtful if the FDA's increased powers would have prevented any of these crises, they did assure that the approval of new drugs would slow considerably.

Notes

1. This essay draws on sections of a previously published monograph on the history of government involvement in public health. 2007. *Government and Public Health in America.* Northampton, Mass.: Edward Elgar.

2. For discussions of government growth in the United States, see, among numerous others, Thomas Borcherding. 1977. One Hundred Years of Public Spending, 1870–1970 and The Source of Growth of Public Spending in the United States, 1902–1970 in Thomas Borcherding, ed. *Budgets and Bureaucrats: The Sources of Government Growth.* Durham, N.C.: Duke University Press, 19–44 and 45–70; Sam Peltzman. 1980. The Growth of Government. *Journal of Law and Economics* 23: 209–287; Allen H. Meltzer and Scott F. Richard. 1981. A Rational Theory of the Size of Government. *Journal of Political Economy* 89: 914–927; and Douglas C. North and John Joseph Wallis. 1982. American Government Expenditures: A Historical Perspective. *The American Economic Review* 72 [Papers and Proceedings of the Ninety-Fourth Annual Meeting of the American Economic Association]: 336–340.

3. Robert Higgs. 1987. *Crisis and Leviathan: Critical Episodes in the Growth of American Government.* New York: Oxford University Press, 17–19.

4. The Food and Drug Administration's regulatory powers were originally invested in the Bureau of Chemistry of the Department of Agriculture, which in 1927 was transmuted into the Food, Drug, and Insecticide Administration and in 1930 into the Food and Drug Administration.

5. Paul A. Offit. 2007. *The Cutter Incident: How America's First Polio Vaccine Led to the Growing Vaccine Crisis.* New Haven: Yale University Press, 58–59. Even today diphtheria antitoxin is prepared by hyperimmunizing horses with the toxin and then obtaining the blood plasma of these animals.

6. A lengthy discussion of both the St. Louis and Camden episodes is discussed in David E. Lillienfeld. 2008. The First Pharmacoepidemiologic Investigations: National Drug Safety Policy in the United States, 1901–1903. *Perspectives in Biology and Medicine* 51: 188–198.

7. See: 1902. Vaccination, Antitoxin and Tetanus: Official Report of the Camden Board of Health Concerning the Cases of Tetanus which Occurred in Patients Who Had Been Vaccinated. *The Sanitarian* 386: 32–38.

8. For a detailed history of the Biologic Control Act of 1902, see Kamunas A. Kondratas. 1982. The Biologic Control Act of 1902. In James Harvey Young, Chairman of the symposium, *The Early Years of Federal Food and Drug Control.* Madison, Wisconsin: American Institute of the History of Pharmacy, 8–27.

9. It should be underscored that the academic requirements for physicians at the time that Wiley was preparing himself for the practice of medicine were far from rigorous. Indeed, Wiley's formal medical education at Indiana Medical College in Indianapolis, a reputable medical school sponsored by the local Academy of Medicine, comprised only two four-month terms in 1869–70 and 1870–71. See Oscar E. Anderson. 1958. *The Health of a Nation: Harvey W. Wiley and the Fight for Pure Food.* Chicago: University of Chicago Press, 11.

10. It was not until 1889 that the Department of Agriculture was raised to cabinet status.

11. According to Wiley, sugar consumption was a measure of how civilized a country was. He especially urged children to include a large amount in their diets. "Childhood without candy," he is quoted as saying, "would be Heaven without harps." Clayton A. Coppin and Jack High. 1991. Entrepreneurship and Competition in Bureaucracy: Harvey Washington Wiley's Bureau of Chemistry, 1883–1903. In Jack High, ed. *Regulation: Economic Theory and History.* Ann Arbor, Mich.: University of Michigan Press, 100.

