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Miracle Medicine:
The Impact of Sulfa Drugs on Medicine, the Pharmaceutical Industry and Government Regulation in the U.S. in the 1930s.

by

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A dissertation submitted to the Graduate Faculty in History in partial fulfillment of the requirements for the degree of Doctor of Philosophy, The City University of New York

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Foreword

It is impossible to fully understand the enormous impact of the introduction of sulfa drugs without considering them within the context of the pharmaceutical industry, government regulation, and the practice and culture of medicine. Sulfa drugs, or the "miracle drugs," significantly effected all of them. It is equally impossible to understand the importance of sulfa drugs without appreciating the fact that they had another profound importance—they saved hundreds of thousands of lives. Initially, those were the lives of infants and young children and postpartum women with septicemia, or childbed fever.

For many physicians, this meant that for the first time they could efficaciously intervene rather than merely predict the course of infective disease. For women, childbearing became safer, and the likelihood of watching their children succumb to childhood illness or devoting years to the anxious care of children who—like Beth March in Little Women, suffered from the secondary damage from scarlet—all but disappeared.

As one more dispassionate observer explained:

> The chemical compound [called for brevity's sake Sulphonamide chrysoidine] which started a most exciting series of researches in the field of chemotherapy was synthesized...in 1932 and patented on Christmas Day of that...and in the hands of clinicians there followed a series of dramatic curative results.[1]

These drugs served as a catalyst for critical changes in medicine, pharmacology, the drug industry, and government regulation of health care. The reaction to their introduction provides a framework for exploring the relationship

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[1] W. L. Holman and G. L. Duff, "Progress of Medical Science" *American Journal of the Medical Sciences*, 195, no. 3 March 1938, 379.

of science to medicine, pharmacy, and the chemical industry. Sulfa drugs were the indisputable products of the scientific laboratory, but by the time that the anti-infective potential of sulfanilamide—the active ingredient in these drugs—was recognized, the substance was in the public domain. Within a few years, literally hundreds of sulfanilamide compounds appeared on the market, and dozens of pharmaceutical companies made enormous profits.

In pursuit of those profits, one company introduced an over-the-counter sulfa compound, which unfortunately contained a toxic solvent that poisoned over 100 people. Activists who had been working for years to increase government regulation of healthcare had an issue that dramatically illustrated the importance of the reforms they advocated. The law that Congress passed in response, the 1938 Pure Food, Drug, and cosmetic Act, created a new category of regulated non-narcotic drugs. These drugs, which included sulfanilamide, were too potent to be left in the hands of the lay public. Medical miracles were indeed possible, but they could only be obtained through the intercession of a physician.

Though there were few differences in the sulfa drugs used in the United States as opposed to those used in Europe, their effects on the culture and economics of medicine were significantly different. The historically specific circumstances into which their drugs were introduced are as critical to their impact as was their efficacy. Protected by tariffs that restricted the importation of German chemicals, American pharmaceutical manufacturers had thrived in the 1920s. They were a scientific business in an age when business itself was considered a science. Ironically, sulfa drugs, developed in Germany on the eve of

World War II, proved to be the catalyst for the rapid development of American pharmaceutical companies that supplanted Germany's domination of the scientific world in the postwar era.

When the Depression of the 1930s forced Americans to recognize some of the inhumanities of industrial capitalism, government regulation of business became to some extent a part of the American ethos. The debate over pharmaceutical regulation focused on the relationship of industry to the common good, including the ethics of patenting medical discoveries. Changes in food and drug regulations, as well as in the structure of the Federal Drug Administration, were part of a broader social agenda; but just as clearly, they were also partially shaped by sulfa drugs.

The history of sulfa drugs raises historical and historiographic issues about the role of science in society and in medicine. The development of the modern hospital has become synonymous with the idea of modern medicine, often obscuring the fact that the rise of laboratory medicine was a distinct event of its own.[2] In some ways, doctors considered themselves scientists before sulfa drugs were introduced, but the content of that science changed.[3] Sulfa drugs redefined the relationship between laboratory experimentation and clinical practice.

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[2] For an overview, see Andrew Cunningham and Perry Williams, editors, *The Laboratory Revolution in Medicine*, (New York: Cambridge University Press, 1992)

[3] For a more complex discussion, see John H. Warner, *The Therapeutic Perspective: Medical Practice, Knowledge and Identity in America* (Cambridge, Harvard University Press, 1986)

The economic aspect of medical developments in the 1930s is also critical. Social historians as well as business historians have identified the role of economics in the development and practice of medicine.[4] In his 1979 book Rockefeller Medicine Men, Richard Brown suggested that the medical profession viewed scientific medicine not only as effective technology, but also as a way to increase professional status and income.[5] His critics denounced the fact that he had removed the idea of science from the history of medicine. In one sense, this is a valid criticism, since Brown connects the rise of scientific medicine to industrial development and the fact that research was financed with the profits of industry without discussing the very real technological developments in basic research in the early twentieth century. The connection among science, technology, profit, and medicine is an extraordinarily complex one, as well as an important aspect of understanding the development of modern medicine. Sulfa drugs provide a critical case study for unraveling these interwoven threads.

In their 1979 essay, "Beyond the Great Doctors," David Rosner and Susan Reverby suggested the need to balance social history and the history of science.[6]

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[4] For example, see David Noble, *America by Design: Science Technology, and the Rise of Corporate Capitalism*, (New York: Knopf. 1977); Jonathan Liebenau, *Medical Science and Medical Industry: The Formation of American Pharmaceutical Industry*, (Baltimore: Johns Hopkins Press, 1987); Joel D. Howell, *Technology in the Hospital: Transforming Patient Care in the Early Twentieth Century*, (Baltimore: Johns Hopkins Press, 1995)

[5] Richard Brown, *Rockefeller Medicine Men: Medicine and Capitalism in America*, (Berkeley: University of California Press, 1979).

[6] David Rosner and Susan Reverby, "Beyond the Great Doctors," in *Health Care in America: Essays in Social History*, (Philadelphia: Temple University Press, 1979)

While it is generally acknowledged that there is a relationship between social construction and disease, the parameters of that relationship are continuously redefined, often in the context of general skepticism about the "scientific enterprise."

When, as intelligent observers, we examine contemporary health issues, we are quite aware of the complexity of disease. We understand illness to be an interaction of biological agents, economic and social factors. We are mindful of the fact that issues of class, race, and gender cannot be ignored. We accept that to some extent the relationship of science to medicine is equally complex. We examine it in a broader context, knowing that otherwise we cannot fully understand the situation.

Similarly, the only way to explore the impact of sulfa drugs is in the broadest of historical frameworks. Their importance lies in the intersection of social history, business history, the history of science and of medicine, and of politics and government regulation. Their efficacy does not tell the whole story, nor does their profitability. They changed medical practice, but just as importantly they changed public expectations. Once the laboratory had developed one miracle, the public expected more. Once doctors felt that technology increased their status, rather than de-skilling them, they greeted new developments with enthusiasm. Once pharmaceutical companies found that the cost of supporting research could pay off, they were willing to spend more, and once they were willing to spend, academic pharmacologists began to look to them for funding.

The history of sulfa drugs is one of overlapping stories, and the picture only emerges when each is examined. For that reason, this study peels the layers apart and explores each individually. The first chapter examines the historical context into which these drugs appeared. The second chapter moves back in time to explore the beginnings of the chemical industry in the United States. The government played a critical role in protecting the infant industry by manipulating tariffs and patent law to the advantage of American chemical companies. During the First World War, it was not so much science as political and economic developments that made the spectacular growth of the American chemical industry possible.

The third chapter is concerned with physicians. The culture of medical practice and education shaped the ways in which sulfa drugs were used even as the drugs themselves changed medical care and treatment outcomes. Medical authority is a mediated relationship between patients and doctors, so this section examines the expectations that the lay public had of physicians before the introduction of sulfa drugs, and the ways in which those expectations were changed once sulfa drugs became available.

The fourth chapter examines pharmacy, pharmacology, and the drug industry before the advent of miracle medicines. Academic pharmacology was a developing discipline in the United States. In the first decades of the twentieth century it held itself aloof from the commercial drug industry, which was associated with unscientific nostrums and with profits rather than science. Sulfa drugs changed that relationship. Indisputably the products of the research

laboratory, they helped forge new bonds between industry and academic science. Sulfa drugs made drug companies respectable members of the healthcare industry. They also provided a bridge between pharmaceutical companies and physicians. After the advent of sulfa drugs, patients needed them both—the drug to cure the disease and the doctor to prescribe it.

The fifth chapter discusses the role of the government in regulating health care. Consumer advocates and public health officers had been trying to gain some measure of control over the pharmaceutical industry long before the introduction of sulfa drugs. As more sophisticated medications were developed, their concerns had grown. Untested and unregulated drugs were sold freely. Some were useless and others were dangerous. In addition to the dangers of these nostrums, public health physicians feared patients were not seeking medical help and were ineffectually self-medicating instead. Sulfa drugs provided the demonstration of these dangers and convinced Congress to provide some form of government regulation.

The fifth chapter describes the events surrounding the poisonings of over 100 people by the Massengill Company's over-the-counter and tested sulfa drug. The surrounding publicity moved long-stalled legislation out of committee and onto the floor of Congress. The Food and Drug Administration shepherded the legislation that became the 1938 Pure Food, Drug and Cosmetics Act through Congress, while responding to pressures from the industry, organized medicine, irate consumers, and citizens concerned about the expanding power of the Federal government.

The sixth chapter of this study is concerned with the aftermath of the passage of the 1938 law, and the attempts of the Food and Drug Administration to deal with their new responsibilities. The era of miracle medicine had arrived, and it brought with it new demands from physicians, from the lay public, and from the drug industry. It did not bring a larger budget or significantly strengthened regulatory powers.

The concluding section focuses on the fact that although it seemed in the 1930s that a new age had dawned and that the conflicts within medicine had been resolved, the age of miracle medicine turned out to be just one chapter of an ongoing tale. Thirty years after the introduction of sulfa drugs, doctors were, once again, faced with challenges to their authority from a public that felt betrayed or, at least, disillusioned. The laboratory was, once again, regarded with suspicion. And, perhaps most importantly, disease had not been conquered after all. The age of miracle medicine turned out to be just another social construction. We don't have miracles anymore, we have advances—and they always come coupled with warnings about false expectations.

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Chapter 1 Miracle Medicines: How One Drug Meant So Many Different Things To So Many Different People

On July 1, 1924, Calvin Coolidge, Jr., the 16-year-old son of the President, played a game of tennis on the White House tennis courts. He developed a blister on the big toe of his right foot, but thought nothing of it. The next day he was in some pain, and the following day, he felt worse. His doctors suspected he might have appendicitis. They ignored the blister, and "the small wound, showing no signs of infection, concealed the bodily ravages it had created."[1]

The boy's condition declined still further, and three days after his tennis game, he was operated on at Walter Reed Hospital in a desperate attempt to save his life, "which has been in great danger due to septic poisoning." The operation involved "slicing the flesh of the lower left leg to the bond and inserting drains through which the poison was to be carried off." The President's secretary announced to the waiting press that the operation had been a success. "There was nothing to do now...except to wait...and watch what progress his vitality could make in the fight for his life."[2]

By the next day, Calvin, Jr., was so ill that "only a miracle could save his life." His doctors, "experts who were with him every moment," would not venture a prediction. This was the moment when his "ordered and carefully disciplined life" was his best protection. "He has the morale to fight successfully if he can muster the strength." There was little that the doctors could do. They

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[1] "Surgeons Operate on President's Son," *The New York Times*, 6 July 1924, sec. 3,1.

[2] Ibid.

could not alter the outcome of the boy's illness; they could only predict its course. The case had become "a battle between the white corpuscles and the bacteria," and there was no medical way to further intervene. Letters and telegrams of condolence and advice flooded the White House. While some came from dignitaries and politicians, many were "from ordinary individuals in whose families such an illness as Calvin's had occurred." His parents, his doctors, and the nation were "watching...to see whether the white corpuscles were able to do the work of fighting the poison germs."[3]

They were not. At 10:30 p.m., despite the efforts of the "seven principal physicians [who] concentrated their talent and experience" to save him, the "bright and lovable sixteen-year-old son of the President and Mrs. Coolidge" died at Walter Reed Hospital of septicemia. It was less than one week after his tennis game.[4]

Twelve-and-a-half years later, in late December 1936, Eleanor Roosevelt rushed to the bedside of her son, Franklin, Jr., who was stricken with "sinus trouble" and a "septic sore throat." Doctors feared that the streptococcus bacteria might enter Roosevelt's bloodstream and, as Time Magazine writers explained in the December 28, 1936 issue, "In such a situation, a rich and robust Harvard crewman is no safer from death than anybody else."[5]

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[3] "President's Son, Calvin, Jr., 16, Dies as Parents Watch," *The New York Times*, 7 July 1924, 1.

[4] "Grave Fears Felt for Coolidge's Son, Fighting For Life," *The New York Times*, 8 July 1924, 1.

[5] "New Drug Arrests Roosevelt Jr.'s sinus Trouble," *Newsweek*, 26 December 1936, 8.

Strictly speaking, that was not entirely true. There were some significant differences between the Roosevelts and "anybody else." Unlike most Americans, the concerned First Lady was able to call upon the skills of Dr. Perrin H. Long, a physician and investigator at Johns Hopkins University who, she had been informed, was the American expert on a new German drug, Prontosil. The drug had already been in use in Europe for over a year. After consultations with Roosevelt's personal physician, Dr. George Loring Tobey, Jr., the President's son was injected with Prontosil, which was the first sulfonamide, or sulfa drug. American doctors had little experience with Prontosil and, in fact, were somewhat suspicious of the product that was reported in the popular press, incorrectly as it happens, to affect the production of white blood cells in an unknown, and potentially destructive process. Time explained the reluctance of physicians to use the drug because, "whatever [a drug] stimulates [it] may also destroy."[6] Roosevelt's doctors went ahead, however, and used the "new chemotherapeutic agent to ameliorate the streptococcus infection." This President's son survived, "thus providing an auspicious introduction for a product about which U.S. doctors have known little."[7]

Within a few years, in fact, almost "every mother's son" in the United States would have access to these drugs, and many thousands would survive infections that previously would have killed them. In the twelve years between these two Presidents' family case studies, there was a significant technological

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[6] "Prontosil: Cure for Streptococci Infections," *Time*, 28 December 1936, 21.

[7] "Roosevelt Jr.'s Sinus Trouble."

transformation in the practice of medicine, which accounted for these different outcomes and ushered in a new era in medicine. The development of sulfa drugs marked the opening of what some quickly called the age of "miracle medicine" in which, seemingly overnight, a host of infectious diseases were no longer terrifying death sentences but treatable illnesses. Sulfa drugs were the first effective anti-infective agents to come out of the pharmaceutical laboratory. Many others would soon follow them.[8]

The fact that these drugs sharply reduced mortality from infectious disease is itself enough to make them of historical importance. The "age of miracle medicine," however, is a social construction involving much more than an efficacious therapy. The cultural importance of sulfa drugs lies in the impact they had on the social, political, and economic world into which they were introduced. In turn, sulfa drugs would not have been so miraculous if it were not for the social and political, as well as the scientific, changes that were occurring in the United States at the moment when they were introduced. Through this intersection of technology and economic and cultural transformation, sulfa drugs were catalysts for changes in the practice of medicine, the pharmaceutical industry, and government regulation of health, which were significant and based on more than

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[8] Erlich had popularized the term "magic bullet" earlier in the century, with his discovery of a drug to treat syphilis. He predicted that soon other drugs would be found to treat other diseases. No other weapons followed Salvarsan (synthesized in 1909), and eventually both the lay public and much of the medical profession had given up hope. When sulfa drugs appeared, they were quickly labeled "miracles" in the popular press. In early reports of their use, even professional journals referred to them as "astounding" and "miraculous." To cite one example, "Great discoveries in chemotherapy are rare...We must then regard (the development of sulfa drugs) as the opening of a new era. Barclay Newman, *Scientific American*, June 1939, 362.

just a new class of drugs, however effective they may have been. It was this combination of a technological development and a culture so profoundly in transition that made the introduction of sulfa drugs a significant event in the social history of medicine and pharmacology.

"Miracle drugs" affected patients as well as medical practitioners. Their introduction led to a radical change in the expectations of lay people about the role of physicians. The public quickly began to assume that doctors, aided by laboratory science, could and would conquer disease. The patient no longer had to rely, as had Calvin Coolidge, Jr., on his or her own "moral fiber" for survival. Instead, the patient could count on assistance in the battle against disease from the pharmaceutical technology newly at the disposal of his or her doctors. With the development of sulfa drugs, doctors could intervene in the course of infectious disease. Patients and the popular press increasingly expected them to do so, and do so successfully. As one 1938 article described it, "Fourteen major victories over disease within three years...and the end is certainly not yet in sight, for fresh victories are reported in almost every issue of medical journals the world over..."[9]

Because modern cures relied on laboratory-produced therapeutics, sulfa drugs helped forge new relationships between physicians and pharmaceutical companies. Patients demanded to be treated with the most up-to-date modern medical miracles. Doctors had to know about drugs as soon as they were introduced and had to know how to use these new potent drugs and those that so quickly followed. Thus, these drugs also carried with them new obligations for

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[9] June Stafford, "Life-Giving Dye," *Science Newsletter*, December 1938, 362.

physicians and for medical training. As the New York Times editorialized in 1936, "the lesson from Roosevelt's illness is to make sure your doctor stays current with the medical literature."[10] Calvin Coolidge, Jr.'s doctors had wisdom and experience—but he died. Franklin Roosevelt, Jr.'s doctors had the cutting edge technology of the scientific laboratory at their disposal and he survived. The romance of these potent drugs appealed to the public as an example of the hope contained in modernity and progress. As one lay medical writer put it: "There is all the difference in the world between the pills given to my grandfather and the pills that my little daughter takes today." That difference transcends mere technology. "The twentieth century doctor protects my little girl with a single magic bullet, aimed straight at the exact devil that tries to harm her."[11]

The relationship between laboratory science and clinical practice was, and is, constantly renegotiated. The extent to which physician authority is rooted in science is always fluid, but there were several specific reasons why these were critical issues in the United States in the 1930s. The Roosevelt Administration was extending the regulatory powers of the government in many directions, including that of healthcare and the pharmaceutical industry. Most of the programs under discussion had been developed by "New Dealers" who were rarely physicians. Their interest was in social reform and the practice of government, not in medicine. Physicians, however, were dismayed at what they perceived to be an erosion of their authority. At the same time, physicians'

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[10] *The New York Times*, 29 December 1936, 22.

[11] Milton Silverman, *Magic in a Bottle*, (New York: Macmillan Company, 1941), xi.

incomes had declined because of the Depression.[12] Many patients were relying on self-medication and patent medicines because they simply had no financial alternative. Physician concern over patent medicines was not new, but threatened with government interference on one hand, and a self-medicating public on the other, physicians had little choice but to stress the scientific nature of their profession as a way of holding onto their position. There were numerous conflicts among the public, the medical profession, drug companies, and the government, ranging from specific policy issues—for example, a national health insurance program—to critical public health questions such as the extremely high maternal mortality rate in the United States.[13]

A German chemist, Gerhard Domagk, who was employed by I. G. Farbenindustrie, a large chemical company, discovered Prontosil in 1932. He had been assigned the task of developing a "magic bullet" against streptococci, a major cause of death in women and children. The bacterium was the cause of a significant number of cases of puerperal septicemia, or childbed fever, which was the leading cause of maternal death.

The first major field trial of Domagk's drug took place in England in 1935 at Queen Charlotte's Hospital in London, which was a maternity hospital. The

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[12] Davis G. Johnson, *Physicians in the Making*, (San Francisco: Jossey-Bass Publishers, 1983, 12. Between 1929 and 1933 physician income had dropped 60 percent.

[13] In 1933 there were 6.2 maternal deaths for every 1000 live births in the United States. For comparative purposes, that same year, in Sweden there were 3.1 deaths. Frank G. Dickinson and Everett Welker, "Maternal Mortality in the United States in 1949," *Medical Economic Research*, vol. 144, no. 116, 1395-1400.

drug was used on women who had been diagnosed with serious cases of septicemia. There was no control group for this study. Only the sickest women were given the experimental drug, and the results were compared with the historical record. The gross mortality rate for septicemia patients had been 20% in the three years before the drug trials began. The mortality rate among the patients who were treated with Prontosil was 4.5%. Keeping in mind that only the acutely ill had been given the drug, these startling results were an even more impressive statistic.[14]

In the 1930s, more than 20,000 women a year died in the United States from childbirth complications, the overwhelming percentage of which were septicemia.[15] Doctors were aware of the problem, and so were the lay public and the popular press. "Even a normal childbirth leaves mothers severely wounded," as a Newsweek article explained, "...but let there be an invasion of streptococci—and a grisly tableau starts unfolding..."[16] What was particularly alarming was the fact that—despite the "modernization" of medicine, which had begun thirty years earlier in the Progressive period and the ongoing development of new gynecological techniques and practices—these numbers were actually rising. For example, in one study in 1910, the maternal mortality for women between ages

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[14] G. F. Gibberd, "Prontosil and Similar Compounds in the Treatment of Puerperal Hemolytic Streptococcus Infections," *British Journal of Medicine*, 9 October 1937, 695.

[15] Irvine Loudon, *Death in Childbirth: An International Study of Maternal Care and Maternal Mortality*, 1800-1950, (Oxford, England: Oxford University Press, 1992), 254-258.

[16] "Streptococci: A Reddish Dye Comes to the Aid of Childbirth," *Newsweek*, 27 June 1936, 42.

20-24 was 337 deaths per 100,000 live births. By 1930, it had climbed to 487 per 100,000 live births.[17] Another study showed a maternal mortality rate of 6.1 in 1915, while in 1927 it was 6.7 per thousand births. More than 40 percent of these deaths were due to infection. In Massachusetts in 1901, there were 3.8 deaths per thousand live births, and in 1924 the rate was 5.8 per thousand live births.[18]

In attempting to interpret these figures, it is clear, particularly in retrospect, that there are a number of possible explanations. The most obvious is that there are a number of possible explanations. The most obvious is that there were changes in the way in which deaths, as well as the causes of death, were reported. Efforts at standardization and institutionalization of such reports were, of course, ongoing. An act of Congress in 1893 had provided for the weekly collection of data from state and municipal authorities. In 1902, the Surgeon General established an annual conference to discuss methods of standardizing reporting of mortality and morbidity. In 1912, the Public Health Service began organizing the data nationally and published annual reports.[19] To be sure, these methods were, and are, continuously revised; the collection of statistics did not undergo particularly radical changes in the 1930s. Nor did physicians, while noting that it might be possible to attribute some of these results to revised

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[17] Charles King, "The New York Maternal Mortality Study," *Bulletin of the History of Medicine*, no. 65 (Winter 1991), 482.

[18] John Osborn Polak, M.D., "Puerperal Morbidity and Mortality with Especial Reference to the Effects of Previous Infection and Operative Delivery," *Journal of the American Medical Association*, vol. 93, no. 19 (November 1929), 1436-1437.