12. Wiley defined adulteration as not solely the debasement of a product but as "any purposeful change that altered its composition or the meaning of the name under which it was sold." Anderson, *Health of a Nation,* 69. Thus, should a product include any cosmetic or preservative, it would be regarded as adulterated.

13. Anderson, *Health of a Nation,* 75.

14. Quoted in Anderson, *Health of a Nation,* 75. Compare Wiley's comments before the Franklin Institute in Philadelphia in December 1892, where he noted that only a small proportion of the food that Americans consumed was adulterated, and even that portion was "not so dangerous on account of being deleterious to health as because of [its] pretensions to furnish to the poorer part of our people a food ostensibly pure and nutritious, but in reality valueless." 1893. *Journal of the Franklin Institute* 137: 266–288; quoted in Anderson, *Health of a Nation,* 80.

15. 34 U.S. Stats. 768 (1906).

16. Details of the elixir sulfanilamide disaster can be found in: 1981. Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident. *FDA Consumer* [75th Anniversary Issue] 15: 18–21; James Harvey Young. 1983. Sulfanilamide and Diethylene Glycol. In John Parascandola and James C. Whorton, eds. *Chemistry and Modern Society: History Essays in Honor of Aaron J. Ihde* [ACS Symposium Series 228] Washington, D.C.: American Chemical Society, 105–124; and 1937. *Elixir Sulfanilamide: Letter from the Secretary of Agriculture* [In Response to Senate Resolution No. 194, Document No. 124, 75th Cong., 2d sess.]. Washington, D.C.: Government Printing Office. Reprinted 1979. In *Food and Drug Administration, A Legislative History of the Federal Food, Drug, and Cosmetic Act and its Amendments.* [24 vols. +10 vols. of appendices] Rockville, Md.: Department of Health, Education and Welfare, Public Health Service], 5: 883–921.

17. The mixture was not invariably fatal. "Many persons who took it but discontinued use with the onset of the symptoms completely recovered." Charles O. Jackson. 1970. *Food and Drug Legislation in the New Deal.* Princeton: Princeton University Press, 155.

18. "For some years prior to Watkins' employment of diethylene glycol, the Food and Drug Administration had advised against the use of glycol solvents in foods, declaring that definite, comprehensive conclusions as to the physiological action of these chemicals could not be reached on the basis of existing scanty research. . . . Beginning in 1931 more explicit reports of the poisonous nature of the chemical appeared in medical journals." Young, "Sulfanilamide," 109.

19. The Food and Drug Administration's official magazine, the *FDA Consumer,* in recounting the calamity, noted: "Through the dogged persistence of Federal, State, and local health agencies and the efforts of the AMA and the

news media, most of the elixir was recovered." "Taste of Raspberries," 20.

20. See Sir William Holdsworth. 1903–1977. *A History of English Law.* 17 vols. London: Methuen & Co., Inc., 3: 387 and 8: 69. In fact, a similar case was punished under common law in Massachusetts as early as 1630! See Wallace F. Janssen. 1975. America's First Food and Drug Laws. *FDA Consumer*, 17.

21. Young, "Sulfanilamide," 116.

22. Massengill could have received a prison term of 261 years!

23. Ruth deForest Lamb, in charge of publicity for the FDA, even boasted that 20th Century Fox was planning on making a film out of the American Chamber of Horrors. Jackson, *Food and Drug Legislation,* 166.

24. Jackson, *Food and Drug Legislation,* 165.

25. Elixir Sulfanilamide in Food and Drug Administration. *Legislative History of the Federal Food, Drug, and Cosmetic Act* 5: 883–921.

26. Campbell, whose area of expertise was enforcement, had been appointed to succeed Carl Alsberg as head of the Bureau of Chemistry in 1921. However, there was strong sentiment that a scientist should head the agency, and as a result Charles A. Browne, an agricultural chemist, replaced Campbell as chief of the bureau in 1924. At the same time, Campbell was given authority over all of the bureau's enforcement operations. With the creation of the Food, Drug, and Insecticide Administration in 1927, Browne, whose interests were in research, became head of the new Bureau of Chemistry and Soils while Campbell was appointed chief of the new enforcement agency, the FDIA. He retired from the position in 1944.