[19] Carl C. Daver, Robert F. Korns, and Leonard M. Schuman, *Infectious Diseases* (Cambridge: Harvard University Press, 1968), 7-8.

definitions or increased reporting standards, feel that the rising mortality rate could be responsible for the problem. In fact, one study concluded:

> Such statistics in the face of the advances made in prenatal study...suggest that women are not receiving clean or scientific intrapartal care, and that something is wrong with the teaching and training given to the undergraduate.[20]

Contemporary studies also made it clear that the safest births were at home, attended by a well-trained midwife.[21]

When the New York Academy of medicine Committee on Public Health Relations published its own extensive study of maternal mortality in New York City in 1933, it attributed many maternal deaths to physicians. Many doctors were outraged by the Committee's report. Their distress was caused not only by the conclusions reached by the Committee, but also by the fact that the report had been released to the public. So great was the outcry that a few months later, the Academy released a second report emphasizing that the problem lay not with properly trained obstetricians but rather with general practitioners.[22] Clearly, this reflects a division within the profession over the issue of specialization. While many doctors used the findings of maternal mortality statistics to emphasize the

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[20] Polak, "Puerperal Morbidity and Mortality," 1436.

[21] King, "New York Maternal Mortality Study," 489. There were a number of studies done during this period, all of which came to the same conclusions. See, for example, Ransom S. Hooker and James Miller, *Maternal Mortality in New York City, A Study of All Puerperal Deaths*, 1930-1932 (New York: Oxford University Press, 1933). "Frances C. Rothert, *Obstetrics and Gynecology*, no. 26 (1933), 279-290. "Maternal Mortality in Philadelphia," reprinted in *Classics of Obstetrics and Gynecology*, (New York: Classics of Obstetrics and Gynecology Library, 1991).

[22] King, "*New York Maternal Mortality Study*," 490-491. Hooker and Miller, *Maternal Mortality in New York City.*

importance of obstetrical specialists, not everyone agreed. In fact, in the minds of some, obstetricians were part of the problem, not the solution. The author of one article published in the Journal of the American Medical Association suggested, "Much of the present day mortality...is directly the result of...prominent obstetricians who have been busy inventing operative procedures..."[23]

There were other, though separate, variables. For instance, considerable effort had been expended in the first decades of the twentieth century in a successful effort to convince women, especially middle-class women, to have their babies in hospitals. By 1935, the percentage of women who were having hospital deliveries had risen to 70%.[24] The movement to make childbirth an institutionalized medical procedure had numerous implications. As historian Judith Waltzer Leavitt pointed out, "Physicians could not come into the birthing room and do nothing.[25] The frequency of cesarean sections and the enthusiastic use of forceps were contributing factors to the high rate of maternal death. "...[A]

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[23] Polak, "Puerperal Morbidity and Mortality," 1437.

[24] Irvine Loudon, "Maternal Mortality 1880-1950" *Society for the Social History of Medicine*, 1988, vol. I., no. 19. For a general discussion of the history of childbirth in the United States see, among other sources, Pamela S. Eakins, ed. *The American Way of Birth*, (Philadelphia: University of Pennsylvania Press, 1986). Judith Waltzer Leavitt, *Brought to Bed: Childbearing in America 1750-1950*, (New York: Oxford University Press, 1986); Richard Wertz and Dorothy Wertz, *Lying-In: A History of Childbirth in America*, (New York: Free Press, 1977).

[25] Judith Waltzer Leavitt, "Science Enters the Birthing Room: Obstetrics in America Since the Eighteenth Century," *Journal of American History*, 70 (1983): 295.

tendency to resort frequently to surgical procedures to assist or complete the delivery of the child has been developed.[26]

One reason for the high rate of forceps use was the increasing use of anesthesia in childbirth, which, as Leavitt put it, not only freed women from pain but also "enhanced the place and role of physicians in birthing rooms across America."[27]

Science and germ theory had revealed the cause of septicemia decades earlier; and yet in the 1930s, physicians admitted that "next to unclean operative intervention, cross-infection is probably the commonest cause of obstetric fever. The obstetrician must remember that the eleven sources of infection are his ten fingers and his throat."[28] While a midwife can convey septicemia from one patient to another, the physician, who cares for many kinds of infectious cases, is more likely to "carry infection to a parturient patient by way of his hands or clothes."[29] Childbirth in the United States in the first decades of the twentieth century had been professionalized and modernized. It had been made scientific, but it hadn't been made safe.

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[26] R. W. Holmes, M.D., R. D. Mussey, M.D., F. L. Adair, M.D., "Factors and Causes of Maternal Mortality," *Journal of the American Medical Association*, vol. 93, no. 19 (November 1929), 1440.

[27] Leavitt, 292. See also Pamela S. Summey and Marsha Hurst, "Ob/Gyn on the Rise: The Evolution of Professional Ideology in the Twentieth Century," *Women and health 11*, no. 1, (1986): 133-145.

[28] Polak, "Puerperal Morbidity and Mortality," 1439.

[29] Holmes et al., "Factors and Causes of maternal Mortality," 1441

There were exceptions to these distressing statistics, and that fact can be seen as one way to understand the cause of the problem. For example, New York Lying In Hospital had a much lower mortality rate than other contemporary institutions. Its mortality rate never rose above four per thousand live births, and in 1928 it dropped to 2.2 deaths per thousand live births.[30] One reason for the difference may have been the firmly non-interventionist policy of the hospital. While other studies found that forceps were used in more than 12% of patients, the rate at New York Lying In was less than 3%.[31] Students were also instructed to use scrupulous aseptic technique and avoid unnecessary internal examination.[32] What these figures make clear is that it was possible to significantly reduce the maternal mortality rate through methods that were known and understood by the 1930s, but steps had not been taken to do so in most cases. Hospitalization, and the attempts on the part of physicians to discourage the use of midwives, had actually been, in many cases, counter-productive.

In the late 1930s the maternal mortality rate began to drop sharply. The maternal mortality rate in 1941, by which point sulfa drugs were in common use,

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[30] Polak, "Puerperal Morbidity and Mortality," 1438. Nancy Scrom Dye, "Modern Obstetrics and Working Class Women: The New York Midwifery Dispensary, 1890-1920," *The Journal of Social History*, vol. 20, no. 3 (1987): 559. A random sampling of case studies from 1924 included no deaths from septicemia, though there were two deaths from other causes and only four cases of infection that seriously extended the length of hospitalization.

[31] Holmes et al., "Maternal Mortality," 1444. Dye, "Working Class Women," 557.

[32] Polak, "Puerperal Morbidity and Mortality," 1438.

had dropped to 3.2 per 1,000 live births.[33] So rapid was this decline that the maternal mortality rate in 1950 was only one-fifth of that in 1935.[34] The major reason, though not the only reason, was the invention of sulfa drugs. More than 80% of the fall in total maternal mortality between 1934 and 1940 was due to a reduction of deaths from puerperal sepsis.[35] Not only had the mortality rate fallen, but so had the length of hospital stays for infected women—so that instead of remaining in the hospital for weeks or months after the birth of their children, the women were home in days. "First to go down before the onslaught of sulfanilamide...is the childbirth horror, puerperal fever. This dreaded sickness that used, so often, to make motherhood a death sentence..."[36]

The public focused on the miraculous nature of the drug as a way of saving women's lives and, indeed, so did many general practitioners. It is clear that the maternal mortality rate could have been reduced in other less dramatic ways, but in most cases, that simply did not occur. Sulfa drugs were developed and embraced and the problem was solved, changing not just the practice of

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[33] Dickinson and Walker, "Maternal Mortality in the United States in 1949," 1395.

[34] Loudon, *Death in Childbirth*, 254. In another study of maternal mortality, "Puerperal fever, the streptococcus, and the sulphonamides, 1911-1945," *British Medical Journal*, 298, (August 1987) 485-490, Loudon examines other possible causes for the drop in mortality, acknowledging that critics have questioned whether or not sulfa drugs were responsible. He concludes that in correcting for socioeconomic conditions, differences in after prenatal care, and other medical technology and hospital delivery protocol the precipitous drop in puerperal mortality can only be attributed to sulfa drugs and, later, to antibiotics.

[35] Ibid., 258.

[36] Stafford, "Life-Giving Dye," 362.

medicine, but the culture of medicine. The infection rate could have been reduced with rigorous antiseptic measure, and by less invasive obstetrical treatment, but it was not. Ironically, in fact, with these new drugs, physicians were able to intervene more radically in childbirth and in other kinds of surgery, because of the reduced risk of fatal infection. The parameters of the proviso to "do no harm" had changed.

The next use of the drug was in the treatment of childhood and infant diseases. Again, mortality rates and the secondary complication rates from these infections dropped immediately and dramatically. For example, a 1937 study of the treatment of meningococci meningitis with sulfa drugs reported a 91% survival rate. The alternative treatment, an antiserum therapy, had a survival rate of 15%-70%, depending on the age of the child.[37] This had an immediate impact on all parents, including, presumably, those who had written to the Coolidges in 1924 and who understood exactly what it was like to sit by the bedside of a sick child and watch that child die. Suddenly, and it did seem to have happened suddenly, doctors were no longer merely observers and predictors of the course of infectious disease—they could now intervene.

In 1982, the great American physician, William Osler, had written about rheumatic fever, a secondary streOptococcal infection, that "medicine has little or no control over the duration or course of the disease, which like other self-limited

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[37] W. Michael Shild and Gerald L. Mandell, "Sulfonamide and Meningitis," *Journal of the American Medical Association*, vol. 251, no. 6, 10 February 1984, 791. For a lengthy discussion of the treatment of children's diseases, see "Roundtable Discussion of Sulfanilamide," *Journal of Pediatrics*, vol. 13, no. 4, October 1938.

afflictions, practically takes its own time to disappear."[38] Perrin Long concurred, writing that "by 1930 it was the almost universal opinion of physicians that nothing could be discovered which would be effective against the ordinary diseases produced by bacteria."[39]

Then came sulfa drugs and, as an article in Scientific American explained, physicians suddenly had enormous new powers. "Suppose you were an officer of the law charged with the duty of arresting the Purple Gang...[and] you have a magic revolver loaded with charmed bullets." According to the article, this is what "physicians who use chemotherapy with care and intelligence can often accomplish." And using their "chemically charged bullet," doctors were now "shooting it at the gangster germs that cause childbed fever, meningitis, pneumonia..."[40]

The popular press saw the dramatic possibilities as endless. "A six-year-old girl lay on a hospital bed gasping for breath...the girl was suffering from spinal meningitis and this almost invariably fatal disease in such an advanced stage usually causes death within a few hours." But the child in question did not

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[38] William Osler, *Principles and Practices of Medicine*, reprinted in *Osler's Textbook Revisited;* a reprint of selected sections with commentaries, A. McGehee ed. (New York: Appleton Century-Croft, 1967).

[39] Iago Galdston, introduction by Perrin Long, *Behind the Sulfa Drugs: A Short History of Chemotherapy,* (New York: Appleton Century-Croft, 1943), VII.

[40] T. Swann Harding, "Chemotherapy and Prontosil," *Scientific American* 158 (January 1938), 28-29.

die, because doctors "carefully injected" Prontosil into her "tissues" and she recovered.[41]

The response to sulfa drugs from the lay public both reflected and created a growing public expectation about the value of the progress that could be made by the pharmaceutical laboratory. In some ways, doctors benefited from this, but many doctors resisted, at least initially, the new chemotherapeutic technology-seeing it as a challenge to their judgment and authority. The relationship between laboratory science and medicine remained ambivalent through the Second World War. To some degree, the biomedical discoveries that changed medicine occurred during the first decades of the twentieth century and simply could not immediately be integrated into the medical curriculum.[42] Several emerging scientific disciplines found themselves in conflict with physicians during the early twentieth century as a result of the ways in which it seemed to physicians that "laboratory science was transforming medicine."[43] An examination of reaction among physicians to the advent of sulfa drugs reveals many of these dichotomies. At the root was a fundamental belief that "regular" physicians, using a variety of

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[41] John Pfeiffer, "Sulfanilamide: The Story of a Great Medical Discovery," *Harper's Monthly*, vol. 178, (March 1939), 386.

[42] In particular, significant changes in biochemistry and pharmacology both in terms of content and methodology changed during these years as these disciplines developed in the United States. These disciplines matured earlier in Europe, so the effects may have been felt there sooner.

[43] John Parascandola, *The Development of American Pharmacology*, 132. See also *Therapeutic Revolution*, particularly Russell Maulitz's article on bacteriology "Physician versus Bacteriology: The ideology of Science in Clinical Medicine," 91-107; and Gerald Geison's article on physiology, "Divided We Stand: Physiologists and Clinicians in the Medical Context," 67-90.

skills, diagnosed each patient on a case-by-case basis and prescribed medications particularly designed to the individual. They used this to provide a contrast between themselves and "sectarian" physicians who, they argued, used one cure for everything.[44] Regular physicians also discouraged self-medication and the use of patent medicines as medically unsound and as potentially dangerous, in part because of the potential toxic effects of these preparation, as well as the belief that self-medicating patients would not see a physician until it was too late.

When sulfa drugs came along, they seemed to many doctors, at least on first inspection, to be yet another nostrum that was being touted as a cure for everything from scarlet fever to gonorrhea. They were sold over the counter. They seemed almost designed for self-medication, and they threatened to de-skill doctors in favor of the pharmaceutical laboratory. While to some physicians these drugs represented a new threat to their professional standing, in fact, the reverse actually occurred. Instead of de-skilling doctors, sulfa drugs proved invaluable to ongoing attempts within the profession to secure status within American society. These new and potent drugs had side effects, carrying with them their own potential risks. The organized medical profession immediately and continually warned the general public that these drugs were too powerful and too dangerous to be used without medical supervision, and events soon seemed to prove them

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[44] There is an extensive historiography on this topic. To list only a few examples, see John Duffy, *The Healers: A History of American Medicine*, (Urbana: University of Illinois Press, 1976), Paul Starr, *The Social Transformation of American Medicine* (New York: Basic Books, 1982), William G. Rothstein, *American Physicians in the Nineteenth Century: From sects to Science* (Baltimore: Johns Hopkins University Press, 1972), John Harley Warner *The Therapeutic Perspective: Medical practice, Knowledge and Identity in America*, (Cambridge: Harvard University Press, 1986).

right. In 1937, and over-the-counter sulfa preparation, Elixir of Sulfanilamide, caused the deaths of more than 100 people before it was withdrawn from the market. Physicians were vindicated.[45]

Sulfa drugs and the Elixir tragedy played an important role in politics as well as medicine. For decades there had been tension between public health officials and organized medicine.[46] The medical community resented what they saw as outside interference in the practice of medicine; but they were unable to totally suppress public interest in reform in the late 1920s, and were even less able to do so after Roosevelt was elected to the Presidency in 1932. The role of government as the protector of the consumer emerged more clearly in these years.[47] As one physician wrote, "The interest in public health may be, and

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[45] The fact that many of the victims of the Elixir were taking the drug per a doctor's instruction was quickly obscured by the American Medical Association, which, by 1937, when the poisonings occurred, had thrown their support behind the political forces trying to reform drug laws. Accounts of the Elixir poisonings can be found in James Harvey Young, "Sulfanilamide and Diethylene Glycol" in John Parascandola ed., *Chemistry and Modern Society*, (Washington, D.C.: American Chemical Society, 1983), 105-125; Charles O. Jackson, *Food and Drug Legislation in the New Deal*, (Princeton: Princeton University Press, 1970), 151-175.

[46] For an excellent general discussion about tensions between public health officials at the turn of the century, which provided the context of the 1930s' struggle over regulation of health care, see Barbara Gutmann Rosenkrantz "Cart Before Horse: Theory, Practice and Professional Image in American Public health, 1870-1920" *Journal of the History of Medicine* (January 1974), 55-73. See also Elizabeth Fee and Barbara Rosenkrantz, "Professional Education for Public health in the United States," in Elizabeth Fee and Roy M. Acheson ed., *A History of Education in Public health*, (New York: Oxford University Press, 1991).

[47] There is an extensive historiography on the New Deal. A few examples include Alan Brinkley, *The End of Reform: New Deal Liberalism in Recession and War* (New York: Knopf, 1995); Alan Dawley, *Struggles for Justice: Social Responsibility and the New Deal* (Cambridge: Harvard University Press, 1991);

probably is, an indication of the social impulse which is fast finding expression in the law."[48] Legislation regulating food, drugs, and cosmetics was drafted and supported by a coalition of regulators within the government, public health advocates, and consumer groups, especially women's organization. Some doctors, for both professional and political reasons, resented fiercely the idea that the government in this case the Food and Drug Administration, would serve as an alternative authority, which challenged the role of organized medicine. Eventually, the American Medical Association changed tactics and began to try and shape legislation in ways that were agreeable to the physicians; but such questions as what would be the role of the government, what would be the purview of the drug industry, and to what extent medicine would be regulated, remained contested. Efforts at reform legislation were stalled until the public outcry that surrounded the deaths from Elixir of Sulfanilamide provided sufficient pressure to force passage of some form of regulation. Sulfa drugs then provided the catalyst for a significant piece of legislation, and for the distinct changes in the role of the Food and Drug Administration that followed in the years immediately following its passage. Doctors had lobbied hard to make sure that any legislation

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Steve Fraser and Gary Gerstle, ed. *The Rise and Fall of the New Deal* 1933-1980 (Princeton: Princeton University Press, 1989); Otis Graham, *Encore for Reform: Old Progressives and the New Deal* (New York: Oxford University Press, 1967); William Leuchtenburg *Franklin D. Roosevelt and the New Deal* (New York: Harper and Row, 1963); Harvard Sitkoff, ed. *Fifty Years Later: The New Deal Evaluated,* (New York: Knopf, 1985).

[48] John C. Krantz, ed. *Fighting Disease with drugs – The Story of Pharmacy* (Baltimore: Williams and Wilkins Company, 1931), 181.

conformed to their firm belief that the potent products of the pharmaceutical laboratory needed to be in the hands of doctors, not laymen or not bureaucrats.

Nevertheless, the 1938 law provided the government with an official role in what drugs doctors could, and could not, prescribe; and what drugs would and would not be available and to whom. In addition to restricting the sale of potentially toxic preparations, the government had other powers. Previously only the sale of opiates, poisons, and—during Prohibition—drugs containing alcohol had been restricted to patients with a doctor's prescription. Everything else could be purchased over the counter. With the 1938 law, new categories of non-narcotic prescription drugs were created. Included immediately were sulfa drugs, which, after the passage of the law, could not be purchased without a doctor's prescription.[49]

The 1938 law shaped the way in which sulfa drugs were used, and to an important extent, the dilemma presented by sulfa drugs shaped the law. As a result of the interaction, the nature of the regulation of pharmaceuticals was changed.[50]

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[49] For a brief but comprehensive overview of these laws, see james harvey Young, "Federal Drug and Narcotic Legislation," *Pharmacy in History*, vol. 37, no. 2, (19950 59-67).

[50] To some extent this temporarily resolved the tension between organized medicine and the government by recognizing physician authority, but doctors remained vigilant. Americans in the 1930s felt a personal connection to the government. Physicians were accurate in their perception that for some of the lay public the government itself represented an alternative authority for all aspects of life, including health care. For example, Mrs. D. S. Thornton wrote to the Food and Drug Administration in 1938 asking for a pamphlet about sulfa drugs but included other queries as well. She wanted to know if it was a good idea to keep on using the phenobarbital tablets that her doctor had prescribed for "sleeplessness due to nervousness." The pills, she complained, "cause a duncy

The first coal-tar chemicals were developed in Germany at the end of the nineteenth and beginning of the twentieth century. Aspirin was one of the first of these; but the next, and perhaps even more critical German medicinal in the first decades of the twentieth century, was Salvarsan, Erlich's "magic bullet," which was the most effective treatment available for syphilis. When World War I began, Germany restricted exports of Salvarsan and other critical coal-tar products. Even before the United States formally entered the war, Congress had authorized American companies to produce Salvarsan as a matter of national security.[51] When the United States did enter the war, the American government confiscated German property in the United States, including the trademarks and patents for many valuable dyes and medicinals that had previously been imported from Germany.[52] American companies produced these chemicals and profited both in the monetary sense, and in terms of the technological experience they gained. As part of the war effort, capital was invested in chemical companies in order to increase their production capacities. This provided a jump-start for an industry that, before the war, had lagged behind Germany, France, and England. By the beginning of the 1920s, American chemical companies were in the midst of enormous expansion. As one contemporary historian described it, "the abrupt

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feeling I do not like." She concluded by "thanking you kindly for all the help we are getting every day from the Farm and Home Hour." Mrs. D. S. Thornton to Food and Drug Administration, January 26, 1938, National Archives, Record Group 88, FDA General Correspondence file, 520-532.

[51] A detailed discussion can be found in Hearings Before the Senate Committee on Patents, 4 June 1917, 65-71.

[52] "Trading with the Enemy Act," June 1918.

snapping of the deeply laid lines of crude-drug supply; the imperative necessity of manufacturing here many medicinal chemicals...previously imported" had an important effect on the American chemical industry. These events "acted as an exhilarating firmament upon the manufacturing drug industry," particularly since German patents and processes were then sold to American chemical companies.[53] The chemical industry grew and prospered in the 1920s, and during the Depression the chemical industry was a stable, even profitable, sector of the economy. The development of sulfa drugs came at a second critical moment of transition from a rapidly growing to an established industry. Almost as soon as the first German studies of Prontosil were published, scientists at the Pasteur institute in Paris isolated the active ingredient in the drug, sulfanilamide. The patent on sulfanilamide had expired. The technology for producing sulfa drugs was similar to that used to produce coal-tar dyes, a technology that American chemical companies had developed during World War I. As a result, production of these new drugs was then easy, rapid, and inexpensive. sulfa drugs became a whole new class of drugs that were profitable and respectable. Their efficacy, combined with their laboratory origins, gave increased standing to the science of pharmacology and bolstered enthusiasm for the increased expenditures on research and development within the industry, which ultimately resulted in the increased dominance of American firms in the area of pharmaceutical research after World War II.[54] For the sector of the pharmaceutical industry that had been

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[53] William Haynes, *The American Chemical Industry* (New York: D. Van Nostrand Company), vol. III, 1943, (reprinted by Garland Publishing, 1983) 304.

working for decades to distance itself from the world of patent medicine, these drugs were invaluable tools. Until the 1930s, academic pharmacologists held themselves aloof from industrial research.

The idea of research for profit made them so uncomfortable that members of the American society for Experimental Therapeutics were not permitted to work for commercial drug companies. Sulfa drugs, straddling the worlds of legitimate academic chemistry and industry, helped close the gap and began to move the chemical industry in the direction of a new organizational model for the role of industrial research and a new legitimacy for drug companies. Initially, the development of sulfa drugs was slightly tarnished in some eyes. As one article in Harper's explained, the inventor "wasn't a famous scientist or a doctor devoting his life to humanity; he was...an industrial chemist employed by Germany's vast dye trust."[55] Within a few years, however, that perception changed, and by the end of World War II the relationship had become regularized and there was an institutionalized connection between academic and industrial organic chemistry.[56]

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[54] For a general overview see Jonathan Liebenau, *Medical Science, Medical Industry: The Formation of the American Pharmaceutical Industry.* (New York: Macmillan Press, 1987). Another useful source is Gregory J. Higby and Elaine C. Stroud, ed. *Pill Peddlers: Essays on the History of the Pharmaceutical Industry* (Madison: American Institute for the History of Pharmacy, 1990).

[55] John Pfeiffer, "The Story of a Great Medical Discovery," *Harper's* (March 1939), 391.

[56] For a more detailed discussion see Liebenau, *Formation of the American Pharmaceutical Industry,* (New York: Macmillan Press, 1987); Parascandola, *The Development of American Pharmacology,*; Parascandola, "Charles Holmes Herty" in John Parascandola and James C. Whorton, ed. *Chemistry and Modern Society* (Washington, D.C.: American Chemical Society, 1983); John Swann, *Academic Scientists and the Pharmaceutical Industry:*

In understanding the social significance of sulfa drugs, another important aspect of the popular context into which these drugs were introduced was their German origins. The articles reporting the success of sulfa drugs in saving Franklin D. Roosevelt, Jr.'s life commented on the drug's German roots. In a Collier's article about sulfa drugs called "Death to the Killer," the author explained that "the most killing creature at large on this earth" was a streptococcus germ. It "destroys Americans more rapidly than the highly efficient German army was able to during the nineteen months we were in the World War..."[57]

This ambivalence about Germany and growing suspicions about the possibility of a worldwide war benefited many American drug companies, especially those that were divisions of large chemical companies. The popular press warned that the American chemical industry needed protection, since it was possible that in the future supplies of important German chemicals might well be restricted. A 1936 article "Shortage of Coal-Tar Chemicals" (sulfa drugs were coal-tar chemicals, as were other medicinals such as aspirin and novocaine) warned that, "Germany has already placed [coal-tar chemicals] on embargo, and indicators are that at least one other country abroad will follow suit."[58]

Cooperative Research in Twentieth-Century America (Baltimore: Johns Hopkins University Press, 1988).

[57] J. D. Ratcliff "Death to the Killer" *Colliers*, 24 December 1938, 18.

[58] "Shortage of Coal Tar Chemicals," *Scientific American*, vol. 154 (May 1936) 264.

Americanizing sulfa drugs dissipated their unsavory origins quickly. In fact, the German discovery of the drug almost disappeared in popular descriptions. Harper's ran a major story on sulfa drugs in the late 1930s that never mentioned its German discoverer by name. The first five pages of the ten-page story concentrated on American clinical trials of the drug. It is not until page six that it is even mentioned that the drug was not developed in the United States. The production of sulfa drugs quickly became an act of patriotism. Their importance was used to justify the legislation that had protected the new industry during the 1920s with high tariffs and import restrictions.

Sulfa drugs were a watershed in the social and economic history of pharmacy, the chemical industry, the practice of medicine, and government regulation. They also served as a symbol, a catalyst—and a miracle.

> Chemotherapy is, to employ an all too common phrase, the miracle of miracles in modern medicine. But the truth is, it is no miracle at all...The achievement of modern chemotherapy is miraculous only in the sense that birth is miraculous. The event was long in gestation.[59]

The impact of the event far transcended its medical importance. To examine the introduction of these drugs is to examine social, political, cultural, and economic change as much as scientific development.

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[59] Perrin Long, introduction to Iago Galdston, *Behind the sulfa Drugs*, ix.

Chapter 2 The American Pharmaceutical Industry: Born in Wartime and Nurtured in a Depression

The story of sulfa drugs is as much about economics as it is about medicine. Their development is intertwined with that of the organic chemical industry in the United States in which they played a key role.[1]

In the United States, industrial organic chemistry was the product of politics as well as technology. During the First World War, presumably as a military measure, the American government suspended German patents and permitted American companies to manufacture previously protected German drugs and compounds. The chemical industry and its profits exploded, all in the interests of national security. The government continued to protect the nascent industry through the 1920s, and the connection between the economic success of the industry and its particular political protection continued until the Depression.

In the mid 1930s, Francis P. Garvan, president of The Chemical Foundation, an industry trade group, announced that the organic chemical industry was "firmly established in this country and...felt that the time was ripe for a compilation of the full record of that noteworthy accomplishment."[2]

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[1] Organic chemistry is the study of compounds containing carbon, including the reactions of inorganic substances with organic compounds. Biochemistry is the study of all chemical reactions that do or can occur in living, or once living, cells. This includes viri and the chemistry of parts of these organisms that may cause disease. Molecular biology is the study of biology from the viewpoint of the action and function of the molecules that are the components of living and once living organisms. (The overlap with biochemistry is obvious. Modern scientists tend to use the term molecular biology, and in fact the primary professional organization has changed its name to the American Society of Biochemical Chemistry and Molecular Biology.)

[2] Haynes, *The American Chemical Industry.*

Garvan's contribution to the industry was a significant one. As president of The Chemical Foundation, he had fought hard for government protection for the infant organic chemistry industry even before the end of World War I. He effectively lobbied Congress in the 1920s to institute embargoes and tariffs and "any other legitimate means that could further strengthen American Chemical enterprises."[3] Garvan firmly believed that the chemical industry had acted patriotically during World War I by manufacturing those chemical products previously imported from Germany, which had been protected by international copyright.

Furthermore, Garvan suggested that "stupendous effort in broadening and modernizing our whole chemical industry" could and indeed should serve as a case study for American industry and an important "practical lesson for American legislators and financiers, economists and historians, technical men and business executives for the whole American people."[4] In fact, an examination of the development of the organic chemical industry and the role that sulfa drugs played in that development provides a useful example of the "practical lessons" and methods used by a successful sector of the American economy in the 1920s and 1930s, illuminating a complex interaction among capital development, government regulation, science, and medicine. Garvan successfully used the industry's patriotic beginnings to justify its privileged position in the 1920s and the industry thrived. Even during the Depression they did relatively well. Between 1929 and 1937, thirty-eight of the forty-five leading American chemical

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[3] Ibid.

[4] Haynes, *The American Chemical Industry.*

companies paid out dividends. In fact, thirty-five of them paid larger dividends in 1937 than they had in 1929.[5] Not surprisingly the protected trade position enjoyed by the chemical industry created resentment during the Depression. Though they quickly raised the specter of growing German might, issuing warnings about becoming dependent once again on imported chemicals, pharmaceutical companies in particular, found themselves on the defensive. They were in a vulnerable position, because organic chemistry had not fulfilled the golden promise of the 1920s and the industry had used those promises as a justification for government protection. In fact, despite the excitement created by Erlich's magic bullet, that discovery began to be seen as an aberration, not a sign of what was to come. Discouraged, it seemed that "[by] the 1930s it was the almost universal opinion of physicians that nothing could be discovered which would be effective against the ordinary diseases produced by bacteria."[6] There were many who felt that given this lack of progress, the extraordinary protection and extraordinary lack of regulation of the chemical industry was unwarranted and unfair. Fortunately for the organic chemical industry sulfa drugs, miracle medicines, were coal-tar derivatives. They were produced in the same way as many chemicals and dyes and could be quickly produced by the very laboratories developed in response to the crises of World War I and protected ever since, thus

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[5] Haynes, *The American Chemical Industry*, 207-210. This is not to suggest that trade barriers were the only reason for the success of the chemical industry, to that the chemical industry was the only one to thrive. Many historians have pointed out that during the economic collapse of the 1930s certain sectors of the economy flourished for a wide variety of reasons.

[6] Long, *Behind the Sulfa Drugs*, vii.

justifying the privileged position of those industries. By the late 1930s, it was already clear to many that there would soon be another war, and sulfa drugs, medical miracles that they were, were a German product and the supply could be restricted in the event of war. Thus, the protection of domestic production became a legitimate matter of national security as well as a redemption of the promise of the chemical laboratory and efforts to build and strengthen organ chemistry in the United States.

Sulfa drugs were not the only important organic chemical discoveries of the period. Other critical coal-tar products included aspirin, novocaine and barbiturates. As one science writer explained in 1937, "Nature has filled the tar barrel with a lavish hand, and it has brought color and comfort to mankind. It is the philosopher's egg, the elixir of life of the modern alchemist."[7] The same writer went on to warn that though the roots of science might be philosophic, the production of the inventions of that science was a business, and a large business at that. "Coal-tar industrialism has grown too big for ethical control...every discovery of science is now tested in the counting house of commerce."[8] From its beginning the production of coal-tar chemicals in the United States was a mixture of science and big business. The two were inextricably bound together.

In Europe, particularly in Germany, the development of the discipline was slightly different. Historians of science generally suggest that the field of organic chemistry began in the 1860s, when the molecular structure of basic carbon

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[7] Victor Robinson, "Coal Tar Contemplations," *Science Monthly*, vol. 45 (1937), 354-356.

[8] Ibid.

compounds became clearly understood. In the second half of the nineteenth century, Germany expanded and improved its system of training chemists. It was these scientists who, in turn, founded an organic chemistry industry. Their research into coal-tar products, first through the establishment of a synthetic dye industry in the 1860s and 1870s led, after 1880, to a synthetic drug industry.[9] Aspirin (acetylsalicylic acid) was among the first and most successful of these pharmaceutical products. Erlich applied the principles of the dye industry in his search for drugs that would destroy protozoa or bacteria. Out of those methods, and as part of the same industry, he developed and patented an efficacious drug against syphilis--Salvarsan.[10] The German industry retained its connection to its scientific roots and was controlled by a technically trained directorate until the 1910s. The link between academic training and industry remained strong. Germany dominated the international chemical market and was almost exclusive worldwide producer of coal-tar based dyes, medicinals, and "fine chemicals" until the First World War.[11]

The chemical industry in the United States developed very differently. In the nineteenth century, American companies produced only heavy chemicals that were cheap and easy to produce and imported fine chemicals from Europe. There were American chemical companies, of course, producing, for example,

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[9] F. Sherwood Taylor, *A History of Industrial Chemistry* (New York: Aberlard-Schuman, 1957), 228-234.

[10] Ibid., 245-247.

[11] Ludwig Fritz Haber, *The Chemical Industry During the Nineteenth Century: A Study of the Economic Aspect of Applied Chemistry in Europe and North America* (Oxford: Oxford University Press, 1958), 142-144.

production of gunpowder. One of the first was the Du Pont powder mills, which were founded in 1802 and began supplying the federal arsenals as early as 1816.[12] Even in the nineteenth century, however, economic organizational issues and questions about competition and monopoly were factors in the chemical industry. A glut of gunpowder on the market after the Civil War led to the formation of the Gunpowder Trade Association in 1872 through which the principle manufacturers divided up the country into exclusive sales districts. Within a few years, progressive reformers began objecting to the Association as restricting trade. As it happened, by the time anti-monopolist opposition to the Gunpowder Trade Association surfaced, the chemical companies had already begun to diversity and the issue was diffused. American companies began producing inorganic chemicals used in petroleum production, such as nitric and sulfuric acids, which were relatively simple to make and cheap to produce but expensive to transport.[13]

With such industrial and relatively unsophisticated technology origins, there was not the same impetus in the United States for strong connections between the academic training of chemists and the early chemical industry. This issue was critical to the way in which the dye industry, as well as the pharmaceutical industry, developed in the United States.[14] The production of

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[12] Gerald Colby, *Du Pont Dynasty* (Secaucus, N.J.: Lyle Stuart Inc., 1974), 47.

[13] Haber, *Chemical Industry During the Nineteenth Century,* 148-149.

[14] For the most complete description of the relationship between academic and industrial pharmacology, see Swann, *Academic Scientists and the Pharmaceutical Industry.* Another excellent history, which contains information about this issue, is Parascandola, *The History of American Pharmacology: John*

organic chemical products was complex and required significant input from chemists during both product development and the production process.[15] Without the supply of trained chemists that Germany, for example, enjoyed, organic chemistry and particularly coal-tar chemistry could not and did not form the basis of the American chemical industry.

Suddenly, with the beginning of the First World War, and increasingly unreliable supplies of German imports, Americans had to produce their own dyes and medicinals. They did so by abrogating German patents and using German technology to quickly develop an American organic chemical industry. This, then, was the industry of which Garvan was so proud. Its origins were industrial rather than scientific. Not surprisingly, many of the companies that profited from Germany's research were divisions of, or were affiliated with, the most powerful companies of the American chemical industry. One reason, though not the only one, why these large companies were the ones who benefited from German technology was the fact that organic chemistry had become technically sophisticated requiring considerable equipment, and production required capitalization.[16]

Abel and the Shaping of a Discipline (Baltimore: John Hopkins University Press, 1992).

[15] Tariff hearings.

[16] The connection between the Alien Property Custodian's Office and the industry was quite complex. When hearings on a proposed tariff on coal-tar dyes began in 1919, Congressman J. Hampton Moore of Pennsylvania maintained that Garvan's organization was essentially a Du Pont subsidiary. Moore's criticism may have been too specific. For example, one of the original members of the Board of Trustees of the Chemical Foundation included two members of the board of Bayer, as well as one from the Hayden Chemical Company. This

The method of economic development was distinctly American in other ways as well. In Germany large cartels controlled the industry. In the United States the issues of competition, cooperation, and regulation were at the center of critical political consideration.[17] In this way, the industry was shaped by the ongoing American political and philosophical debate around monopoly that dominated the early decades of the twentieth century.[18]

By the end of World War I, the nature of American capitalism had changed in many ways that shaped the development of the chemical industry. Industrial applications of organic chemistry in the United States became important only after bureaucratic industrial structures had developed and after a class of industrial managers had appeared. The idea that the market was controlled by supply and demand had been replaced, in Alfred Chandler's terms, with the "visible hand" of management.[19] Mergers and takeovers within the chemical

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information is included in the House Hearings on H.R. 6495, January 1921, 245-249.

[17] There is an enormous historiography of the battle over the issue of the control of monopoly and the relationship of the federal government to business as part of the struggle of progressivism. Martin Sklar's *The Corporate Reconstruction of American Capitalism*, 1890-1916 (New York: Cambridge University Press, 1988), examines the issues of the role of antitrust debates on the American economy at the beginning of the twentieth century.

[18] For more detailed discussions see Gabriel *Kolko*, *The Triumph of Conservatism* (New York: Free Press, 1963); Thomas McCraw, *Prophets of Regulation: Charles Francis Adams, Louis D. Brandeis, James M. Landis, Alfred Kahn* (Cambridge: Harvard University Press, 1984); Robert Weibe, *Businessmen and Reform: A Study of the Progressive Movement* (Cambridge: Harvard University Press, 1962).

[19] There is an extensive historiography on this subject. Among other works, Alfred Chandler's *Visible Hand: The Managerial Revolution in American Business*, (Cambridge: Harvard University Press, 1977), persuasively presents the

industry in the 1920s led to stronger managerial structures as well as scientific expansion.[20]

Though technical and medical innovations are critical to the development of the organic chemistry industry, other factors were at least as important. The industry was developed just before and during the war, allegedly as an act of patriotism. This new industry was created by fiat of the Ward Industries Board, albeit one pleasing to and even suggested by, the chemical industry. So valuable were the products of organic chemistry that Charles MacDowell, the former head of the Chemicals Division of the War Industries Board, as well as the chemist, Charles H. Herty, accompanied the American Peace Delegation to Paris at the end of World War I.[21] Subsequently, tariff and government regulations had a profound impact on the chemical industry in the 1920s and 1930s. Throughout the 1920s, the industry used the rhetoric of patriotism to enter the political debate on free trade, regulation of big business, and patent law in its successful efforts to affect legislation. Until the mid 1930s, through the use of political and economic power, chemical companies were able to protect their industry and privileged

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argument that as industry became more complex, a new professional group of managers emerged. Economic and political institutions, vertical and horizontal integration, all ended the idea of the self-regulating economy. As his title explains, other forces took over.

[20] Jonathan Liebenau, *Medical Science and Medical Industry*, 128. The example he cites is that of Abbott, which acquired Dermatological Research Laboratories in 1922, thus combining a drug company (Abbott), which had a lot of money after the war with a small commercial research group. Abbott then went on to acquire two other small research-oriented companies, H. K. Mulford Inc. and the Sharp Dohme Co., in 1929.

[21] Haynes, *The American Chemical Industry*, Appendix LIV.

trade positions, but pressure to rein the industry in began to mount. Though the industry once again used the rhetoric of anti-German feeling and national defense to counter these attacks, it was the timely development of sulfa drugs, fulfilling the humanitarian promise of organic chemistry, that preserved their position.

The American chemical industry developed in the early twentieth century during the Progressive period at a point when, though the public distrusted the power of unregulated big business and malevolent trusts, they also believed in, and were powerfully attracted to, the virtues of science and modernity. In some ways, chemical companies personified this ambivalence. They required huge capital investments, were clearly associated with America's new position as an international power, and were clearly tied to new technology. They wished to be identified with the humanitarian project of health-care while at the same time remaining emphatically profit-making ventures. They resisted government regulation but demanded government protection.

Central to the development of the industry was an ongoing debate about patent regulations, which dominated the political and rhetorical relationship between government and the chemical industry during the first thirty years of the century. The argument was both whether or not it was appropriate to patent pharmaceutical discoveries, and the relationship of medicine and commerce. The historian Nicholas Jardine has suggested that "patents...illustrate a clear difference between science and technology...[since] one cannot patent scientific discoveries and ideas."[22] In the first decades of the twentieth century,

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[22] Nicholas Jardine, "The Laboratory Revolution in Medicine as Rhetorical and Aesthetic Accomplishment," in Andrew Cunningham and Perry

pharmaceutical companies were trying to prove that they were scientific in order to distance themselves from nineteenth century nostrums that were perceived as neither modern nor scientific, while at the same time they wanted to make a profit.

The question of patents is of singular importance to this issue because of the negative associations with the word, let alone the idea, of patents when used in conjunction with medicine. On the other hand, as patent attorney Arthur C. Fraser explained, "The capitalist considering the investment has to consider that he will be required to supply a very large amount of capital." Patent law, he explained, has always held that it "was in the public interest...to give inventors an incentive to invent" and without a patent, it would be impossible to "enlist the interests of manufacturers to put the product on the market."[23]

By this interpretation, the origins of the modern American commercial pharmaceutical industry can be seen to lie, to some extent, in the U.S. Patent Act of 1861. The law established a seventeen year patent term, and defined patentable inventions as "a process, machine, manufacture or composition that is useful..." The owner of a patent had the right to exclude others from making, using, or selling the invention in the United States. Claims could cover products (product

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Williams, *Laboratory Revolution in Medicine*, (Cambridge: Cambridge University Press, 1992), 310.

[23] Congress, *House, Ways and Means Committee*, Hearings on H.R. 6495, "A Bill to Regulate the Importation of Coal Tar Products to Promote the Establishment of the Manufacture thereof in the United States, and, as Incident thereto, to Amend the Act of September 8, 1916, entitled 'An Act to Increase the Revenue and for other Purposes'" 66 cong.,1st Sess. (hereafter H.R. 6495), 18 June 1919. Testimony of Arthur C. Fraser, chair, Committee on Legislation of the New York Patent Law Association, 121.

patents), product development (process patent), or a method for using the product (use patent).[24]

In 1913, Francis E. Stewart, chair of the Patent Committee of the American Pharmaceutical Association--seeking to strengthen identification with science rather than industry--urged that the members of that organization also oppose the idea of patents on medical discoveries.[25] On the other hand, in his presidential address to the American Institute of Chemical Engineers, Leo Baekeland supported the idea of product patents. He pointed out that without the right to hold patents, industry would not pay for research.[26]

This tension between "science" and "industry" was not the same kind of issue in the German chemical industry. Scientists had been involved in German commercial chemical companies from the beginning. They were at the core of the

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[24] Carolyn Ashbury, *Orphan Drugs: Medical Market Versus Market Value*, (Lexington, Mass.: Lexington Books, 1985), 9.

[25] Francis Stewart, *Pharmaceutical Era*, vol. 45, 1912, 569.

[26] Leo Baekeland, "Presidential Address" *Journal of Industrial Engineering and Chemistry*, vol. 5, 1913, 51. Baekeland's position is not surprising in view of the fact that he had risen to national prominence and personal wealth after he discovered Bakelite. The issue of who will support research is a real one. According to historian John Swann, *Academic Scientists and the Pharmaceutical Industry*, 89-90, in 1939 microbiologist Selman Waksman, who worked as a consultant to Merck while directing a laboratory at Rutgers, signed an agreement with Merck to assign his patents to the company in exchange for funding his efforts discovering antibiotics. Merck agreed to pay a portion of the royalty back to Rutgers. When Waksman discovered streptomycin, he was concerned that he was permitting the monopolization of a valuable therapeutic. In addition, because the drug at the time was the major weapon against tuberculosis, the demand was so large he feared Merck could not supply enough. Merck agreed to reassign Waksman's patents to Rutgers as soon as they had recouped their investment. Beginning in 1946, eight companies produced streptomycin.

industrial process as well as the developmental stage of production. As Joseph Choate, Counsel to the American Dyes Institute, explained:

> In Germany the cooperation between the academic and coal-tar chemists was so complete that it was not an uncommon sight to see, in the dye works laboratories, dozens of academic chemists working side by side with the dye-works chemists on their own individual problems.[27]

German companies smoothly combined science and commerce and patented all their products. Most of these German patents were then registered in the United States. Frequently, however, these patents were not worked in America. German companies took out product patents (as opposed to process patents), which prevented any other company from making the product even if a new method of manufacture was found.[28] This forced American companies to import coal-tar chemicals from Germany. Before World War I, the American industry of dyestuffs and medicines "consisted largely of small assembling plants operating on German intermediates."[29] Critics contended that "the non-working of...patents in the United States, largely accounts for the lack of development of these industries in the country."[30] The system worked well for Germany, however. Before 1914, "Germany manufactured 74 percent of the world's output

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[27] H.R. 6495, Hearing #3, testimony of Joseph Choate, Jr., Counsel to the Chemical Foundation, 96.

[28] Haynes, *The American Chemical Industry*, vol. III, 312-314.

[29] F. W. Vaugham, "Suppression of Non-Working Patents, with Special Reference to the Dye and Chemical Industries," *American Economic Review*, vol. 9, (December 1919), 699.

[30] Ibid.

of dyes. This situation was due to Germany's encouragement of chemists and their research work."[31]

With the beginning of the war, the situation changed. In 1914, Germany declared an embargo on coal-tar dyes, and though it was quickly lifted:

> The invasion of Belgium aroused us to the sudden realization that we needed desperately--the products controlled by the German Dye Cartel.[32]

These products were not just dyes, though the dyes were of major importance. Coal-tar products also included medicinals such as aspirin, vernal, Luminal, novocaine, synthetic adrenaline, and, quite critically, salvarsan.

The American chemical industry was quick to point out that the connection "between the dye industry and the industrial progress of the country was infinitely close." The chemical laboratories and plants that produce dyes "were the only means for the furtherance of organic chemistry...the root of the whole science of medical chemistry."[33] On September 8, 1916, a tariff was placed on coal-tar products in order to encourage the nascent American organic chemistry industry. This was done because Congress recognized that "the development of the manufacture of synthetic drugs is of the greatest public importance."[34]

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[31] Ibid., 699.

[32] Haynes, *The American Chemical Industry*, vol. III, 209.

[33] H.R. 6495, testimony of Joseph Choate, Jr., 95.