27. David F. Cavers. 1939. The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions. *Law and Contemporary Problems* 6: 5.

28. Tugwell had no patience with an economic system based on competitive market forces. In 1933 he maintained in an address before the Bar Association of Western New York that "the jig is up. The cat is out of the bag. There is no invisible hand. There never was. . . . Men were taught to believe that they were, paradoxically, advancing co-operation when they were defying it. That was a viciously false paradox." 1933. Design for Government. Address before the Eighth Annual Meeting of the Federation of Bar Associations of Western New York, June 24. Quoted in Bernard Sternsher. 1964. *Rexford Tugwell and the New Deal.* New Brunswick, N.J.: Rutgers University Press, 13. One historian ably summed up the economic views embraced by Tugwell and the other technocratic progressives, many of whom took an active role in the Roosevelt administration. "They took part in a campaign to publicize the irrationality of the existing capitalist order and create a demand for a planned society guided by 'experts who are not representatives of the capitalists but of the public interest.'" Robert B. Westbrook. 1980. Tribune of the Technostructure: The Popular Economics of Stuart Chase. *American Quarterly* 32: 388.

29. Quoted in James H. Young. 1992. *The Medical Messiahs*. Princeton, NJ: Princeton University Press, 160. In 1933 Tugwell wrote: "It is doubtful whether nine-tenths of our sales effort and expense serves any good social purpose." Rexford G. Tugwell. 1933. *The Industrial Discipline and the Governmental Arts.* New York: Columbia University Press, 180.

30. Jackson, *Food and Drug Legislation,* 15.

31. James Harvey Young reports that Stuart Chase was present at a meeting held by Tugwell with FDA officials to discuss the proposed measure. *Medical Messiahs,* 161, footnote 7. Tugwell and Chase were apparently old friends. They were both part of the delegation that had traveled to Russia in 1927 and had coedited the account of the delegation's findings. 1928. *Soviet Russia in the Second Decade: A Joint Survey by the Technical Staff of the First American Trade Union Delegation.* New York: John Day.

32. The bill is reprinted in *Legislative History of the Federal Food, Drug, and Cosmetic Act,* 5: 924–927.

33. The Federal Food, Drug, and Cosmetic Act, P.L. 75–717. Reprinted in *Legislative History of the Federal Food, Drug, and Cosmetic Act,* 6: 453–474.

34. The American Medical Association was, of course, delighted with the development. Its Council on Pharmacy and Chemistry had long lobbied for these limitations on self-medication. See James G. Burrow. 1970. The Prescription-Drug Policies of the American Medical Association. In John B. Blake, ed. *Safeguarding the Public: Historical Aspects of Medicinal Drug Control.* Baltimore: John Hopkins Press, 112–122.

35. The report continued: "The administrative conclusion was therefore announced that dangerous drugs like aminopyrine, cinchophen, neocinchophen, sulfanilamide, and related products may not be distributed for unrestricted use by the lay public without violating the statute; to insure compliance with the law drugs of this character must be labeled with warnings so conspicuous as certainly to arrest attention and in such informative terms as will unfailingly apprise the user of the danger of irreparable injury if the drug is consumed without adequate and continuous medical supervision." 1939. U.S. Food and Drug Administration. *1939 Report of Food and Drug Administration.* Washington, D.C.: Government Printing Office, 5. Reprinted in Food Law Institute. 1951. *Federal Food, Drug, and Cosmetic Law: Administrative Reports, 1907–1949.* Chicago: Commerce Clearing House, 929.

36. The Food and Drug Administration's 1956 *Annual Report* notes that no less than 90 percent of the prescriptions then written were for drugs not commercially available when the 1938 law was enacted. This figure at the least suggests that most effective medications developed during that period were available to the public solely by prescription.