[34] H.R. 6495, testimony of Gunell Jones, staff chemist of Tariff Commission, 15.

The tariff was meant to encourage the chemical industry, but encouragement was not enough. As World War I continued, the situation grew more critical. The shortage of dyes and medicines grew more acute. Supplies of salvarsan in particular were unreliable and expensive. Concerned, Congress held hearings to discuss ways to address the situation. The German industrial system was seen as the root of the problem. A Johns Hopkins physician, Theodore C. Janeway, testified that there was a "radical difference" in attitude between the German and American medical profession. Had an American discovered salvarsan, it would have "been available at cost or at a reasonable profit by any manufacturer..." This, of course, begs the question of patents. At the time Janeway testified (1917), there was no American drug discoveries that were comparable to German ones. Janeway explained that the reason for this was the propensity of German companies to "support their large research institutes in part by commercializing their products." This explained why the Germans then demanded payment "of large royalties for the drug or process they have invented."[35]

Numerous experts agreed that the effort to maintain a supply of salvarsan was critical. The staff of the Mayo Clinic sent a letter to the committee

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[35] The U.S. Congress Senate's Committee on Patents, 65th Congress, 1st Session, Hearings on S. 2178 A bill suspending, during the present emergency, all rights arising out of any patent granted by the United States upon any compound or medicine of which Salvarsan is a constituent part; S. 2363 A bill authorizing and directing the secretary of war or the secretary of the navy to manufacture for the use of the army, navy, or the people of the United States any drug, medicine, or other remedy or device that is protected by a patent or patents, trademark or trademarks, and which cannot be procured at a reasonable price within the United States, Washington, D.C., GPO, 1917, hereafter S. 2178, statement of Dr. Theodore C. Janeway, M.D., 19.

explaining that the current supply was "insufficient and precarious." What supplies existed had been "doled out to the medical profession at prices which have largely prevented its use to the extent or in the type of cases with the public health demands."[36] The concerns around Salvarsan were real, but even so, they could not be divorced from other political and economic issues. To the staff of the Mayo Clinic, a socially progressive institution with the Progressive concerns around monopoly and the exploitation of the public by unscrupulous trusts, "...the price of Salvarsan as regulated by the Farbwerke-Hoechst Company is a glaring example of a commercial monopoly reaping enormous profits at the expense of sickness and misfortune..."[37]

There was a motion before Congress to abrogate the German patent on Salvarsan for the duration of the war. The Mayo Clinic staff remained focused, however, on their own agenda. They suggested that "even in time of peace the...wisdom of a public policy which permits private monopoly to control and seriously limit the use of remedial agents whose availability is vital to the public health may well be questioned..." The Mayo staff wanted Congress to go further and urged "that such an abrogation shall not merely be for the duration of the war but shall be permanent." They advocated a "radical revision of our patent law, looking to the prevention of private monopoly of remedial agents indispensable to the public health."[38]

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[36] S. 2178, letter read into the record of the Salvarsan hearing, written by staff of the Mayo Clinic, 4.

[37] May letter, Salvarsan hearing, 5.

[38] Ibid.

Congress heard from other medical experts who agreed that the patent should be abrogated. They felt this should not be seen "as a war measure; [but] as a peace measure and to reduce the price, not give it to everyone...Do not let the price be over $1 and give it to us in peacetime. That is what we must have."[39]

The Salvarsan debate involved several important issues. The particular issue of patents, the morality of profits, as well as the regulation of trusts and the issue of monopoly, are clearly part of a larger debate. Those questions, at least to some extent, frame the social context of the attitude of the Mayo Clinic doctors. The chemical industry, however, took advantage of the debate for its own interests and focused the discussion as much as possible, on those specific issues with which industry was concerned. The industry had its own opinions about the morality of profit--they supported it--for all of their products. They saw in the question of Salvarsan production a clear opportunity to promote the relationship of the dye industry to medicines that would benefit mankind. The debate clarified the direct link between dyes and other products in the minds of the public as well as Congress. Other coal-tar products included explosives, photographic chemicals, and poison gas, as well as medicines, so the industry was able to position itself and its products as patriotic as well as humanitarian. As soon as the United States entered World War I, Congress did decide to abrogate the patent on salvarsan and the Federal Trade Commission licensed several companies to produce the drug though the FTC would regulate the price.[40]

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[39] S. 2178, statement of Professor George Walker, M.D., Johns Hopkins University, 18.

[40] The bill was passed on June 4, 1917.

American chemical companies were delighted with the government's action, and thrilled to have access to German patents. They quickly discovered, however, that German patent applications were not detailed, or even accurate, in their descriptions of manufacturing procedure. In fact, it required "six months of study and experimentation to be able to develop the production of [Salvarsan]."[41]

Industry investment and effort was further rewarded in July 1917 with passage of the Trading With the Enemy Act, which provided for the confiscation of German property, including patents. The New York Times' headline describing the bill a few days before its passage placed the bill in its broadest context, "Urges Pending Bill as a Curb to Spies." The accompanying article explained that the bill would "give the President discretionary power to deport or intern without trial or presentation of evidence any alien who he was convinced was engaged in [damaging] activities."[42] It did much more. This was an extreme and sweeping piece of legislation. It was:

> ...one of the most drastic pieces of legislation ever passed by Congress. By the regulations set forth they President took control of American commerce...enemy held patents may be used to aid in the winning of the war...[a censorship board was created] to ensure there would be every possible safeguard around information, which might get to the enemy.[43]

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[41] CIS Congressional Hearings, S. Doc., vol. 5, pt. 1, Hearings on Tariff Act of 1921, H.R. 7456, 67th Congress, 2nd Sess., 25 July 1921, (hereafter H.R. 7456). Testimony of Joseph McMullen, Judge Advocate, War Department, 6-7.

[42] "Urges Pending Bill as Curb to Spies," *The New York Times*, (6 July 1917), 2.

[43] "President Acts to All Trading with Foe," *The New York Times*, 15 October 1917 Supervise 7, 1.

The bill defined the enemy as "a person, corporate or otherwise."[44]

The law created:

> an official to be known as the alien property custodian, who shall be empowered to receive all money and property in the United States due or belonging to an enemy...and to hold, administer and account for the same...The alien property custodian shall give such bond or bonds, and in such form and in such amount, and with such security as the President shall proscribe.[45]

The justification for the seizure of German property was partially patriotic (to prevent the enemy from enjoying any profit from its technology or investments) and partially moral (to reinforce the concept of the sanctity of property law). As the President explained, confiscation would "protect the property and will avoid lawless acts against it."[46]

The issue of patents, particularly coal-tar patents, was specifically addressed during the Congressional hearings. Section 10, subsections (c)-(g) of the Trading with the Enemy Act, outlined the rights of United States citizens to manufacture goods protected by German patents. A citizen applied to the President for a license "nonexclusive or exclusive as he shall deem best, provided that he shall be of the opinion that such grant is for public welfare."[47] The license had to report the prices received at least annually and had to pay "five per centum

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[44] Hearing before the House of Representatives Committee on Interstate and Foreign Commerce, on Trading with the enemy Act, H.R. 4704, 65th Congress, 1st Sess., 29 May 1917, (hereafter H.R. 4704).

[45] *Congressional Record*, 65th Congress, 1st Sess., Chapter 106, Section 6, 415.

[46] H.R. 4704, testimony of Robert Lansing.

[47] Trading with the Enemy Act, 1917, Section 10, subsection (c) 421.

of the gross sums received...and sums so paid shall be deposited by said alien property custodian."[48] The license, unless revoked, would last for the duration of the war.

During the Congressional debate, Section 10 received considerable attention. Legislators questioned the effect the bill would have on salvarsan, for example, as well as how the American Act compared to the Trading with the Enemy Bills passed by other countries. Though other countries had passed such legislation, they had simply forbidden trading. They had not confiscated patents. The only exception had been Russia, and Germany had retaliated by confiscating Russian patents. William Redfield, the Secretary of Commerce, characterized the English bill as more sweeping because it was intended to interrupt trade, whereas the American bill was meant to "protect ourselves against aiding the enemy in a way which would provide as little interruption of our commerce as possible...[because] we are now the world's purse."[49] In light of America's new position, the creation of the Alien Property Custodian,

> indicated an earnest desire to show the people with whom, unfortunately, we are engaged in ware that here is the opposite of confiscation...a reasonable officer...is created who shall receive the property of an enemy and put it in the safest place known to us- that is, in the treasury of the United States...[50]

Fiorello LaGuardia was among the critics of the patent proviso, suggesting that the Germans might retaliate. When members of the Wilson administration

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[48] Trading with the Enemy Act, Section 10, subsection (d) 421.

[49] H.R. 4704, testimony of William Redfield, Secretary of Commerce.

[50] Ibid.

pointed out the importance of certain German patents, particularly Salvarsan, LaGuardia insisted that even Salvarsan didn't compare in importance to United States' patents registered in Germany.[51] There were other critical questions, such as the one asked by Representative John Esch of Wisconsin, who raised the issue of whether it might be possible to interpret the law to mean that a license granted to an American firm was good to the limit of the German patent. "Is it possible to conceive that it might run for 10 years and long beyond the time when peace is restored?"[52] Assistant Attorney General Charles Warren admitted that such a situation could arise. A patent lasted for seventeen years, and many of the German patents confiscated during the war were recent ones. Warren explained that it was proper that the patent should run on past the war in order to allow manufacturers to recoup their investment.[53]

The first Alien Property Custodian that Wilson appointed was a Pennsylvania Democrat, A. Mitchell Palmer. The appointment was a reward for loyal political support to Wilson and the Democratic Party. Palmer had national ambitions, and his appointment provided him with unanticipated scope and power. As Alien Property Custodian, Palmer had to establish a large staff. He resisted the impulse to use the appointments purely for political patronage and appointed competent "dollar-a-year men" to key political positions. Palmer chose a New York lawyer, Francis P. Garvan, as the director of his Bureau of

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[51] Representative LaGuareva Leads Unsuccessful Fight Against Drug Patent, *The New York Times* (12 July 1917), sec. 13, 1.

[52] H.R. 4704, testimony of Representative John Esch.

[53] H.R. 4704, testimony of Charles Warren, Assistant Attorney General.

Investigations. Previously, Garvan had been the Chief of the Homicide, Insurance, and Business Division of the New York District Attorney's office.[54]

When the law was enacted, the Administration claimed that it had no idea how much property was owned by German nationals in the United States. Palmer quickly realized that it was a sizable amount indeed. Given the amount of property owned by Germans, and the importance of that property, Palmer felt that simple custodial duties were insufficient. "Instead of permitting myself to be a mere conservator of enemy property, I have tried to make the Trading with the Enemy Act a fighting force in the war."[55] For the sake of the American public, Palmer felt that certain confiscated property should be sold to Americans. Patents were among that property, since he felt that Germans had only taken out American patents to prevent their manufacture in the United States, thereby forcing the importation of German products. An editorial in The Nation pointed out that "[t]his happens to be the usual purpose of a patent monopoly, protected by the Bern Convention, by Treaties, and by the municipal law in all industrial countries."[56]

> All enemy owned property was not property of casual private German investors, but, on the contrary, was in large part owned by the Junker class and no inconsiderable part was owned by the Royal Family and by the Kaiser himself.[57]

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[54] Stanley Coben, *A. Mitchell Palmer: Politician* (New York: Columbia University Press, 1963), 130.

[55] L.E.X., "Mr. Palmer as Alien Property Custodian," *The Nation*, vol. 110, no. 28, (19 June 1920), 824-5.

[56] Ibid.

[57] United States vs. Chemical Foundation Inc., Circuit Court of Appeals, Third Circuit, 26 March 1925, 137. In his biography of Palmer, Stanley Coben

The Trading with the Enemy Act was amended in 1918 at Palmer's request. The Alien Property Custodian was given the power to manage German property and to sell it as if he were the owner. The sale had to be public, and the property could only be sold to Americans.[58]

> By the end of the war, according to Palmer, he had been so successful that he was supplying the government with many different products and "in some instances the enemy-owned corporations...were running 100 per cent of their capacity on Government business.[59]

In other cases, the factories themselves were not the valuable enemy-owned property. The patents and chemical processes were far more important. Once they were licensed to use German technology, American companies began to produce coal-tar chemicals, including dyes, chemical weapons, and drugs. The American Medical Association set up labs to assay these drugs for purity. Some of the American manufacturers feared that if they continued to use the German names for these drugs, they would, in effect, be creating a market for German products after the war. To prevent German profiteering from the American manufacturing of their drugs, the Federal Trade Commission, the National Research Council, and the American Medical Association Council on

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discusses Palmer's attempts to 'Americanize" German property. Wilson was resistant, so Palmer told the President that his investigations had shown investment by the ruling class. According to Coben, Palmer used the term Junker Class because "these men, known to be militarists and monopolists, were a group that Wilson could despise."

[58] "Alien Property Custodian," Congressional Record, 65th Congress, Session II, Chapter 28, 459.

[59] *Alien Property Report*, 1918, 10, as quoted in Coben, A. Mitchell Palmer, 129.

pharmacology and chemistry issued a list of new, Americanized, and trademarked names.[60]

Not surprisingly, American chemical manufacturers were concerned about what would happen to their businesses when the war ended. They were concerned that German companies would "dump" chemicals and dyes, underselling, and eventually forcing American companies out of business. Several plans for their ongoing protection were under discussion by the time of the Armistice. The discussion was quickly elevated beyond the question of profits for chemical manufacturers into issues of national security:

> We found that the connection between the dye industry and the industrial progress of the country was infinitely close...a nation which has a real dye industry has at its disposal enormous research laboratories...and research chemists who can, incidentally, be diverted to the service of any other form of industry.[61]

Some members of the industry were more direct. Testifying before Congress in 1919, Daniel Walters, president of the Master Dyers Association of Philadelphia, pointed out that the United States needed a dye industry so that "we may be independent from any foreign nature in the future"; but he also reminded the legislators that the men who invested during the war "did expect a reasonable return for their investment...it is only fair, man to man..."[62]

The American chemical industry had thrived because the "stranglehold of the German Dye Cartel" had been loosened, but there "always remained the threat

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[60] Haynes, *The American Chemical Industry*, vol. IV, 243-246.

[61] H.R. 6495, testimony of Joseph Choate, Jr., Counsel American Dyes Institute, 89.

[62] H.R. 6495, testimony of Daniel Walters, 93.

that the restoration of peace would bring back an experienced, ruthless competitor unless the tariff policies...were changed, which under the Democratic Administration, seemed improbable."[63]

Reacting to that threat, many of the members of the chemical industry demanded protective legislation. Even before the end of the war, in July 1918, they asked the government to establish high duties. Concerned that even that might not be enough, they quickly moved beyond tariffs, demanding instead an embargo on many chemicals and dyes, or at least a protective licensing system similar to the one in Britain. Some prominent representatives of the industry warned that even a licensing system might not be sufficient. They pointed out that there were other ways in which Germany could regain control of the chemical industry. They used the Bayer Company as an example. The Alien Property Custodian (Palmer) had sold the Bayer Company's dye and drug patents in 1918 to the Grasselli Chemical Company, an American company. Grasselli, in turn, sold them to another American company, Sterling products. American chemical industry spokesmen commented on the fact that there were a number of men with German-sounding names on the board of directors of Sterling. Palmer then pointed out the possibility that through these German connections, the patents that had been seized could quickly wind up in German hands, and ultimately be used against the American interests.[64]

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[63] Haynes, *The American Chemical Industry*, vol. III, 216.

[64] According to *The American Chemical Industry*, vol. IV, what Sterling Products did after World War I was to establish a company named Bayer to produce aspirin and to set up Winthrop Chemical to produce other coal-tar products, particularly barbiturates.

The Democratic Party had a longstanding commitment to free trade, and Wilson was no exception. He had actively worked for lowering tariff trade barriers early in his first administration.[65] Palmer and Garvan, stalwart Democrats both, needed to develop a proposal that would allow trade barriers to be phased out within a few years, thus upholding the party's political position, while at the same time protecting the chemical industry.

On January 13, 1919, Palmer held a meeting with his staff and representatives of the Federal Trade Commission "having to do with issuing licenses under German patents upon authority of the Trading with the Enemy Act."[66] Palmer instructed his patent counsel to draft a plan that would protect American interests but would not interfere with the idea of open trade, which Wilson was publicly urging on the entire world as part of his peace proposal. Palmer did not ask for a trade barrier or even a licensing system. Instead, he was concerned with protecting the patents that Garvan, as Alien Property Custodian, already controlled. As the ensuing recommendation explained:

> the power of seizure of patents should not be exercised in any wholesale fashion, but only in connection with establishing American business...conferences with the representatives of certain chemical companies indicates a very definite...feeling that a large number of German-owned American dye and chemical industries...our endeavor being to benefit the industry as a whole – and I believe the industry is best qualified to know how this should be done – the industry [should] determine just what patents should be seized...Mr. Poucher of the Du Pont Company...states that The

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[65] For a more complete discussion see Martin J. Sklar, *The Corporate Reconstruction of American Capitalism*, 1890-1916 (New York: Cambridge University Press), particularly 14-42.

[66] United States v. Chemical Foundation Inc. (Circuit Court of Appeals, Third Circuit), 26 March 1925, 193.

> Institute of Dye Manufacturers...will make a request to the custodian that he take and sell the...patents, on the grounds that proper protection is not afforded by the Federal Trade Commission...[67]

The plan that Garvan and Palmer developed and that Garvan presented to representatives of the American Dyes Institute, the National Aniline Companies, and Du Pont proposed that the Custodian seek approval for the private sale of confiscated German patents to a private corporation, the Chemical Foundation Inc.--to be organized by the Dye Institute and Francis Garvan. The participants in this plan did not initially make their intentions known either to the public or to the government, but moved ahead with private financing. The American Dye Institute agreed to pay for placing patent attorneys from National Aniline Company and Du Pont in the U.S. Patent Office, who were instructed to compile a list of which patents should be included in the sale. They also settled on a price of $250,000 amongst themselves, and the "terms of the sale were framed so as to explode all competitive bidding." It was also agreed that Garvan would become president of the corporation. Wilson agreed to the completed proposal as it had been outlined. On February 19, 1919, the charter of the Chemical Foundation, Incorporated, was filed.[68]

On March 4, 1919, Palmer resigned as Alien Property Custodian and became Attorney General of the United States. Though his subsequent activities focused more on tracking down ostensible communist threats to national security,

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[67] Ibid. This passage comes from a letter written by Mr. Houget, Patent Counsel to the Custodian, and is included in the judgment.

[68] This history comes from the judgment handed down in United States v. Chemical Foundation, 190-197.

he remained closely tied to Francis Garvan, who was appointed his successor as Alien Property Custodian. On March 8, 1919, while still holding that position, Garvan:

> became president of The Chemical Foundation and from that date was both president of the corporation purchasing the patents and Alien Property Custodian making the sale, and in these wholly opposite official positions determined the price which should be paid by one of his principals and received by the other.[69]

Approximately 4,700 patents were sold to the Chemical Foundation for $250,000. Only afterwards was the sale made public. In a press release, Garvan explained that the Foundation would "not only protect the American manufacturers against German importation of chemicals, but stimulate as well an interest among commercial chemists in organic chemistry, in which the Germans were masters...before the war."[70]

Palmer later testified that he was aware of "the Federal Trade Commission's view, and of what I knew to be the general policy of the Administration...a plan had to be worked out by which it would be a competitive industry."[71] In the spirit of fair-mindedness, it was agreed that the Chemical Foundation would grant nonexclusive licenses "under all its patents to all qualified American manufacturers...to hold the patents in trust for American

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[69] Ibid., 196.

[70] *The New York Times* (12 March 1919), 13. F. P. Garvan makes public second chapter of report of A.M. Palmer on German dye interests and organization of chemical foundation, which will place secrets at disposal of American dye-stuff manufacturers.

[71] Ibid., 201.

industry and protect them against infringers."[72] The Chemical Foundation would determine who the qualified manufacturers were.

Not surprisingly, there was opposition to the Foundation; but this issue became further complicated almost immediately. During the treaty negotiations that followed the end of World War I, the question of chemicals and dyes became part of the complex issue of what German reparations would be made. German delegates to the Versailles Peach Conference proposed paying at least a part of their debt with coal-tar chemicals.[73] Charles MacDowell, the former head of the Chemical Division of the War Industries Board, and John Pennie, a New York patent attorney, were dispatched to Paris as the official chemical counselors to the American Peace Delegation.[74] French and British textile manufacturers embraced the proposal enthusiastically. The newly invigorated American dye industry obviously did not.[75] Though American textile manufacturers found some merit in the plan, the chemical companies and the Chemical Foundation Inc. immediately warned that the "stranglehold on our industry insidiously obtained by Germany before the war was nothing short of amazing" and vigorously opposed the proposal.[76]

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[72] Ibid.

[73] Haynes, *The American Chemical Industry*, vol. III, 262.

[74] Ibid., Appendix LIV.

[75] "Bernstoff Used Dyes as War Club," *The New York Times* (16 June 1919), 4.

[76] *Literary Digest*, "He balked the attempt to grab out industries" vol. 60, (Jan. 1919), 41-42. See also Haynes, *The American Chemical Industry*, vol. III, 262-268.

American Dye manufacturers suggested that not only should Germany be prevented from using stockpiled coal-tar chemicals for reparation payments, but that there should be a total embargo on German products. Later they modified their position. Their compromise position called for a very high protective tariff. They also wanted to further protect American interests by introducing a licensing system controlled by the Chemical Foundation, which would determine which American companies could produce the organic chemicals using German patents.[77] Although Wilson opposed the tariff, presumably for that very reason many Republicans supported it.

In July 1919, Congress held hearings before voting on a bill to "Regulate the Importation of Coal-Tar Products, and to Promote the Establishment of the Manufacturing thereof in the United States" (H.R. 6495). Necessarily included as part of the issue under discussion was the Chemical Foundation itself. If the licensing system were permitted, the Foundation would appoint the Licensing Commission's members and oversee its activities. This was only logical, since the commission would be regulating patents that had just been sold to the Foundation. The transfer of the German patents was fiercely defended by both the chemical industry and the Office of the Alien Property Custodian as more than merely patriotic necessity.

> Organic chemistry is, of course, at the root of the whole science of medical chemistry, and medical chemistry is in its infancy. For a thousand years, the physicians have been pouring into the unfortunate human system drugs of which they know nothing...the drugs are organic chemicals...now the dye laboratories furnish the

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[77] Haynes, *the American Chemical Industry*, vol. III, 265-267.

> means, and the only means, for the furtherance of organic chemistry.[78]

The tariff was the ostensible topic of the hearings, but the discussion extended to protectionism, licensing, and the formation of The Chemical Foundation itself. The Republicans favored a high tariff, which the Democrats, in turn, rejected. Democrats claimed that they supported the proposed licensing system not as protectionism for the chemical industry, but as a way to provide the government with the income lost by lowering tariffs. Objections to the idea of a licensing system were quickly raised. The Republican opposition was led by a Representative Moore of Pennsylvania, a longtime political opponent of Palmer, who was also from Pennsylvania. Moore suggested that licensing would create monopolies that would be under the control of the Chemical Foundation, and that, in fact, was the main purpose of the proposal. In his questions he made it clear that he believed that the licensing idea had been presented to the industry by the Chemical Foundation, which had developed the idea in order to insure its own stranglehold on chemical products and processes to consolidate the power of its Board of Directors.[79]

Moore asked Andrew Imbre, Treasurer of United States Finishing Company: "As a businessman, would you not prefer to see the business of the Government disassociated a bit from private business...formed for the purpose of issuing stock and making money?"[80]

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[78] H.R. 6495, testimony of Joseph Choate, Jr., 95.