37. Peter Temin. 1980. *Taking Your Medicine: Drug Regulation in the United States.* Cambridge: Harvard University Press, 121.

38. The FDA was fortunate in being able to capitalize on an article in the *Washington Post* by Morton Mintz, who credited Kelsey's "determined opposition" to thalidomide for the fact that it was not available in the United States. Mintz himself was one of the strongest supporters of legislation to expand the powers of the FDA and had written a book, *The Therapeutic Nightmare* (Boston: Beacon Books, 1965), calling for many of the powers later awarded the agency by the Kefauver-Harris amendments. The second edition of Mintz's book was titled *By Prescription Only: A Report on the Roles of the United States Food and Drug Administration, the American Medical Association, Pharmaceutical Manufacturers, and Others in Connection with the Irrational and Massive Use of Prescription Drugs That May Be Worthless, Injurious, or Even Lethal.*

39. In 1998 thalidomide was approved for treating, among others, the symptoms of leprosy, use as an anti-neoplastic agent, and in treating AIDS, by reducing inflammation.

40. This is not, strictly speaking, true. At the time the FDA permitted thalidomide's American distributor to issue samples of the drug to doctors for "clinical trials" while awaiting approval. About 2,500,000 pills were given to over 1,000 physicians who, in turn, distributed them to approximately 20,000 patients between 1958 and 1961. It is estimated that seventeen victims were born in the United States.

41. Young, *Medical Messiahs,* 415.

42. The Senate's tribute to Dr. Kelsey, which contains a summary of the president's remarks, can be found at *Congressional Record: Senate,* vol. 108, August 7, 1962, 15745. Reprinted in *Legislative History of the Federal Food, Drug, and Cosmetic Act,* 22: 175. The idea that President Kennedy honor Dr. Kelsey with the gold medal originated with Senator Estes Kefauver of Tennessee, who had written the president to that effect and who addressed the Senate on her "heroism" on July 18. See Richard Harris. 1964. *The Real Voice.* New York: Macmillan, 187–189. In 2005 the FDA named one of its highest awards after Dr. Kelsey, the Dr. Frances O. Kelsey Drug Safety Excellence Award.

43. See Young, *Medical Messiahs,* 390–407. Young, in dismissing those elements opposed to further undermining the government's right of choice in determining medication, writes: "Waving the banner of 'medical freedom,' these groups spent thousands for propaganda in an appeal to millions of Americans who were in some way disenchanted with life–the sick, the unhappy, the ignorant, the illogical, the fearful, the bored, the lonely." 392.

44. See *United States v. Johnson,* 221 U.S. 488; 31 S. Ct. 627 (1911).

45. The Department of Health, Education, and Welfare was created in April 1953, assuming the responsibilities of the Federal Security Agency (FSA), which had taken over supervisory control of the FDA from the Department of Agriculture in 1939. President Eisenhower had decided to reorganize certain divisions of the executive branch, particularly the FSA. Besides its infelicitous name, which conjured up images of spies and code breakers, the agency's budget had at that point exceeded the combined budgets of the departments of Commerce, Justice, Labor, and the Interior.