[79] H.R. 6495, testimony of Representative Moore, 58.

[80] Ibid., 59.

Imbre protested that making money wasn't the purpose of the Chemical Foundation, which had been founded in order to benefit American society and further the cause of science.[81] Moore asked if it were not true that chemical companies had been urged to subscribe to and financially support the Foundation because of the Foundation's access to the Alien Property Custodian. (Which was considerable, since the Alien Property Custodian and the president of the Foundation were one and the same). Imbre said that he didn't understand the question, to which Moore replied: "My question was as to the ethics of that proceeding. I want to know whether you, as a businessman, think it is a wise thing to encourage public officials to engage in an enterprise of this kind?"[82]

Testimony was also presented before the Committee by textile manufacturers who felt that they were being victimized by the American dye industry. They complained that "there is too much relation between the dye manufacturers and the Foundation to be healthy for the consumers of dyes in the United States."[83]

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[81] In the biographical entry included in Haynes, *The American Chemical Industry*, the Foundation explained its mission. "The emancipation of the American organic chemical industry from foreign domination after World War I, and its extensive educational programs for the benefit of the American Chemical Industry," vol. VI, 76.

[82] Ibid., 59.

[83] Ibid., Testimony of Tom Grusher, representing the United States Worsted Company and other worsted manufacturers, Boston, Massachusetts, 307.

Witnesses complained also of the inferior quality of American dyes, and of the fact that American dye companies refused to guarantee their products.[84] The record of the hearings makes it quite clear that the chemical industry had significantly more political influence than the textile industry.[85]

Ignoring the question of quality control, Moore and others continued to focus on the issue of monopoly, pointing out that it seemed to him that the Chemical Foundation would control the entire American industry, given that it controlled all the patents. The Foundation had the authority to grant licenses to companies to produce under those patents, and could deny patents to any companies it did not wish to assist. After much dodging, John Choate, representing both the Chemical Foundation and the American Dye Institute (which he said was not a conflict of interest, since the membership of the two organizations was essentially one and the same) admitted:

> The [Licensing Commission] could, if they choose to act crookedly, control one-quarter of the industry, but there it is, that is a fact...that is why we were so careful to keep the control of this thing out of selfish hands...[86]

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[84] Ibid., 158-160. One member of the committee, Representative Young, pointed out that "while the people of the United States will stand for an increased price for their dyes, they will not stand for higher prices for poorer quality." He also held up a faded garment for the committee's inspection, pointing out that the offending article had only been washed once.

[85] There were many fewer witnesses from the textile industry who were allowed to make statements, and those witnesses were generally brushed aside. Only Representative Young seemed particularly concerned about the effect of proposed legislation on consumers. No other committee member even raised the issue.

[86] Ibid., 114.

Choate went on to explain that while it was theoretically possible that certain companies, which were not members of the Dye Institute and which had not funded the Foundation, might conceivably be discriminated against in the awarding of licenses, he felt sure that the honor of the Licensing Commission precluded such concerns. If the Commission refused a license, it would only be because the applicant was incapable of producing chemicals that would meet the Foundation's high standards.[87]

Dismissing these concerns, Choate explained that because of the possibility of corruption, the organizers of the Foundation had been careful to "keep the control of this thing out of the selfish hands."[88] He tried to redirect the focus of the Committee away from monopoly by reminding them of the humanitarian promise of organic chemistry. He pointed out that in the coal-tar industry lay "the promise, the only promise for the discovery of drugs to cure the cruel diseases that are the scourge of humanity." American companies had to do what was necessary to compete with the German system that allowed "huge cartels to be formed." German business practices were unethical. "They cut pries to get business and were ruthless." Fortunately, the Alien Property Custodian's office had recognized the problem and "for reasons of public spirit...began to scratch our heads to see if we couldn't find some way of helping this industry here."[89]

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[87] Ibid., 120-122.

[88] Ibid., 114.

[89] Ibid., 101-106.

Charles H. Herty, the editor of the Journal of Industrial and Engineering Chemistry, spoke, representing the American Dye Institute. He emphasized to the Committee the important fact that, until recently, Germany had been training virtually the entire world's supply of organic chemists. Thanks to recent events, however, the situation had changed and the potential benefits were incalculable:

> There are now classes in the chemistry of a size never heard of before In our educational system. They are all figuring on going into the dyestuff industry. They are going to be prepared to do a more important task for the nation, I think than the making of dyestuffs...[They will] not be content with supplying things that satisfy the aesthetic side of life but...will alleviate the suffering of humanity.[90]

Politics were at least as compelling to the Congressmen holding the hearings as the sufferings of humanity, and their focus remained on the whole fixed on questions of political patronage and the sensitive issue of monopoly control. The Republican, Moore, was unable to keep from personally attacking Francis Garvan. He suggested that Garvan was guilty of either a conflict of interest or, at best, an over-extension of commitments. Garvan had remained on Palmer's staff after the establishment of the Chemical Foundation. The Attorney General's office was a busy one, and its primary and critical activity was the extensive pursuit of putative communists. Moore pointed out:

> [Palmer] is now President of the Chemical Foundation Inc., which, because of certain information it has obtained, due to the seizure of German patents and German papers, proposes to control the dyestuff industry in the United States. It may be a proper transaction, but it seems to me that if ever there was a case of doubling up offices and concentrating several functions in the hands of a single individual, this is a flagrant case. If ever there was a time when the Attorney General and his assistants should

[90] H.R. 6495, testimony of Charles H. Herty, 151.

> devote their time to the apprehension of bomb throwers and other anarchistic criminals for the sake of peace and welfare of the country, this is the time...[91]

Moore tried to continue in this vein but was ruled out of order. Before subsiding into silence, he did manage to include in the record his assertion that the trustees of the Chemical Foundation were rich businessmen who knew the worth of patents and who were, not incidentally, big contributors to the Democratic Party.[92]

Garvan rebuked all his critics. He explained that the Chemical Foundation had been organized to serve as "a trustee for American industry" to "grant nonexclusive licenses upon equal terms...to qualified American Manufacturers." The private sale of the patents to the Foundation had successfully prevented them from "falling into the hands of purchasers who would be unwilling or unable to put the inventions coveted into use, or would use them for purely speculative purposes." The private sale had therefore been held only "so as to secure the foregoing benefits for the public" and to avoid unnecessary inconvenience, expense or delay.[93] Public spirited as the Chemical Foundation and its founders may have been, the patents controlled by the Foundation were licensed to the very companies who were the original stockholders of the Chemical Foundation.[94]

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[91] Ibid., 225-226.

[92] H.R. 6495, 229-230.

[93] Ibid., 275.

[94] For more details see Haynes, *The American Chemical Industry*, vol. III. Appendix L contains the distribution of patents, Appendix LII contains the original stockholders; Appendix LIII lists German patents licensed by the Chemical Foundation.

On September 26, 1919, Congress passed legislation that established high duties on the importation of dyes and coal-tar medicinals for three years.

Three years later, in April 1922, the Senate Committee on Patents began holding hearings on legislation that was intended to address the patent statutes that controlled nonworking patents as well the issue of tariff barriers. In the course of the hearings, the question of the disposition of the seized German patents was once again raised. Simultaneously, in what proved to be a poorly calculated and inflammatory move, the Chemical Foundation formally demanded payment from the Alien Property Custodian, Thomas W. Miller, for royalties collected by the Custodian on patents that were held by the Foundation.

The Foundation's demand was seen as outrageous by those who had questioned the propriety of the original transfer of the patents, and the matter was brought to the attention of the Harding administration. The President announced that, having investigated the matter, he felt that the original price paid by the Chemical Foundation for the patents was "so nearly nominal a sum that there is reason to believe that this Government has not faithfully observed the trust which was implied in the seizure of this property."[95]

Politics clearly played a role in the issue. This was a Republican administration, demanding recovery of property from its Democratic predecessors. The Harding administration maintained that Garvan and Palmer had exceeded the authority granted to the Alien Property Custodian by Congress. Further, the government once again raised the charge that the purpose of the

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[95] "President Orders Return of Patents," *The New York Times*, 2 July 1922, 1.

Chemical Foundation had been the creation of a monopoly for "certain persons and corporations engaged in the dye and chemical industry..." and that the "transfer of the patents to the corporation was a donation...given to a private industry."[96]

Palmer responded to the administration's attack with accusations of his own:

> It is a great shame that the war and its lessons should be so soon forgotten. If these patents are recovered from the Chemical Foundation they cannot be sold again to American citizens and the inevitable next step will be back to the old days when we were at the absolute mercy of the German dye trust. We conceived the plan of conserving (German patents) for the general public benefit and to build a great American industry free from the evils of monopolistic control.[97]

He reminded his fellow citizens that the funding for the Chemical Foundation had come from "persons interested in a new chemical industry...American citizens of high character and undoubted patriotism."[98] He made it clear that the motives of the contributors to the Foundation, as well as his own motives and those of his staff, had nothing to do with the profit and everything to do with creating a strong, modern America.

> The Government attack on the American chemical industry is the greatest victory Germany has won since Pershing turned back their legions at Chateau-Thierry. It will be hailed with delight in every German household, both here and in the fatherland. But will real Americans stand for this belated surrender?[99]

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[96] United States v. Chemical Foundation Inc. (District Court, Delaware) January 1924, 294 Federal Reporter, 317.

[97] "Palmer Defends Dye Patent Sale" *The New York Times*, 3 July 1922, 6.

[98] Ibid.

[99] Ibid.

The Harding administration was not willing to cede patriotism to Palmer, or to the Wilson administration, which had permitted the original transaction. It filed a suit against the Chemical Foundation for recovery of the patents. While the Justice Department maintained that their case was the only logical response to the demand for payment made by the Foundation, the language used by Alien Property Custodian Miller makes it clear that it was patriotism itself that the Harding administration was protecting. In a statement, Miller explained:

> He was not prepared to call the President's action [in bringing the suit against the Chemical Foundation] a part of the war frauds prosecution campaign. There was a twilight zone, he said, between the war frauds and the grounds on which the President's action was based...[while the Government was not] prepared to characterize the sale of enemy patents to the Foundation as 'clean as a hound's tooth' neither was it prepared to say there was fraud...involved.[100]

Garvan responded to allegations of illegal activity on his part by charging that the reason that the Harding administration wanted the patents back had nothing to do with the Chemical Foundation's actions or its possible impropriety. Instead, he accused the administration of succumbing to pressure from Germany. Garvan claimed that Harding had met with representatives of the German chemical industry who wanted their patents returned and that he had agreed to their demands.[101] At that point, the Justice Department decided to press criminal instead of civil charges. Enraged, Garvan defended himself:

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[100] "Demand, the Suit in Dye Patent Row" *The New York Times*, 6 July 1922, 6.

[101] "Joins German Plea and Harding Order," *The New York Times*, 8 July 1922, 1.

> [He] asserted that the Government's investigation of the Chemical Foundation had been in the control of Gaston B. Means, a former German agent who was known as 'Z 13' and whose salary of $1,000 a week from Germany was sworn before the Overman Committee.[102]

Almuth Vandiver, counsel to the German chemical interests, rebuked Garvan, suggesting that he and Palmer had exceeded the mandate of the Trading with the Enemy Act. Vandiver insisted that the idea that the Chemical Foundation had been established to safeguard American interests was fictitious. "Protection of American industry rests where it has always rested since the establishment of the republic; that is in the hands of Congress."[103] Garvan, in turn, warned that if the patents were returned to their original owners, "Germany will regain her prewar organic monopoly of the world."[104] Garvan maintained that not only should the Foundation be exonerated, but that further government protection of the chemical industry should be extended.

Senator Moses of New Hampshire led the argument against the protectionist measures that the dye industry was demanding. The industry wanted embargoes on some chemicals, and high tariffs on others. Moses called the chemical and dye industries the "spoiled children of the Senate Committee on Finance," maintaining that the industry was "conceived by conspiracy and fostered by falsehood...[by the] Chemical Foundation and the E.I. Du Pont de

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[102] "Daugherty Begins Criminal Action on German Patents," *The New York Times*, 10 July 1922, 1.

[103] "Garvan Turns Over Dye Patents Data," *The New York Times*, 12 July 1922.

[104] "Chemical Foundation Fight," *Literary Digest*, 29 July 1922, 15.

Nemeurs Company."[105] He rebuked the industry by insisting that the proposed tariffs "were in themselves all the protection that the industry needed or merited." Furthermore, he charged, the Du Ponts were trying to "secure for themselves an embargo in the American Market in order that they may mulct from the American consumers the sums they have found themselves unable to take from war-stricken Europeans or the simple-minded Oriental."[106]

The case came to trial on June 4, 1923, in the District Court in Delaware. The government charged that the Chemical Foundation had deliberately created a monopoly. It also claimed that the Alien Property Custodian had exceeded his power, and that the amount collected by the government for the patents was "grossly inadequate." The government wanted the patents returned.[107]

The Foundation responded that the 1918 Amendment to the Trading with the Enemy Act had been specifically conferred new powers on the Alien Property Custodian. The issue of monopoly had not entered into the picture, because the only motivation for the actions of the Custodian's office had been to "create an American chemical industry."[108]

The District Judge who first heard the case apparently accepted the honesty of the Foundation's motivation. He immediately dismissed the issue of

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[105] "Moses Condemns Embargo on Dyes," T*he New York Times*, 15 July 1922, 1.

[106] Ibid.

[107] United States v. Chemical Foundation Inc., *Federal Reporter, Second Series*, vol. 5, (St. Paul: West Publishing Co. 1925), 192-193.

[108] Ibid., 199-200.

the inadequacy of the price paid by the Foundation for the patents. He pointed out that:

> Public interest is not a synonym for money...It embraces all the great public needs...With the safety of the nation, the permanence of peace and the health of its citizens it is vitally concerned. In the category of the public needs these are not outranked by the nation's revenue.[109]

In his ruling, the Judge went further. "The sale was in effect a sale to America and its citizens, not to persons then engaged in chemical and allied industries."[110]

The court also agreed with the Foundation that the seizure of the patents had in fact been lawful, and that the President had given permission to the Alien Property Custodian to dispose of the property as he so chose. The court also ruled that Congress had the right to "eliminate enemy ownership by enemy-held properties in this country," and that, by amending the law, Congress had appropriately "transformed the Trading with the enemy Act from a purely conservation measure to one of action, and definite and drastic." In the opinion of the court, the Alien Property Custodian had acted within the limits of the law.[111]

On appeal, the Third Circuit Court pointed out that although the critical issue that the government was trying to raise was restraint of trade, that was an inappropriate issue.

> If the Foundation had been a complete American monopoly and had that fact been known to the Government officials dealing with it, that would not, in and of itself, have invalidated the sale...

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[109] United States v. Chemical Foundation Inc., 294 *Federal Reporter*, (St. Paul: West Publishing Co.), vol. 294, 1924.

[110] Ibid.329.

[111] Ibid., 204-207.

> [Only] if you were trying the monopoly under the Sherman Act would it be pertinent...[112]

In an editorial called "Legalizing Fraud," The Nation called the "Decision of the Federal Court in the Chemical Foundation suit...amazing."[113] The Literary Digest, however, suggested that "the German chemical industry, which is recognized as the cornerstone of the industries of the Reich, received a severe setback" with the dismissal of the suit to force return of the patents.[114] The Supreme Court upheld the Lower Court's opinion.

In the 1920s, the American chemical industry changed. While some of these changes were reflections of technological and scientific discoveries, others were reflections of more general developments in the American economy.[115] In the 1920s, there were a series of mergers and takeovers throughout the country that led to stronger managerial structures, and the chemical industry was no exception to the trend.[116]

Many of the companies that were contributors to the Chemical Foundation and received patents from the Alien Property Custodians went on to become major pharmaceutical companies. The participated in the general economic

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[112] "Tells of Purchase of Seized Patents," *The New York Times*, 9 June 1923, 1.

[113] "Legalizing Fraud," *The Nation*, 23 January 1924, 80.

[114] "Not to Restore the German Patents," *Literary Digest*, 26 January 1924, 15.

[115] Sklar, *The Corporate Reconstruction of American Capitalization*; Chandler, *The Visible Hand.*

[116] Liebenau, *Medical Science, Medical Industry*, 128.

pattern of the 1920s, forming mergers and developing new management systems. A number of these corporations were the leading manufacturers of sulfa drugs in the 1930s.

For example, the American Cyanamid Company was organized in 1907 by a civil engineer named Frank S. Washburn to manufacture calcium cyanamide. A supporter of the Chemical Foundation, the company was licensed to produce chemicals using confiscated German patents. In 1929, the company acquired the Calco Company, which produced intermediate coal-tar products, pharmaceuticals, vitamins, and later, sulfa drugs. In 1930 it acquired Lederle Anti-Toxin Laboratories, as well as the Chemical Construction Company, which manufactured heavy chemicals.[117]

Another pattern can be seen in the General Aniline and Film Corporation, which was created in 1939 through the merger of I.G. Chemical Corporation, incorporated in 1929, and the General Aniline Works, which had been founded in 1868 and was one of the earliest coal-tar dyestuff manufacturers in the United States. The General Aniline Works was a fairly small enterprise. Its first plant was located in a residential neighborhood until it was driven out when it began to manufacture a magenta dye, which cast a reddish tinge over the entire community. The merger brought advantages to each. The I.G. Chemical Corporation brought enormous technical expertise to the operation based on many years of experience. The company had been the American branch of the German company, I.G. Farben, and many of its executives had lost control of the company during the

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[117] Haynes, *The American Chemical Industry*, vol. IV, 21-25.

First world War, because of their German roots. The General Aniline Works had proposed during the war and brought its unassailably patriotic credentials to the merger.[118]

The general trend of mergers combined in specific ways with the acquisition of German patents. In 1913, an American company, the Hudson Aniline and Color Works, changed its name to Bayer and Company, to reflect its new association with the German Bayer Company, which had licensed it to produce certain chemicals under German patent, including aspirin. Because of those associations, when the United States entered World War I, the company was seized by the Alien Property Custodian and sold to the American company and contributor to the Chemical Foundation, Sterling Drugs. Sterling Drugs had begun in 1900, manufacturing "a single packaged medicine for a...horse and buggy delivery range of Wheeling, West Virginia."[119]

The company was incorporated in 1901 under the name of Neuralgalene and Company, with a capital investment of $25,000. In 1902, it bought several other companies. In 1909, it bought Sterling Remedy Company, and in 1917 it changed its name to Sterling. The first auction held by the Alien Property Custodian was for Bayer, which had been created to sell aspirin and other coal-tar drugs and dyes. Sterling bought it for just over $5,000,000. They kept the license for aspirin and continued to manufacture it under the name of Bayer, because the public associated the name with their product. They organized Winthrop

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[118] Ibid., 36-39.

[119] Ibid., 87.

Chemical as a subsidiary for other drugs. In 1924, Sterling sold off the coal-tar products to another American company and Foundation supporter, Grasselli Chemical.[120]

Merck also had German origins. It had been established in 1891 by George Merck, a German immigrant who became a United States citizen in 1908. He incorporated his company with $250,000 in stock and a $750,000 debt. In 1917, the capital stock was increased to $1,000,000 and the debt was retired. At the beginning of World War I, George Merck turned over common stock to the Custodian, and in 1919 it was sold to a group headed by Goldman, Sachs, and Co. and Lehman Brothers, who kept George Merck in control.[121]

Abbott was founded in 1880 by Wallace Calvin Abbott, and incorporated in 1900 as Abbott Alkaloidal Co. In 1916, the name was changed to Abbott Laboratories. although the laboratories themselves were not built for several decades. During World War I, "at the request of the Government, Abbott undertook the manufacture of many synthetics formerly imported from Germany" and for their contributions received a distinguished service citation. They also prospered. They, too, were original contributors to the Chemical Foundation and were granted licenses of German drugs. Reflecting another aspect of the broader economy as well as changes in the chemical industry, Abbott Laboratories increased its capital stock from $500,000 to 4!,500,000 in 1919.[122] In 1922,

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[120] Ibid., 174-177.

[121] Ibid., 271-275.

[122] Abbott Company Prospectus, 1936, 1.

Abbott acquired Dermological Research Laboratory. In 1928, they bought John Milliken and Co., and in 1930, Swan-Meyers.[123]

Another established company, Upjohn, had been founded by William Upjohn, M.D., in 1865 with a capital stock of $60,000. In 1913, the company hired its first chief chemist to set up a laboratory and work on vitamins. They, too, were supporters of the Chemical Foundation, and were licensed by it to produce coal-tar products. In the 1930s, they expanded their research facilities, again reflecting increased general corporate interest in research and development as well as specific scientific developments. In the 1930s, they also manufactured sulfa drugs.[124]

S. E. Massengill was founded in 1897 by Samuel Massengill who, though he was a medical doctor, never practiced medicine. Instead, he set up a drug manufacturing company that made many drugs, including private formulas for physicians and druggists. The company headquarters was in Bristol, Tennessee. By the 1930s, Massengill was the largest pharmaceutical company in the south. Massengill also produced sulfa drugs in the 1930s, with unexpected consequences.[125]

Though Germany had lost the First World War, and though German chemical companies had lost many of their patents, the German scientific-

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[123] Ibid., 2-4.

[124] Haynes, *The American Chemical Industry*, vol. IV, 456-457.

[125] *Report of the Secretary of Agriculture on Deaths Due to Elixir Sulfanilamide-Massengill*, U.S. Congress, Senate Documents 124, 75th Cong., 2nd Session (1937), 1. Hereafter Secretary's Report.

industrial structure survived. American companies would continue to benefit from German chemical research, particularly with regard to coal-tar products.

In 1927, a young chemist named Gerhard Domagk was hired by I.F. Farbendustrie as head of its laboratory in experimental pathology and told to search for bacteriostatic compounds. He began with dyes. He was employed, after all, by a dye company. He designed a series of studies using azo dyes on mice who had been infected with streptococcal septicemia. In 1932, he found one he named Prontosil, which had astonishing results in vivo.[126] In 1936, Leonard Colebrook and his associate, Maeve Kenny, who were trying to reduce rates of puerperal septicemia a Queen Charlotte's Lying In Hospital in London, used the drug on a group of postpartum women who were suffering from septicemia—with most impressive results.[127]

As exciting as Domagk's and Colebrook's work was, perhaps the most thrilling paper on Domagk's discovery--in the eyes of the drug companies--was one published in France by scientists at the Louis Pasteur Institute. They isolated the active ingredient in Prontosil sulfanilamide.[128] Sulfanilamide (para-amino-

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[126] For more detailed descriptions see Harry Dowling, *Fighting Infection: Conquests of the Twentieth Century* (Cambridge: Harvard University Press, 1977); Iago Galdston, *Behind the Sulfa Drugs;* Domagk's original paper, along with other critical publications, can be found in translation in B. Homstedt and G. Liljestrand, ed. *Reading in Pharmacology,* (New York: Pergamon Press, 1963).

[127] Leonard Colebrook and Maeve Kenny, "Treatment with Prontosil of Puerperal Infections Due to Hemolytic Streptococci," *The Lancet,* 5 December 1936, 1321.

[128] J. Trefouel, Mme. Trefouel, F. Nitti, D. Bouvet, "Activities de p-amino-phyenylsulfamide sur infections streptocciques de las souris et du lapin." *Comtes-rendusde seasnces de la societe de Biologique,* 120, 1935, 756-658. Translated in *Three Centuries of Microbiology,* (New York: McGraw Hill, 1965).

benzene-sulfonamide) had been patented in 1909. The drug's bacteriostatic properties had not been identified earlier because it was only effective when used in vivo. In test tubes, all it did was dye things red. By the time Domagk identified it as effective against streptococci, the patent had expired. Sulfanilamide, the active ingredient in Domagk's wonder drug, was in the public domain.

Samuel Massengill once explained that the beginning of the twentieth century had seen the "large scale manufacture of elegant pharmaceuticals develop into a large industry." He predicted that "our age will live in the history of medicine...as a time when men learned more and more about the physical and chemical reactions...in the human body.[129]

The development of sulfa drugs depended on scientific developments. Their importance rested on both their efficacy and their profitability. The German technology appropriated during the war, and the economic growth of the 1920s, transformed the American chemical industry as well as the disciplines of biochemistry and organic chemistry. By the time the age of miracle drugs arrived, America had sufficiently sophisticated organic chemical industry to exploit it to the fullest.

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[129] Samuel Evans Massengill, *A Sketch of Medicine and Pharmacy* (Bristol , Tennessee: Printed by S. E. Massengill Company, 1943), 237.

Chapter 3 Physicians, Drugs, and Authority

It is impossible to discuss so important a medical therapy as sulfanilamide without considering the role of physicians. Doctors are critical agents in the social history of sulfa drugs. They had a significant effect on how, and by whom, these drugs were received and used. At the same time, the new technology itself had a profound effect on the way in which doctors practiced medicine, and on the public's perception of physicians and medical authority. The ways in which doctors responded to sulfa drugs and the ways in which they applied this new therapy were shaped by social forces as much as by scientific information. In constructing a balanced historical picture of the "miracle medicine" era, it is quickly apparent just how much the social context was responsible for the changes in medicine that occurred with the beginning of the antibiotic era.

> The nature of this interaction was changed by sulfa drugs, but it can also be better understood by examining the response to these new chemical agents. Perrin Long, the acknowledged American "expert" on sulfa drugs, remarked in 1940, 'It is extremely interesting to note that American interest and knowledge of the new chemotherapeutic compounds lagged well behind that of Europe." Long substantiates his claim by pointing out that "one can search Volumes 105 and 106 [1935-1936] of the Journal of the American Medical Association without finding any reference to investigations being carried out in Germany and France." Long adds that "the original report of Domagk and his collaborators was not even mentioned in the abstract section of The Journal...nor did these extraordinary reports sufficiently impress the 'Berlin Correspondent' enough to be included in that weekly column."[1]

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[1] Perrin Long and Eleanor Bliss, *The Clinical and Experimental Use of Sulfanilamide, Sulfapyridine and Allied Compounds*, (New York: Macmillan Company, 1939), 9.

The role that doctors played, in what Long referred to as this 'lag," is a complex one and connected to several critical issues intrinsic to not just the technical practice of medicine, but to the culture of medicine as well.

Physician training and licensing had been affected by general efforts of the Progressive Movement toward regularization and science.[2] The reform of the American Medical Association, the creation of licensing organizations and stricter professional control, and the restructuring of medical education culminating in the "Flexner Report" in 1910, are "typical" of changes in other professions during the period.[3] The changes in the structure of the American Medical Association and

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[2] Defining the "Progressive Movement" is a complicated task. While some historians suggest that there was no such movement at all, others maintain there was a sufficiently large number of loosely related reform movements in the first decades of the twentieth century and that they can be characterized in some fashion of one reform impulse. The term is used here in the sense of a general belief among many educated and/or middle-class Americans that some level of social reform was necessary and that the best way to achieve social order was through the employment of scientific principles in an organized, modern, and systemic fashion. For more detailed discussion, see, among others, John Milton Cooper, *The Pivotal Decades: The United States, 1900-2910, (1990)*. Alan Dawley *Struggles for Justice: Social Responsibility and the Liberal State* (Cambridge: Harvard University Press, 1991). James Wienstein, *The Corporate Ideal in the Liberal State, 1900-1918* (Boston: Beacon Press, 1968), Robert Weibe, *The Search For Order, 1877-1918* (1967).

[3] Abraham Flexner, *Medical Education in the United States and Canada*, Bulletin no. 4, (New York: Carnegie Foundation for the Advancement of Teaching, 1910). Flexner's report, commissioned by the Carnegie Foundation, found that medical training in the United States was frequently inadequate. In order to raise professional standards and to reduce the number and type of practitioner, he advocated a standard curriculum as well as the closing of several medical schools. Coupled with increasing licensing requirement, also a standard Progressive reform, the medical profession did change. This type of restructuring was by no means limited to medicine. There are several excellent studies of the general movement toward professionalization during the Progressive period. See Burton J. Bledstein, *The Culture of Professionalism*, (New York: Norton 1976); Samuel Haber, *The Quest for Authority and Honor in the American Professions, 1750-1900*, 1991; for a general discussion of professionalism, see Nathan O.

state licensing boards, and increased standards in medical education, which included efforts to restrict the practice of medicine, were intended to reform, regularize, and professionalize medicine. These changes were also publicized in order to help the public distinguish between "regular," well-trained physicians and alternative practitioners and "quacks." The public, however, may not have been completely persuaded about the value of modern, scientific medicine and medical authority.

According to the historian, Ronald L. Numbers, in the early 1930s, after over twenty years of strenuous efforts on the part of the medical establishment to limit the practice of medicine to "regular physicians," one-quarter of American healers were Christian Scientists, osteopaths, chiropractors, or other "irregular" practitioners.[4] In its final report, published in 1932, the Commission on the Costs of Medical Care stated that "of the $3,656 million spent annually for medical services, $125 million is spent for the services of osteopaths, chiropractors, naturopaths and allied groups...and $360 million for patent medicines..."[5]

Hatch ed. *The Professions in American History* (Notre Dame: University of Notre Dame Press, 1988), which contains descriptions of reforms in medicine in the context of this general movement; and Kenneth M. Ludmerer, *Learning to Heal: The Development of American Medical Education* (New York: Basic Books, 1985). For a more critical look see Richard Brown, *Rockefeller Medicine Men* (Berkeley: University of California Press, 1979); Gerald Markowitz and David Rosner, "Doctors in Crises: A Study of the Use of Medical Education," *American Quarterly*, vol. 25 91973), 83-107.

[4] Ronald L. Numbers, "The Fall and Rise of the medical Profession," *Professions in American History*, 65. These figures interestingly enough are about the same as the number of people seeking alternative medical care in the late 1990s by insurance company estimates.

[5] Committee on the Costs of Medical Care, *Medical Care for the American People: The Final Report of the Committee on the Costs of Medical*

This interest in alternative practitioners has many explanations, but the statement confirms the fact that the American public was not totally committed to the idea of "regular" practitioners as the only healers, nor had they abandoned the idea of patent medication. They self-medicated, using over-the-counter drugs or using those drugs at the suggestions of salesmen, advertisements or pharmacists.

One reason for the lack of confidence on the part of the lay public may perhaps have been a suspicion that the efforts at reforming and modernizing medical education and practice had not been totally successful. If so, there may have been grounds for skepticism. The Committee on the Cost of Medical Care reported that in addition to the sums spent on patent medicines and alternative practitioners, "possibly even greater sums are wasted through inferior services rendered by some licensed physicians..."[6] The Committee suggested that, though medical science had made advances in the last 50 years, those advances were not necessarily fully utilized by the average practitioner.[7]

It is critical to recognize that science and medicine were not seen as synonymous by physicians, laboratory scientists, or the lay public. The ambivalent relationship between the two affected the practice of medicine in complex ways. The introduction of sulfa drugs is therefore neither simply the story of new technology nor that of how medicine became "modern and

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Care, (Chicago: University of Chicago press, 1932), 15. The Committee had been formed in 1927 to examine health-care issues. It was funded by eight foundations and turned out a total of 26 reports.

[6] Ibid., 17.

[7] Ibid.

scientific." Instead, it's the story of the ways in which the interaction of clinical practice and laboratory experimental medicine shaped the medical culture into which sulfa drugs were introduced.

Perhaps the most familiar embodiment of this dilemma is Sinclair Lewis's Arrowsmith, published in 1924. One of the themes of this novel is the conflict between the experimental scientist and the physician. The novel chronicles the professional life of a research-oriented physician. After many years of work, the hero achieves prominence during a plague in an unspecified Latin American country when he uses the outbreak as a field test for a vaccine he has been developing against the disease. He deliberately withholds the vaccine from part of the population in order to use it as a control group. Arrowsmith's own wife dies of the disease, sacrificed to his obsession with science. Though this novel is sometimes interpreted as celebrating "scientific medicine," in fact, to Sinclair Lewis and Paul De Kruif, his technical advisor, the conflict between science and the practice of medicine was, to some extent, irreconcilable:

> [Arrowsmith] had seen the suffering of the plague and he had...been tempted to forget experimentation, to give up the possible saving of the millions for the immediate saving of thousands.[8]

He did not, however. In the end, Arrowsmith leaves the practice of medicine for the laboratory because, in the author's view, it was impossible to do both.[9] In his

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[8] Sinclair Lewis, *Arrowsmith* (Signet Classic, 1980), 358.

[9] For an extended discussion of the social meaning of the novel and of De Kruif and Lewis's relationship, see Charles Rosenberg, "Martin Arrowsmith: The Scientist as Hero," *No Other Gods: On Science and American Social Thought*, (Baltimore: Johns Hopkins University Press, revised edition 1997), 123-134.

essay on Arrowsmith, the historian Charles Rosenberg points out that De Kruif believed that 'the physician is a skilled technician of applied science. The attempt to train each practitioner as a scientist was simply delusive." Rosenberg suggests that to Lewis, the scientist's profession was the more noble."[10] Contemporary critics saw Arrowsmith as "an unsparing onslaught upon the healing art, as practiced in America."[11] For Lewis, "as able, self-sacrificing, and understanding as the best physician might be, he could never transcend the social relationships which formed the fabric of his professional existence."[12]

Clinicians, too, perceived many scientific disciplines as in conflict with the practice of medicine. The very social relationships that Lewis deplored, were, for many doctors, the heart and soul of their profession. Laboratory science was seen as transforming medicine, but many physicians were not certain that that was a universally good idea.[13]

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[10] Rosenberg, *No Other Gods*, 130.

[11] Henry Longan Stuart, "'Arrowsmith' by Sinclair Lewis", *The New York Times*, 8 March 1925, reprinted 6 October 1996, *The New York Times Book Review*, 36.

[12] Rosenberg, *No Other Gods*, 130.

[13] Parascandola, *The Development of American Pharmacology*, 130-134. For an extended discussion of the social history of the relationship of laboratory science to medicine see Morris J. Vogel and Charles Rosenberg, eds. *The Therapeutic Revolution* (Philadelphia: University of Pennsylvania Press, 1979), particularly Chapter 2, Robert E. Kohler, "Medical Reform and Biomedical Science: Biochemistry" a Case Study; Chapter 3, Gerald L. Geison, "Divided We Stand: Physiologists and Clinicians in the American Context," and Chapter 4, Russell C. Maulizt, "Physician versus Bacteriologist: The Ideology of Science in Clinical Medicine."

In a series of articles called "Our Medicine men by One of Them," published in the 1920s in Harper's, the anonymous author remarked that doctors were beginning to be venerated as 'chosen disciples of the new God of Science" and that it was not a good thing. "The old-fashioned doctor played an important role in the community."[14] An admirable doctor is one who relies on "his clear mind and intuitive judgment," not on "modern diagnostic paraphernalia."[15] Investigators might study diseases scientifically, but the doctor's "relation to his patient should be that of a comrade coming to the aid of a stricken friend."[16]

This article directly addresses Arrowsmith's predicament, the moral and intellectual justification for the idea of testing a new cure by giving it to some and withholding it from others. The author rejects such a possibility, since a doctor must save everyone and cannot sacrifice a control group. "Humanity in general is certainly not ready for a martyrdom to the process of knowledge."[17] In writing about the development of biochemistry, Robert Kohler has pointed out that though the Flexner reforms introduced laboratory science into the medical school curriculum after 1910, laboratory scientists were increasingly focused on issues that appeared irrelevant to clinicians. Some doctors felt that scientists without medical degrees were not qualified to discuss clinical issues while, in turn,

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[14] "Our Medicine Men by One of Them," *Century Magazine*, (1992) Part I, 416-426; Part II, 593-601; Part III, 781-789; Part IV, 950-956. Quote from Part I, 418.

[15] Ibid., 420.

[16] Ibid.

[17] Ibid., 422.

biochemists feared that clinicians would try and dominate the course of science. Referring to a 1906 article in the Philadelphia Medical Journal, Barbara Rosenkrantz has commented that:

> More than one physician remarked on the very different attitude of the laboratory scientist and the physician toward the patients, a difference in part conceived as the interposition of concerns that were foreign and contrary to the welfare of the patient.[18]

This tension continued, unresolved, through the 1920s. After the 1930s, laboratory and clinical medicine began to diverge still further.[19]

Medical schools increased the amount of science in the curriculum; but at the same time, separate research facilities and departments were established with fewer, or no, clinical connections at all. In 1917, the Association of American Medical Colleges endorsed the idea of establishing separate departments for medical research, as opposed to tying such efforts into the general medical curriculum.[20] This separation was further formalized. In 1928, the "Central Society for Clinical Research" was founded. In 1944, the organization began publishing the Journal of Laboratory and Clinical Medicine.[21]

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[18] Rosenkrantz, "Cart Before Horse," 66.

[19] Robert Kohler, "The History of Biochemistry: A Survey," *Journal of the History of Biology*, vol. 8, no2. (fall 1975), 275-318. Kohler also points out that in the late 1930s and early 1940s, clinical chemistry evolved into a specialization adapted to the needs of hospital diagnostic laboratories. This redefinition was fluid. Even as laboratory training was introduced into the preclinical medical curriculum, scientific disciplines were developing and separating themselves from clinical medicine.

[20] A. McGettee Harvey, *Science at the Bedside: Clinical Research in American Medicine, 1905-1945* (Baltimore: Johns Hopkins University Press, 1981), 146.

[21] Ibid., 123-124.

Doctors responded to what they perceived as the encroachment of laboratory science on their practices. One physician wrote that:

> In an attempt to be up-to-date, physicians use the methods of these auxiliary branches so that clinical medicine toils laboriously in their rear, and to a great extent becomes subservient to them. It should be realized and strongly and persistently insisted upon, that all these special methods fall far short of the ideas of what is wanted in clinical medicine.[22]

In 1938, the Pennsylvania Chapter of the American Medical Association tried to limit medical research to those holding doctor of medicine degrees, insisting that doctorates in laboratory science were not adequate credentials.[23] Part of the hostility that doctors felt was rooted in an essential belief in the value of clinical experience and intuitive diagnostic skill.[24]

Another explanation or cause for this hostility on the part of clinicians may have been their lack of laboratory training, despite medical school reforms.

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[22] Sir James MacKenzie, *The Future of Medicine* (London: oxford university press, 1919), 189.

[23] "Practice of medicine and the Practice of Chemistry," *Science*, 21 October 1938, 370.

[24] In the first of the Doctor Kildare series by Max Brand, *Young Doctor Kildare*, (New York: Grosset and Dunlap, 1938), the hero proves his worth to the irascible old genius Dr. Gillespie by diagnosing Gillespie's own cancer, simply by feel. He just touches Gillespie's hand, arm, and elbow. Gillespie is a brilliant diagnostician, gruff and intimidating, but with the heart and soul of a doctor. "Every case that came to the great Gillespie was, according to his inexorable rule, a charity case." An obviously wealthy and clearly desperate mother has brought the doctor the child, which cries, making a "weak, scratchy noise." Gillespie touches the baby and returns it to its mother. "There's *nothing* to do?" begged the mother. Gillespie roars at her, "Of course there's something to do. Get a new milk prescription...and give the baby an enema; then he'll live forever" 217. He takes Kildare on as his assistant, "For twenty-five years I've been looking at the faces of young doctors...There was never a diagnostician's brain among them until you came along" 233.

William Mansfield Clark, who taught at Johns Hopkins Medical School, wrote that:

> In the 30s it was estimated that about half of the entering students had inadequate instruction in those more elementary parts of physical chemistry that are involved in all parts of the science and that are essential in a first approach to an understanding of matters of clinical importance.[25]

Clark complained that when he arrived at Johns Hopkins in 1927, the "laboratory equipment and space [was] totally deficient in what was required for...student instruction."[26] In 1928, Hans T. Clarke was "invited by Columbia University to direct the department of Biological Chemistry in the College of Physicians and Surgeons." The faculty had recognized the importance of developments in biochemistry and felt it was time to depart from the "classical approach of Physiological Chemistry to the problems of medicine." Clarke found that the laboratory "though new, was not well equipped with modern facilities." The organization that eventually came to his rescue was, interestingly, the Chemical Foundation, which gave him a grant that "made possible the supplementation of laboratory installations and the purchase of a truly adequate series of chemical journals for the general library."[27]

Even more pointed is the comment of another chemist, Rudolf Lemberg:

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[25] William Mansfield Clark, "Notes on a Half Century of Research, Teaching, and Administration," *Annual Review of Biochemistry*, vol. 31, (1962), 10.

[26] Ibid.

[27] Hans T. Clarke, "Impressions of an Organic Chemist in Biochemistry," *Annual Review of Biochemistry*, vol. 27, (1958), 3.

> Perhaps my work in a hospital laboratory has...contributed something to raise the standards of hospital biochemistry, and the status of the hospital biochemist, who in the past, was often a poor and oppressed servant of the medical doctor.[28]

There were efforts toward reconciliation. Not all doctors were antagonistic to laboratory science. One physician writer suggested that "the present status of medicine as a science encourages conservatism...authorities in medicine...have been prone to oppose innovations that implicate their economic and psychological vested interests."[29] An article in The Annual Review of Biochemistry, published in 1936, tactfully pointed out that "throughout history the relation of clinical medicine to the more fundamental physiological sciences has been one of competitive collaboration." The article advised biochemists to work hard to "properly emphasize more particularly the problems and contributions of medicine..."[30]

Physicians looked for ways to comfortably integrate laboratory science into traditional ideas of medicine. Some of these reservations around science were simply generational—the new "modern" medical science as opposed to the old "humanist" way. Others saw the possibility of compromise as true American modernity. "The German school took the ground that medicine could not be both

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[28] (Max) Rudolf Lemberg, "Chemist, Biochemist, and Seeker in Three Countries," *Annual Review of Biochemistry*, 34, (1965), 18.

[29] Bernard Stern, *Social Factors in medical Progress*, (New York: AMS Press, 1968), 33.

[30] John P. Peters, Clarence L. Robbins, and Paul H. Lavietes, "Clinical Applications of Biochemistry," Annual *Review of Biochemistry*, V, (1936), 295.

art and science...but the 20th Century has proved...that a physician may be scientific and still succeed in the art of healing the sick."[31]

At the root of this conflict was the essential issue of where medical authority would be located. Was the physician a compassionate healer whose methods and authority were rooted in the values of the community and whose position was that of a respected elder of society—or was that authority rooted in the alien specialized knowledge of the laboratory? John Harley Warner has suggested that the situation is further complicated by the fact that in the late nineteenth and early twentieth centuries, the very definition of what constitutes science in medicine was changing. Some of these changes are the result of emerging new scientific disciplines, but other reflex more the cultural change in the root of medical authority than changes in the biochemical sciences.[32]

To some extent, this is part of the broader issue of modernity in the early decades of the twentieth century, which has been characterized in many ways. Historians have discussed the sense of loss and change at the beginning of the twentieth century, describing it variously as nostalgia, a fear of modernity, or the efforts of the elite to maintain their position in the community. One aspect of the struggle over the role of laboratory medicine can be seen in this argument.[33]

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[31] James Warbasse, *Doctor and the Public*, (New York: P. B. Hover, Inc., 1935), 337.

[32] John Harley Warner, "Science in Medicine," *Orsis*, 2nd Ser. 1 (fall 1985), 37-58.

[33] Several critical discussions are found in Richard Hofstader, *The Age of Reform: From Bryan to FDR*, (New York: Alfred A. Knopf, 1955); Jackson Lear's *State of Grace;* Daniel Joseph Singal, *The War Within* (Chapel Hill: University of North Carolina Press, 1982); Robert Wiebe, *The Search For Order.*

Traditionally, the doctor's experience and position in the community—not only scientific knowledge—gave him his authority. In the eyes of many, this was how it should be. As one physician wrote in 1927:

> In Medicine, dealing as it does with the human organism in relation to its complex environment, it is difficult to speak with certainty of proof...[For the doctor] the choice [of treatment] must be guided by faith in authority and by his own experience...[34]

The laboratory seemed to challenge the importance of clinical experience. This was not true of all doctors, especially the "new modern" doctors, who integrated laboratory science into the practice of medicine without difficulty.[35] The conflict within the medical profession was generational, as well as a reflection of elite medical training versus less modernized instruction. One physician wrote in his memoirs:

> In 1923...I was beginning to be asked by local medical societies from all over the state to come and discourse on the newer treatment of diabetes. I recall one such trip to Port Tobacco on the Potomac River...The rural physicians were attentive but asked few questions...To most of the older among my listeners the discussion of the pathological physiology of diabetes mellitus might just as well have been given in Greek...medical education of the period had given them very little of biochemistry or the physiology of the metabolism.[36]

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[34] Stern, *Social Factors in Medical Progress*, 20-21.

[35] See Regina Markell Morantz-Sanchez, *Sympathy and Science: Women Physicians in American Medicine* (New York: Oxford University Press, 1985), for an examination of the role that gender plays in the construction of medical authority. See also Virginia Drachman, *Hospital with a Heart* (Ithaca: Cornell University Press, 1984).

[36] William McCann, unpublished memoirs as quoted in *Science at the Bedside*, 150.

The conflict also extended to the idea of specialization as opposed to the idea of the general practitioner. A popular version of the debate can be seen in a serialized novel, published in Ladies' Home Journal in 1936, called "Private Duty," in which the heroine, a nurse disillusioned with medicine:

> ...suddenly remembered a doctor who came very occasionally to the hospital, but whose practice was very general and in the outlying farm districts. He was old, weathered, genial and beloved. The younger men disliked him; he was too versatile to please them; he'd take on a case of measles, a broken leg, a ruptured appendix or a delivery with equal equanimity.[37]

There were numerous reasons for locating medical training more firmly in laboratory science, but there were unexpected consequences as well. To many doctors, the laboratory seemed to directly attack the practice of medicine. As Barbara Rosenkrantz has written:

> The notion that specific measures directed against specific disease could reduce the personal contingencies presented by specific patients was hardly calculated to attract enthusiasm from a professional group such as physicians, whose clients demanded individual attention.[38]

To many doctors, the idea that there was a formula cure for a patient meant that their expertise was undermined. If a standardized product of the laboratory could provide a standardized cure, the physician's role was unnecessary. They were threatened with de-skilling.[39] Public health crusades—again, a "Progressive

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[37] Faith Baldwin "Private Duty," *Ladies' Home Journal*, March 1936, 120.