46. Young, *Medical Messiahs,* 392–394.

47. The subcommittee's examination of the prescription drug industry was part of a larger inquiry into administered prices throughout the economy, which was launched in July 1957. By 1961 the subcommittee had issued four reports and had published twenty-six volumes of hearings. The fourth report is: 1961. *Administered Prices: Drugs* [Report of the Committee on the Judiciary, U.S. Senate, Made by the Subcommittee on Antitrust and Monopoly, 87th Cong., 1st sess., Report No. 448]. Washington, D.C.: Government Printing Office. Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 17: 178–374. One of the fallouts of Kefauver's investigations was the resignation of Dr. Henry Welch, then director of the FDA's Division of Antibiotics. In 1959 an article in the *Saturday Review* [J. Lear. 1959. The Certification of Antibiotics. *Saturday Review* (Feburary 7): 43–48] reported that Dr. Welch's objectivity was compromised by improper financial connections with the pharmaceutical industry. Investigations undertaken at the direction of Senator Kefauver later uncovered the fact that Welch had been paid approximately two hundred thousand dollars over a period of seven years by a medical publishing firm selling advertising space and journal reprints to pharmaceutical firms. As a result of these revelations, Welch was forced to resign his office. See Peter Barton Hutt. 1983. Investigations and Reports Respecting FDA Regulation of New Drugs. *Clinical Pharmacology and Therapeutics* 33: 539.

48. Remarks by Estes Kefauver, Chairman. 1961. *Drug Industry Antitrust Act* [Hearings before the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U.S. Senate, 87th Cong., 1st sess., S. 1552]. Washington, D.C.: Government Printing Office, 2. Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 17: 566.

About the Author

RONALD HAMOWY is Research Fellow at The Independent Institute and Emeritus Professor of History at the University of Alberta, Canada. He received his Ph.D. from the University of Chicago, and has written on two disparate areas: eighteenth-century British political and social history and the intersection between medicine and law in twentieth-century North America. Among his books are *Government and Public Health in America*, *Canadian Medicine: A Study of Restricted Entry*, *The Scottish Enlightenment and the Theory of Spontaneous Order*, *Dealing with Drugs: Consequences of Government Control*, and *The Political Sociology of Freedom*. He has edited and annotated the eighteenth-century British classic political text, *Cato's Letters*, and the new edition of F. A. Hayek's *Constitution of Liberty*, to be published in Hayek's collected works by the University of Chicago Press.

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49. The legislative history of the Kefauver-Harris amendments are discussed in some detail in Harris, *Real Voice.*

50. The bill is reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 17: 122–143.

51. The FDA had attempted to impose a requirement of efficacy on medications prior to the passage of the Kefauver-Harris amendments. The FDA's trade correspondence of June 27, 1945, noted that certain glandular preparations possessed no useful therapeutic properties despite the fact that they were in demand by certain medical practitioners. "If further scientific evidence demonstrates conclusively that the products of this class are therapeutically useless," the correspondence continued, "the Administration will have no alternative but to regard them as misbranded because among other things, their labelings cannot bear adequate directions for drug use." As one commentator noted: "This apparently means that if the Administration concludes that a drug is therapeutically useless it will regard it as contraband of commerce regardless of whether some physicians want to employ it in their practice." Edward B. Williams. 1947. Exemption from the Requirement of Adequate Directions for Use in the Labeling of Drugs. *Food, Drug, and Cosmetic Law Journal* 2 (June): 160. For a history of attempts by the federal government to prohibit the distribution and sale of remedies that were ineffective, attempts that date back to the nineteenth century, see John Swann. 1977. Sure Cure: Public Policy on Drug Efficacy Before 1962. In Gregory J. Higby and Elaine C. Stroud, eds. *Inside Story of Medicine: A Symposium.* Madison, Wis.: American Institute of Pharmacy, 223–261.

52. *Consumers' Protection and Interest Program* [Message from the President of the United States, House of Representatives, 87th Congress, 2nd Session, Document No. 364]: 7. Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 21: 9.

53. H.R. 11581. Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 21: 19–51. On the following day Harris introduced a second bill relating to cosmetics and therapeutic devices: H.R. 11582. Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 21: 53–80.

54. Sam Peltzman. 1974. *Regulation of Pharmaceutical Innovation: The 1962 Amendments* (AEI Evaluative Studies 15). Washington, D.C.: American Enterprise Institute for Public Policy Research, 7.

55. The bill is reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 22: 351–384.

56. P.L. 87–781 (1962). Reprinted in *Legislative History of the Food, Drug, and Cosmetic Act,* 23: 228–244.

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