[38] Rosenkrantz "Cart Before Horse," 72.

[39] Linda Gordon, among other historians, has suggested that the physicians advocated restrictions in access to birth-control information and devices in order to strengthen their professional position. One of the ongoing arguments about the birth-control movement is the extent to which some advocates permitted the issue to be "medicalized" in order to win the support of the American Medical

Reform" that emphasized environment, biomedical controls as opposed to individualized care—threatened doctors, and many resisted public health efforts. For example, some physicians were in opposition to establishing regularized dosages for vaccinations and inoculation, insisting that the physician needed to calibrate an individual dose for each patient.[40] Such a system made it impossible for the establishment of massive vaccination programs that would use nurses or other public health workers instead of doctors. In this context, it is easy to see how sulfa drugs could be seen as a de-skilling technology.

Without question, the Flexner Report and the reforms it engendered did change medicine, but these changes were not necessarily reflected in changes in the public's perception of medical authority. Middle-class women's magazines in the 1930s were filled with romantic stories. The tone of this fiction was generally optimistic and positive, and doctors were rarely the heroes of these stories. Women wanted to marry men who "accomplished things," either in terms of material success or for the good of humanity. The preferred careers for husbands seemed to be engineers (especially those who were going to build major damns in Latin American countries) or businessmen who, in their independence and desire to "contribute" to society, were wholly admirable Americans. Doctors were simply not good marital catches in the eyes of the editorial boards of many of these magazines—and presumably in the minds of their readers.

Association for legislative changes that made access to birth control more widespread. See Linda Gordon, *Woman's Body, Woman's Right: A Social History of Birth Control in America* (New York: Grossman, 1976).

[40] Rosenkrantz, "Cart Before Horse," 71.

To some extent, the position of doctors can be seen as much by their omission as by the ways in which they were portrayed. To use Collier's Magazine as a case study, in 1936, the year in which sulfanilamides were first used in Europe, there were only two stories in which doctors appeared at all. One was a long, serialized novel with a nurse heroine, who in the end renounced her boyfriends, excitement, and glamour and married a doctor.[41] The other piece is a short story set in a hospital at Christmastime, in which a nurse comes to understand the true meaning of Christmas from sensing the harmony of the whole community, including patients, doctors, nurses, and cleaning staff.

There are no doctors at all in any piece of fiction published in Colliers in 1937. In 1938, there is one story that features a doctor, "The Doctor Said Ouch!" The heroine of the tale is a doctor's receptionist, the only member of the office staff not intimidated by the doctor, who has no sense of humanity or respect for the suffering of his patients. When the doctor gets sick, he acts like a baby. When other doctors are called in, they are all proved to be incompetent or foolish. Only the sensible receptionist is able to deal with the situation. The doctor is, of course, smitten and asks his receptionist to marry him, but she refuses. Instead, she marries a former patient, a man who owns a printing company.[42]

Not only were doctors unlikely to be the heroes of romantic fiction, they were not likely to be dispensers of advice. For example, the 1936 index of

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[41] Terese Hyde Philips, "The Prodigal Nurse," *Colliers,* 23 May through 13 June 1936.

[42] Frederick Hazlett Brennan, "The Doctor Said Ouch!" *Colliers* (27 August 1938).

Parent's Magazine lists 22 articles on child health and care. Of those, only 12 were written by physicians. In the Education, Behavior, and Psychological section, there were 31 articles. Of those, none was written by a doctor, including articles that would appear to have medical content, such as "how to Deal with color Blindness" or "Beginning Sex Education."[43]

In a long 1938 article in Colliers on how to care for sick children—written by a nurse—the only mention of doctors was the comment that "calling up the doctor for a child's every sniffle, stomach ache or sprain can be overdone." The author makes it clear that for the most part, "after the nursing treatment outlined, the child will feel like himself within twenty-four hours." Should this not be the case, "there will still be time to call in your physician."[44]

Advertisements for drugs, tonics, and other medical products are other indicators of the degree to which doctors were seen as authority figures.[45] The Metropolitan Life Insurance Company ran an extensive advertising campaign in many magazines in the 1930s that emphasized health issues. Those advertisements did refer occasionally to doctors, but even they emphasized that people should take care of themselves and their health. Doctors played a role in that effort, but ultimate responsibility rested with the individual. One ad in the

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[43] These authors of these articles had no professional credentials at all, or at least none that were revealed by the magazine.

[44] Lucille McGorkey, R.N., "That Child's Problem: How to Solve It," *Colliers* (May 1938), 56.

[45] This discussion is based on an examination of advertisements in 1936. There are changes by the end of the 1930s, in part because of the provisions of the 1938 Pure Food, Drug, and Cosmetic Act, which reinforced physician authority. See Chapter 5 for a more complete discussion.

Ladies' Home Journal in 1936 was headlined: "When do you see your Doctor?" The copy went on to suggest:

> If you wait until sickness you are taking advantage of only part of your doctor's skill! Make him your health counselor at all times—not only when you are ill but when you are well. It is the modern way to take care of yourself.[46]

The appeal in the Metropolitan Life advertisement focuses on modernity as much than anything else. In 1936, Ladies' Home Journal, aiming at a middle- and upper-middle-class female audience, carried numerous advertisements for tonics, vitamins, and cold remedies. Eight nurses, pictured in full uniform, are giving advice. Interestingly, there were no images of doctors, although they were occasionally mentioned in the ad copy. Mothers, on the other hand, are featured players. Typical headlines include statements in bold type like "HEAD COLDS? TREAT PROMPTLY, MOTHER!" in an ad for nose drops, or "MOTHER: THERE'S NOTHING LIKE PENETRO FOR YOUR CHILD'S COLD!" in an ad for a mutton, suet-based salve.[47]

Science is not ignored in these advertisements—quite to the contrary; but the references to science do not require the mediation of experts. It is science that is available to the lay person McKesson's Cod Liver Oil stressed that mothers were fighting a war against illness and the weapon was McKesson's product. "WILL YOUR CHILD WIN STRONG TEETH AND BONES, A BODY FREE FROM RICKETS?" The ad points out that there is nothing old-fashioned about

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[46] *Ladies' Home Journal*, 2 February 1926, 45.

[47] *Ladies' Home Journal*, January 1936, 37.

cod liver oil. "Arm you child with modern weapons. Build up his resistance with McKesson's High Potency Cod Liver Oil."[48]

Germs and their dangers are frequently mentioned. Lysol advertisements often featured the Dionne Quintuplets. Nurses played an important part in the advertising campaign. The quits were delivered by a heroic doctor, and his role was well publicized, but it was not part of their everyday world. Their birth was an extraordinary achievement of modern medicine, but Lysol needed to connect the event to the needs of the average consumer. The advertising copy was focused on the more ordinary aspects of childrearing to which every mother could relate:

> Since the day of their birth, "Lysol" has been—and still is—the only disinfectant used to help protect these five famous babies from the constant danger of infection. The very first registered nurse who reached the Dionne home, that exciting birthday morning in May 1934 had "Lysol" with her in her kit and went to work with it at once.[49]

Every mother could protect her baby from germs in exactly the same way as the quintuplets had been protected. The advertisement stresses the scientific importance of germicides, making it clear how effective and accessible this technology was. "The scientific care given to the Dionnes is an example every mother should follow." To further emphasize how easily every mother could be modern, as well as demonstrate the unmediated nature of science, the ad

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[48] *Ladies' Home Journal, February* 1936, 82.

[49] *Ladies' Home Journal,* July 1936, 83.

concludes with "Full directions for the correct use of 'Lysol' come with each bottle."[50]

A survey of advertisements in Collier's Magazine from 1936 included plenty of images of authority figures—mechanics, lawyers, businessmen—but no doctors. For example, in the January 11, 1936, issue, there were 15 advertisements for over-the-counter medical products. An advertisement for toothbrushes made no mention of dentists, though a "science professor" was mentioned in the text. Buried in the copy of a Bayer Aspirin advertisement is the claim that "People by the thousands are combating sore throats this way. Doctors endorse it. And scientists acclaim it..." An ad for EX-LAX pictured a kindly pharmacist recommending the product as a cure for colds, since regularity is important for good health. There is no mention of either doctors or science in an advertisement for Vapo Cresolone, an inhalant intended to fight bronchitis. Nor were doctors referred to in numerous cough drop or antacid advertisements. The copy of an advertisement for Listerine described the ways in which Listerine fought colds in a "sensible, scientific way." The ad featured a small scroll at the bottom inscribed:

> For more than 50 years Listerine has had the commendation of outstanding men in the fields of medicine, bacteriology and chemistry. In addition it has won high awards at great Centennial Fairs; has been tested in Laboratories of international repute, and

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[50] Ibid. Labeling became a critical focus of the attempts to limit self medication and the use of patent medicines. After the passage of the 1938 Pure Food, Drug, and Cosmetic Act doctors applied enormous pressure on the Food and Drug Administration to restrict the amount of information on labels. The Lysol ad quoted above is an example of why. The less information on labels, the more the patient would have to rely on the physician's directions.

today is approved by the famous Good Housekeeping Bureau in New York City.

At the bottom of the scroll was a large Good Housekeeping seal and several Centennial Fair models. The copy made numerous references to science. "Don't go on suffering with heavy colds that undermine your strength. Don't put up with painful sore throats. Go after these conditions in the sensible scientific way..." The advertisement also presented the evidence, "Scientific tests in 1930-31, 1931-32 and 1934 have shown this comforting result: that those who gargle with Listerine twice a day or oftener caught fewer colds than non-garglers."[51] These advertisements suggest that science itself was an authority that could be believed and understood by the lay person.

These advertisements were effective. Americans bought drugs. The Committee on the Costs of Medical Care reported that Americans spent as much on medicines as they spent on physicians and hospitals. The Committee went on to characterize manufacturers and vendors of drugs and medicines as "engaged in the healing arts."[52] The physician was undercut again. Pharmaceuticals threatened the physician's position—even pharmacists could be seen as a threat. As an illustration, in his autobiography Bobst, Pharmaceutical Pioneer, Elmer Bobst reports that in the early 1900s, "all pharmacists were called Doctor." The "physician druggist" that Bobst first worked for maintained a pharmacy in his home that provided the only medical care in "that poor neighborhood." The

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[51] *Colliers*, 11 January 1936, 3.

[52] "Final Report of the Committee on the Costs of Medical Care" (1932) 28.

"physician druggist" and Bobst found themselves practicing medicine. "We revived attempted suicides and failed o revive a few; we tended injured people who came into the pharmacy for help."[53]

Drugs were divided into categories, ethical and proprietary drugs. Proprietary drugs were patented substances. Their formulas were kept secret, and they were advertised to the general public. Ethical drugs were those that were advertised only to the medical profession, and their ingredients and patent information were disclosed. Only patent medicines were prepackaged. In the case of ethical drugs, the pharmacist or physician prepared the prescription. There were, however, no stipulations attached to the prescription. The druggist could make up enough for a whole family or package and sell the doctor's prescription to the general public (unless it contained opium).[54]

Two directories were published to inform doctors about drugs. One was the United States Pharmacopoeia, published every ten years by a group of physicians and pharmacists, which listed drugs and preparations. The other was the National Formulary, which contained pharmaceutical formulas in current use.[55] Even though both the Pharmacopoeia and the National Formulary were well established by the turn of the century, many physicians made little use of

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[53] Elmer Bobst, *Bobst, The Autobiography of a Pharmaceutical Pioneer*, (New York: David McKay Company, Inc., 1973).

[54] James G. Burrow, "Prescription Drug Policies of the AMA," John B. Blake, ed. *Safeguarding the Public* (Baltimore: Johns Hopkins University Press, 1970); Jan McTavish, "Aspirin and the AMA," *Bulletin of the History of Medicines*, 61. No. 3, 1986, James Harvey Young, *Toadstool Millionaires*, (Princeton: Princeton University Press, 1961).

[55] Parascandola, *The Development of American Pharmacology*, 90-93.

them. A 1907 survey among members of the American Medical Association revealed that fewer than half had ever seen the Pharmacopoeia and that less than a third had seen the National Formulary.[56]

In order to establish guidelines for physicians, and in order to have control over those guidelines, the American Medical Association created the Council on Pharmacy and Chemistry in 1905. The Council was directed to examine new products and began publishing a listing of what were determined to be acceptable drugs in the New and Nonofficial Remedies (N.N.R.) in 1907. When a medicine was submitted to the Council for approval, it had to be accompanied by accurate information on active ingredients. All trademark and patent applications had to be submitted to the Council as well. In addition, these medicines could not be advertised to the lay public. While officially the cardinal faults were intentional deception and secrecy of composition, in reality more drugs were rejected for inclusion in the N.N.R. because of surreptitious advertising to the public than for all other reasons combined.[57]

Physicians felt that self-medicating undermined their authority and income. Drug companies were obviously aware of those concerns. The advertisements quoted above do more than retrospectively reveal a lack of popular perception of doctors as the ultimate medical authority. They were an irritant at the time to physicians, as well as a cause for concern. Doctors were

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[56] Burrow, "Prescription Drug Policies of the AMA," *Safeguarding the Public.*

[57] John Blake ed., *Safeguarding the Public,* 114.

well aware that they had not established their professional position to the extent that they had wished.

George Bernard Shaw put it bluntly when he wrote that the doctor "is made of the same clay as the ignorant, shallow, credulous people who call him in when they have tried in vain every bottle and every pill the advertising druggist can persuade them to buy."[58]

In the American Medical Association magazine aimed at lay readers, Hygeia, one 1935 article explained that the reason modern childhood was safer was because of the "new attitude toward the importance of pediatrics," creating the role of the "third parent of the child of today." The lengthy article tried to persuade readers that they should not turn to neighbors and friends, nor should they "depend on baby books for advice." The author emphasized that "the doctor is the best and only source...for guidance [and] his judgement should be accepted without question."[59]

An examination of the issue of maternal mortality illustrates another aspect of this conflict over medical authority. The United States had a relatively high maternal and infant mortality rate compared to other industrialized countries. The public health profession had attempted to address the problem. At its urging, a law had been passed in 1902 "[a]uthorizing the Bureau of the Census to collect

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[58] George Bernard Shaw, "Preface on Doctors," *The Doctor's Dilemma*, 1909.

[59] Beulah France, "Modern Doctors for Modern Babies," *Hygeia*, November 1935, 1022-1026.

mortality statistics annually."[60] The American Medical Association officially recognized the problem to the extent that it sponsored the First Conference on the Prevention of Infant Mortality in 1909, though many physicians continued to underreport maternal mortality. By 1933, all the states theoretically registered birth and death statistics, though the reporting was inaccurate, despite the plea from public health officials that such figures were necessary.[61] Even underreported, the numbers were disturbing. Some statistics put the United States 17th in the industrial world in maternal mortality in 1920; but according to the Children's Bureau, the United States ranked 20th in maternal mortality among industrialized countries. The differences between first and twentieth place were not minor. Denmark had the lowest maternal mortality rate, 23.5 per 10,000 live births. The United States' maternal mortality rate was 79.8 per 10,000 live births.[62]

Inspired by the successful organization of the country during the First World War, as well as basic Progressive principles, in 1921 Congress passed the Sheppard-Towner Act. The bill funded a federal program that would provide funds for prenatal and antenatal care to those states with particularly high maternal and infant mortality statistics. The program would be administered through the Children's Bureau.

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[60] Martha M. Elliot, M.D., "Consumer Demand for Vital Statistics: The Need of the Child Hygienist," *American Journal of Public Health*, 26 (May 1936), 494.

[61] Ibid., 494-496.

[62] R. M. Woodbury, *Maternal Mortality*, Children's Bureau Publication, no. 15, Washington, D.C. (1926), 57.

The American Medical Association vigorously opposed the legislation. Dr. Alfred H. Quessy testified before the Senate Education Committee and explained:

> There is no evident desire on the part of the American public for such legislation. The women who are clamoring for it are those who have time to waste and money to burn. This legislation comes from the erroneous idea that the health of the American nation has gone below the standard. This is not the case.[63]

> A letter was read into the Congressional Record written by John Howland, M.D., the Chief of Pediatrics at Johns Hopkins, in which he stated that "he opposed the bill because he did not believe any such emergency existed as was claimed or that there is any basis for the statement that the United States stands seventeenth in the maternal death rate.[64] Doctors complained loudly about women's organizations that were bringing pressure, warning that what they were suggesting was socialism. This met a responsive note in Congressman Hawes of Missouri, who voiced many concerns important to doctors. He worried that the law created a precedent for the "promulgation of...doctrines totally antagonistic to the American idea of the rights of the home and the fundamental fact that motherhood is the fruition of love and not of science."[65]

This debate took place at the height of the Red Scare (led by A. Mitchell Palmer, former Alien Property Custodian) and the rhetoric of socialized medicine, or "un-American" activities, was a potent one.

John J. Kindred, M.D., another spokesperson for the American Medical Association, dismissed the argument in the simplest manner possible. He explained:

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[63] R. M. Woodbury, *Maternal Mortality*, Children's Bureau Publication, no. 15, Washington, D.C. (1926), 57.

[64] "House Debate on Sheppard-Towner Bill," *Journal of the American Medical Association*, 76, no. 33 (December 1921), 1913.

[65] "House Debate on Sheppard-Towner Bill," *Journal of the American Medical Association* (November 1921), 1913.

> the organized medical profession of the country was solidly against the measure and through no selfish reason whatever;...there is no disquieting death rate at the present time...and the various states can more effectively carry out measure for maternal and child welfare than the 'mongrel measure' pending before us...[66]

Congressman Barkley, a Democrat from Kentucky, responded by asserting the government's interests. He:

> resented the insinuation that the members of the House were influenced by a women's lobby...Congress appropriated money without hesitation for the welfare of animals, and there was no reason why it should not make appropriation for the welfare of mothers and children.[67]

Physicians had their supporters in Congress who responded to their concerns directly. Senator James Reed explained that the whole Sheppard-Towner Bill was unnecessary, because there were already "a hundred and fifty thousand physicians" who were more than capable of taking care of the situation. Certainly, "what they cannot accomplish will not be brought about by a society of spinsters trekking over the country in automobiles, armed with...fantastic notions."[68]

There were some doctors who urged caution while at the same time rejecting the bill. A letter was published in the Journal of the American Medical Association from a physician from New York who wrote, "No one can deny that proper or sufficient obstetrical care is inaccessible to large numbers of our people." He even admitted that the American maternal mortality rate "is not

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[66] Ibid.

[67] House Debate Congressional Record, 67th Congress, First Session (1921), 1932-1933.

[68] Ibid.

commensurate with its standing as a leading nation..." and pointed out to his fellow doctors that American medical education and practice has not "yet come to the realization that obstetrics and gynecology are major divisions of medical practice." The profession should take steps to remedy this, especially in medical schools. He warned that "too much responsibility has been thrown on the social workers, visiting nurses, etc. and the physician graciously permitted to occupy a subordinate position." This was clearly wrong. He explained that though "there must be a thorough understanding between the physician and layman, this cannot be secured if the latter's point of view is made the overshadowing one."[69]

The Secretary of the American Medical Association's Council on Health and Public Instruction warned in 1921 that doctors had to address the issue of public perception of doctors. "A change has taken place in the relations of physicians and the public" and not one for the better.[70] Part of the problem could be blamed on the public health movement, which tried to extend its influence beyond the Sheppard-Towner Bill to other schemes that smacked of socialism, such as compulsory health insurance, to which the "organized medical profession is...unqualifiedly opposed..."[71] Connecting his argument to basic political issues and the "American way of life," he pointed out that physicians were not trained in public health because "a physician makes his living by charging individual

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[69] George W. Kosmak, M.D., Letter to the Editor, *Journal of the American Medical Association*, 76, no. 19 (May 1921), 1319.

[70] Frederick R. Green, M.D., "The Social Responsibilities of Modern Medicine," *Journal of the American Medical Association*, 76, no. 22, (May 1921), 1477.

[71] Ibid., 1481.

patients for individual services."[72] He suggested changing that tradition. Science recognized the importance of public health and if doctors did not take leadership positions:

> we must expect to see this field taken over by nonmedical workers; as has actually occurred in the last few years in social welfare organizations, made up almost entirely of men and women without medical knowledge and in many cases without scientific training.[73]

While physicians prevented the renewal of the Sheppard-Towner Act, that did not mean that they had been able to consolidate their position in the minds of the lay public. It also did not mean that maternal mortality rates declined.

The Depression exacerbated these issues of physician authority. Citizens simply could not afford doctors. Instead, they were more likely to spend their limited funds on over-the-counter medication. Between 1929 and 1933, physicians had a 60% drop in income.[74] The story quoted earlier from Ladies' Home Journal, "Private Duty," which described the old general practitioner adored by patients and resented by young doctors, explained that the younger men disliked him because "his house calls remained at two dollars, and his office visits at one. Old Bronson, they grumbled, took the bread out of their mouths."[75]

In 1926, an independent body of economists, physicians and public health specialists began to meet, funded by private foundations, calling themselves the

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[72] Ibid.

[73] Ibid., 1478.

[74] Davis G. Johnson, *Physicians in the Making*, (San Francisco: Jossey Bass Publications, 1983), 14.

[75] Faith Baldwin, "Private Duty," 120.

Committee on the Costs of medical Care. Their focus was the issue of the cost and distribution of medical care.[76] The Depression raised even more concerns among New Deal reformers about the abilities of Americans to obtain health care. In 1932, the committee made its final report. Many of the committee's recommendations did not please organized physicians. Several of the physicians on the committee refused to sign the final report.[77] "We have been reading a great deal about this iniquitous report" by the Committee on the Cost of Medical Care, "which would turn over the medical profession to a group of laymen and would...introduce the Russian system of the practice of Medicine."[78]

Some doctors, like R. G. Leland, director of the Bureau of Medical Economics of the American Medical Association, reminded his colleagues:

> We ought to admit that there are groups in this country which are not able always to take care of the costs of medical care...[for whom] even the physician's charges are exceedingly hard to meet, but I am firmly convinced that if we will search far enough, we will find that inability to pay for medical care does not lie in the cost of medical care...as much as it lies in some of the other industrial social, and commercial relations of these people.[79]

Other physicians tied their opposition to the report directly to their support of capitalism and their opposition to Roosevelt and the New Deal. Charles

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[76] Paul Starr, *The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry* (New York: Basic Books, 1982), 260.

[77] Ibid.

[78] Dr. H. Sheridan Baketel, "Proceedings of the 1933 Annual Meeting of the American Pharmaceutical Manufacturers Association" 169.

[79] R. G. Leland, "The Economics of Medicine," Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association, (1933), 184.

Whalen, the editor of the Illinois State Medical Journal, reminded doctors that their allies might not necessarily lie with science, but rather with those who were fighting on many fronts to preserve the American way of life:

> the future of medicine depends upon the degree to which our national conscience rouses to fight the imminent menace of socialist usurpation...the fate of medicine is bound to be the common fate of all...the same communistic tendencies striving to disrupt medicine today are so engaged with the destruction of all existing order...So medicine asks of industry this question, we have let you look into this crystal, do you fight with us or stand idly by?[80]

Organized medicine could serve as a model in many ways; "the medical method of approach to problems is quite as applicable to social, business, or national affairs as to the bedside."[81] Many doctors agreed, pointing out that "physicians must run their practices as business...state medicine is the American way."[82]

Even doctors who identified themselves politically with the left agreed with the basic AMA position. One non-physician reformer complained that though the Daily Worker, "organ of the Communist Party of the United States," ran a daily health column written by Communist Party member physicians, "the professional patterns which obtain among conservative physicians are accepted

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[80] Charles J. Whalen, "The Future of Medicine," Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association, 1933, 170-178.

[81] James Warbasse, *The Doctor and the Public*, 386.

[82] Baketel, "Proceedings of the 1933 American Pharmaceutical Manufacturers Association." Dr. Baketel went on to add that it might in fact be necessary to provide some kind of health care for the poor, using physicians who "for one reason or another would be to work effectively under salaried conditions" 199.

uncritically" without any regard to the underlying economic issues that shaped many of those patterns. Communist doctors are so "conventional in their treatments that it is clear that their 'political radicalism' doesn't overcome their medical training."[83]

The public continued to stubbornly focus on certain health issues, among them essentially unchanged maternal and infant mortality rates. The Department of Labor Children's Bureau, scorned by opponents during the Congressional debate on Sheppard-Towner, continued to collect statistics. In 1933, they published "Maternal Deaths—A Brief Report of a Study Made in 15 States."[84] The study reported maternal mortality rates of 67 per 10,000 live births. Furthermore, the Children's Bureau findings determined that 40% of those deaths were the result of puerperal septicemia, defined as "obvious and unmistakable sepsis, and the number of deaths attributed to this cause is the minimum."[85]

In 1933, the New York Academy of Medicine Committee on Public Health Relations published a study of maternal mortality in New York. They, too, found the leading cause of maternal death to be septicemia.[86] The committee

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[83] J. B. Matthews, *Guinea Pigs No More* (New York: Couici, Friede, 1936), 45.

[84] U.S. Department of Labor, Children's Bureau Publication, no. 221, *Maternal Deaths "A Brief Report of a Study Made in 15 States,* U.S. Government Printing Office, 1933. The states included in 1927 were Alabama, Kentucky, Maryland, Michigan, Minnesota, Nebraska, New Hampshire, North Dakota, Oregon, Rhode Island, Virginia, Washington, and Wisconsin. In 1928, California and Oklahoma were included as well.

[85] Ibid., 37.

[86] The New York Academy of Medicine Committee on Public Health Relations, Ransom S. Hooker, M.D., Director of the Study, *Maternal Mortality in*

examined each death to determine if the death was "inevitable" based on the criterion of "the best possible skill, both in diagnosis and treatment, which the community could make available." Interestingly, the study went further and determined "where responsibility of preventable death should be lodged on the attendant, whether physician or midwife, or on the patient herself."[87] Of the septicemia deaths, 75.1% were considered preventable, and 81.7% were ascribed to physician error.[88]

> It has been a reproach to obstetrics that the high incidence of deaths from puerperal septicemia has not materially lessened during the antiseptic and aseptic era, as it has been in surgical practice...[89]

The report concluded regretfully that "in the majority of puerperal infections, especially in the fatal ones, the infecting organism has been introduced from without."[90]

The Children's Bureau convened a conference on "Better Care for Mothers and Babies" in 1938, and announced that there seemed to have been almost no reduction in the maternal mortality rate during the twenty-two years for which records were available. The percentage of maternal deaths caused by

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New York City: A Study of All Puerperal Deaths, 1930-1932 (New York: Oxford University Press, 1933), 36.

[87] Ibid., 19.

[88] Ibid., 32-33. The blame for the other deaths was apportioned as follows: 3.7% were ascribed to midwives and the remaining 14.6% to patients.

[89] Ibid., 72.

[90] Ibid., 74.

septicemia remained about the same as well.[91] The conference was focused on finding solutions for those deaths that had been judged as preventable. Perhaps not surprisingly for a government agency, they felt that the best solution was a massive government program to improve maternal and infant health. The conference also expressed concerns over medical training:

> It was brought out that while a medical student ought to attend at least fifty confinements if he is to handle such cases in practice, many Grade A medical schools do not require the student to be present at any deliveries before graduation and others require only two to fifteen cases...[92]

Some members of the medical profession agreed, recommending better obstetrical training.[93] They accepted responsibility for their role in the problem:

> It is futile to educate the public to recognize and demand certain minimum standards of the medical standards if the medical profession fails to make these standards available. Any such practice...tends to undermine the confidence of the lay public in the medical profession.[94]

The establishment in 1930 of the American Society of Obstetrics and Gynecology was also part of the movement to improve training and care. The American Committee on Maternal Welfare, made up of "elite Practitioners and Institutions," was formed to write an extensive booklet, Maternal Care: The Principle of Antepartum, Intrapartum and Postpartum. The committee made recommendations about proper care, including a lengthy discussion of septicemia.

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[91] Beulah Amidon, "Women and Children Last," *Survey Midmonthly*, 74, (February 1938), 34.

[92] Ibid., 39.

[93] Hooker and Miller, *Maternal Mortality*, 219.

[94] Ibid., 49.

The authors concentrated on prophylactic measures. The text warned doctors not to contaminate a patient by going to a labor from treating scarlet fever, to sterilize sheets and towels if possible, etc. If infection did occur, these elite practitioners recommended fresh air, sunshine, blood transfusion and nursing care. At the end of an eight-page section on care of the infected mother, there is one paragraph referring to sulfanilamide. "Recently, sulfanilamide has been strongly advocated in streptococci puerperal infections...like all new preparations it has found friends and critics." What is critical to note is that this booklet was published two years after the Lancet articles reporting on the use of Prontosil in queen Charlotte's Hospital in London. It was also two years after Newsweek ran a story, "Reddish Dye Comes to the Aid of Women in Childbirth," which described the drug and its successful clinical trials to the general public.[95]

The New York Academy of Medicine report advised doctors to take the lead in this issue, because 'there are not lacking among lay writers those who are eager to inform or misinform their readers as to the proper conduct of the physician."[96] There was no question that physicians were genuinely concerned about the high maternal mortality rate, but they were also enraged by the public attention and outcry around the issue.

The Ladies' Home Journal published a four-part study of the problem in 1936. Written by Paul de Kruif, it began:

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[95] "Reddish Dye Comes to the Aid of Women in Childbirth," *Newsweek*, June 1936, 42.

[96] Hooker and Miller, *Maternal Mortality*, 217.

> To the mothers of America: Every 14 seconds some mother brings into being a new life - and for each 175 new lives some mother trades her own. Is this necessary?...NO! Can it be prevented?...YES![97]

The article goes on to assure women that maternal mortality rates can be lowered, but that the mothers themselves must become active in that fight. "Protest now! Protest to your Physician, to your Mayor, to you Congressman, to your President—NOW!" De Kruif went on to lay the responsibility firmly on doctors: "Many physicians, not knowing it, have carried death from sick women to healthy and more often than not this unwitting murder does not out."[98] De Kruif also explained that part of the problem was that doctors had not considered childbirth an illness, so medical students were not adequately trained.

Many of these criticisms were the same ones that members of the medical profession had essentially agreed upon among themselves. De Kruif's solutions, however, were quite different from those of the New York Academy of Medicine. He ended his series (which ran from March to December 1936) with the assertion:

> A band of women, nation-wide, is going to inquire why all our powerful science isn't used to guard every last mother who now runs needles risk of dying to give the world new life...Their fight will not be an easy one. In the beginning there may be individual doctors, even societies of physicians, who will not want our mothers as soldiers in this battle. Medicine is a proud and ancient profession, and does not easily admit plain, non-medical people into its fight with death.[99]

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[97] Paul de Kruif, "Forgotten Mothers," *Ladies' Home Journal*, March 1936, 16.

[98] Ibid.

[99] Ibid., December 1936, 12.

Not surprisingly, the American medical establishment was not pleased with De Kruif's articles. At a 1936 meeting of the American Medical Association, mention of "blatantly emotional" and sensational magazine articles provoked comments from the floor. Time reported that obstetricians were stirred to angry outbursts. One physician, Dr. Buford Garvin Hamilton, protested, "American obstetrics seems to be becoming a competitive practice to please American women in accordance with what they read in lay magazines."[100]

Of course, not all magazine articles were as critical of doctors. Some certainly gave physicians more authority and respect and most definitely did no encourage consumer activism. An interesting example is a very long piece that ran in the June 1936 issue of Good Housekeeping, called "Two Out of Three Can Be Saved." The article began by recounting the story of a woman who has just died in childbirth. Her husband overhears the doctor say to a nurse that the wife could have been saved with proper prenatal care. The text goes on to admonish husbands that even if their wives die in a hospital, "the causes of her final tragic failure will have begun, perhaps many months before, in the home where you are lord, master, and protector." The main focus is clearly an appreciation of and advocacy for doctors (presumably, male doctors) and medical progress. The issue of gender is extremely relevant, in that, essentially, the writer of the article proposes a negotiated sharing of authority. Husbands must make the right decisions for their wives, and that decision included acknowledging the doctor's superior expertise. Leaving aside the question of why an article theoretically

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[100] "Nature v. Drugs," *Time*, May 1936, 34-36.

addressed to men was published in a magazine read primarily by women, husbands were promised that in exchange for properly respecting and following the doctor's advice, they would be able to properly take advantage of the gifts of modernity. "Modern medical science is pointing...down a highway leading to normal, happy motherhood," but the only way to travel on that road is with a doctor.[101]

The article goes on to warn husbands of the many mistaken decisions they might make by recounting stories of the preventable death of women. For instance, one woman's doctor had advised her to avoid rigorous exercise, but her husband wanted to go hiking. "Say, who's running this family?" [her husband] quizzed. She died of over exertion.[102]

Another man bragged about his large family. He had had nine children in thirteen years. The family's doctor advised against more children, but the husband was adamant: his family wasn't large enough. His wife died of "functional exhaustion." As the doctor sadly said, "she tried but just couldn't make it." The article instructs husbands that "skilled medical advice can be the only guide."[103]

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[101] "Two Out of Three Can Be Saved," *Good Housekeeping*, June 1946, 60.

[102] Ibid., 220.

[103] Ibid., 221-222. What the article does not mention is precisely how the doctor might have advised the couple in question to avoid adding to their family. Contraceptives were legally available in the 1930s to married women if their doctors felt that further childbearing would risk their health.

Skill is an important criterion. Another cautionary tale was that of Nellie, who was attended by Old Dr. Phipps, "...who had a beautiful, long, white beard. The kind birds nest in." Nellie, a modern woman, wanted a 'younger medical man," but her husband and mother-in-law insisted on Dr. Phipps. She died of "septic poisoning." While "we can only honor those fine older men of the medical profession, the pioneer practitioners whose lives have been spent in almost Christian devotion to their task of alleviating human suffering," it is time to move on. It may be time to find a new doctor. "Only you husbands can decide that question."[104]

The article concludes that the medical profession is not without "a share of the responsibility" for having held to "good old-fashioned ideas and resisted the newer knowledge issuing from or scientific laboratory, modern hospitals, and medical schools."[105]

Physicians felt pressured from all sides; the public was making demands, government threatened to seize control of public health, and the maternal mortality figures were indisputably high. What doctors did not do, however, was embrace sulfanilamide as a solution. Doctors felt threatened and de-skilled by laboratory science, and over-the-counter drugs seemed to make their expertise unnecessary. According to the Committee on the Costs of medical care, less than one-third of the drugs and medicines consumed annually were used at the order of physicians. When sulfa drugs first appeared, they were over-the-counter drugs.

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[104] Ibid., 222-223.

[105] Ibid., 218.

Although a physician could—and some did—prescribe sulfa drugs, a prescription was not legally necessary. Anyone could go into a drug store and buy them. As sulfa drugs began to be considered to be a cure for sexually transmitted diseases, particularly gonorrhea, many people did take advantage of the privacy of "self-medication."[106]

Of course, much of the caution shown by doctors was more than reasonable, even if not based entirely on medical reservations:

> The physician's conservatism is intensified by his desire to guard against the tremendous influence of mass suggestion on the part of physicians and the general public. It is further heightened by his fear of losing his professional status by being classed as a 'quack' or 'faddist' thus suffering economic loss.[107]

Sulfanilamides were a new technology and one that was embraced with enthusiasm by the lay public. Many physicians were hesitant to make extensive use of sulfa drugs simply out of reluctance to use an unproven drug, especially one that the lay public embraced with such enthusiasm. The public response to sulfa drugs, not necessarily the drugs themselves, appeared to threaten their position.[108]

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[106] There are numerous articles in medical journals discussing the drug as a cure for gonorrhea. In 1937, when the toxic solvent used in Massengill's over-the-counter drug, Elixir Sulfanilamide, caused more than 100 deaths, the Secretary of Agriculture's investigation included lists of victims. They were children or men who purchased the drug to cure sexually transmitted diseases (Report of the Secretary of Agriculture).

[107] Stern, *Social Factors in Medical Progress*, 25.

[108] In "Remembering medicine's Past," *Annals of Internal Medicine*, (15 September 1998) 12(6): 515-516, physician and historian Baron Lerner used sulfa drugs as an example of the problems that could occur when doctors used drugs before there was adequate information about side effects and possible toxicity. Lerner was discussing drugs that were used in treating HIV/AIDS,

In June 1936, in their article in the British medical journal Lancet, Leonard Colebrook and Maeve Kenny wrote, "Early in 1935 a startling chemotherapeutic success was announced by Domagk in Germany." The two went on to describe the results of their experimental use of Prontosil at Queen Charlotte's Hospital.[109] In June, the Newsweek article "Streptococci: A Reddish dye Comes to the Aid of childbirth," describing the Queen Charlotte Hospital trials and promising an end to the terror of childbirth, was published and created enormous interest among the lay public.[110]

There was much less excitement in medical journals. In October 1936, an article appeared in the prestigious New England Journal of medicine called 'Hospital Puerperal Sepsis." This was not an article about sulfanilamides, despite the fact that the title and date might suggest at least a mention of that new technology. Quite to the contrary, the article concerns a movie. The author explained, "[W]ithin the past few months we have had the opportunity of seeing, in a really worthwhile moving picture, the life of Louis Pasteur."

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which were used before testing was completed, because without the use of those drugs the patient would die. He argued that in treating fatal diseases, it was still necessary to have this information before prescribing these medications. His article was in rebuttal to the argument that since there were no alternative treatments, the benefits outweighed the risks. In the case of puerperal septicemia, while prophylactic measure could in part protect against infection, once infection had occurred, there was little that could be done.

[109] Leonard Colebrook, Maeve Kenny, "Treatment of Human Puerperal Infections and of Experimental Infections in Mice with Prontosil," *The Lanced*, 6 June 1936, 1279.

[110] "Streptococci: A Reddish dye Comes to the Aid of Childbirth," *Newsweek*, June 1936, 42.

The movie tells the story of Pasteur's successful efforts to inoculate sheep against anthrax, and the later developments of his germ theory, with many references to the work of his contemporary, Lister. The film focuses on the lack of support for Pasteur from the French medical establishment. The final drama of the film involves Pasteur's daughter's baby to wash his hands and instruments. The local doctor agrees to follow Pasteur's instructions if Pasteur will publicly recant his germ theory. Pasteur, a loving father, agrees. The local doctor delivers the baby safely and then tells Pasteur that he is now convinced, not by scientific proof, but by Pasteur's paternal passion, of the validity of germ theory. The article did not comment on that aspect of the movie. It does mention that there was a current problem in the United States with high septicemia rates; but it does not propose sulfa drugs as a solution, nor dies it recognize that sulfa drugs came from the same essential source as Pasteur's discovery—the laboratory.[111]

A New England Journal of Medicine editorial published two months after Dr. Shipton's article discussed sulfa drugs, acknowledged the publicity, and issued a warning:

> The newspapers are crediting "Prontylin" and "Prontosil" with the power to overcome the effects of the invasion of the human body by streptococci...Published clinical results are far from convincing to one that is inclined to be skeptical...There is no report of consideration of the efficacy of these compounds by the Council on Pharmacy and Chemistry of the American medical Association at the present time, and it would be well for the medical profession to leave further trials of them to competent observers even though statements of reputable physicians are impressive.[112]

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[111] George M. Shipton, "Hospital Puerperal Sepsis," *The New England Journal of Medicine*, 215, no. 18 (29 October 1936).

[112] "Prontylin and Prontosil," *New England Journal of Medicine*, 215, no. 27 (31 December 1936), 1311.

The New England Journal of Medicine editorial was published on December 31, 1936, just a few weeks after Franklin Roosevelt, Jr.'s illness had been treated with Prontosil, with attendant publicity. The Journal may have tried to restrain enthusiasm for sulfa drugs until further testing, but the same week that the above editorial was published in the New England Journal of Medicine, Time ran a story entitled, "Prontosil: Cure for Streptococci Infections."[113]

In April 1937, the New England Journal of Medicine printed and editorial, "Prontolyn and Prontosil," reminding its readers that the effectiveness of these drugs "can only be determined by exhaustive experimental and clinical trials in trained hands." Eventually, the editorial concluded:

> it must be acknowledged that a number of astonishing "cures" through the use of these drugs have been reported, both in the literature and by word of mouth; and there seems to be a certain amount of justification for their trial by the practitioner in certain cases.[114] [emphasis N.E.J.M.]

The same issue carried a letter to the editor from a physician who complained:

> There is no question about the over-enthusiasm of the medical profession for "sure cure' remedies. I do not see how this remedy gained such quick recognition, but it goes to show that doctors are just as gullible to exploitation of cures as the laity. In the future I shall consign all ultra scientific literature to the wastebasket and I hope that a great number of other physicians will do likewise.[115]

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[113] "Prontosil: Cure for Streptococci Infections," *Time*, 28 December 1936, 21; other publications ran similar stories, for example, "New Drug Arrests Roosevelt Jr.'s Sinus Trouble," *Newsweek*, 26 December 1936, 8.

[114] "Prontolyn and Prontosil," *New England Journal of Medicine*, 216, no. 16, (April 1937), 706.

[115] Ibid., Paul Nettle, "Letter to the Editor." 711.

In the May 1937 issue of the Journal of the American Medical Association, the Council on Pharmacy and Chemistry reported that "the Council decided that it was advisable to issue a report on the present status of sulfanilamides." They reported that seven major drug companies had submitted drugs for inclusion in New and Nonofficial Remedies.[116] The Council felt that the "toxic effects of the drugs have not been particularly alarming," and that they would include sulfanilamide as the therapeutic agent and planned to proceed with "determining the acceptability of the various brands that have been submitted."[117]

It is clear from several articles in prestigious journals that sulfanilamide drugs were being used by the lay public. These drugs were available over the counter. In some cases, doctors prescribed them; in other cases, patients were self-medicating. The Journal of the American Medical Association somewhat reluctantly moved forward in establishing "standards for identity and purity" after acknowledging that the products were in use anyway. The setting of standards for drugs, and for many other products, was part of the American Medical Association's work. The July 1937 issue that included a brief discussion of sulfanilamide in the "New and Nonofficial Remedies" column also included another column on the same page, called "Council on Foods," which discussed

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[116] "Report of the Council on Pharmacy and Chemistry," *Journal of the American Medical Association*, 108, no. 22 (May 1937), 1888. The companies listed were Calco Chemical Co; Lederle Laboratories; Eli Lilly and Company; Merck and Co. Inc.; Parke, Davis and Company; E. R. Squibb and Sons; Winthrop Chemical Co.

[117] Ibid., 1889.

which baby foods, cereals, syrup, evaporated milk, and pineapple juice would be accepted.

In the summer of 1937, the Journal of Pediatrics devoted an issue to a major symposium of sulfanilamide. Pediatricians reacted to the advent of sulfa drugs with significantly more enthusiasm than did other medical specialists:

> No therapeutic agent has appeared on the medical horizon for many years which has attracted so much attention and interest as sulfanilamide. The few brief published preliminary reports of its use are literally amazing.[118]

The editorial board of the Journal explained that it was clear that whatever the official position, sulfa drugs were being used "experimentally in a large number of conditions in practically every pediatric clinic...it is being used widely and indiscriminately in private practice." For that reason, the editorial board had decided that it would be a service to provide a forum for exchanging "experience to date." Therefore, they had invited a group of clinics to report their anecdotal "experience with sulfanilamide up to June 10, 1937."[119]

Sulfanilamide was not a narcotic, and unless mixed with alcohol it was not regulated by the Food and Drug Administration. The law did not permit any other regulation. The agency was aware of its use, however, and was deeply concerned about irresponsible dosages and toxic side effects. At the direction of J. J. Durrett, chief of the Drug Division, Food and Drug officials met with the American sulfa drug expert, Perrin Long, and an associate from Johns Hopkins to

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[118] "Symposium on sulfanilamide Therapy," *Journal of Pediatrics*, vol. 11, no. 2, August 1937, 157.

[119] Ibid.

discuss the drug. They estimated that 25,000 pounds of sulfanilamide was being manufactured per week by ten American manufacturers and sold to two or three hundred distributors. Further, the FDA officials reported:

> Both physicians agreed that this chemical is an important medicine of today; that its use is on the ascendancy; and that it is a definite potentially dangerous drug, inasmuch as the dosage is high.[120]

In the journal, Hygeia, published by the American Medical Association for a lay audience, an article appeared in October 1938 called "Magic Bullets," which described the long search for "magic bullets" to destroy "trouble making influences." Announcements from "authoritative medical sources during the last year or two" have suggested that treatment so long dreamed-of showed promise of becoming a reality. The article was very cautious, but concluded that "medicine is able to report to the people of the world a boon to mankind...It augers well for the future of scientific medicine."[121]

The term, "sulfanilamide," appeared in the index of the New England Journal of Medicine for the first time in November of 1937. Up until then, the few articles published had been listed under the name Prontolyn, one of the first sulfa drugs to be introduced, not as a class of drugs or a new therapy. An editorial in that issue stressed, once again, the need for caution in the use of "Prontosil, Prontolyn, and other drugs of the sulfanilamide group." The editorial reminded readers that though articles about the use of these compounds had been published,

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[120] Memo to J. J. Durrett, Chief Drug Division, from F. L. Wollard, Chief Baltimore Station, 14 October 1937, Food and Drug Administration Central Correspondence Box 93, National Archives, Record Group 88.

[121] Donald B. Armstrong, "Magic Bullets," *Hygeia*, October 1938, 892.

there was little reporting on "methods of therapeutic procedure for they are determined by the individual case." This is important to recognize, since this insistence on individual protocols permitted doctors to retain control over the drug.[122]

Articles in professional journals stressed the need for medical supervision. Many suggested that the drug should only be used in hospitals, though that seems to have been impractical considering how easily the drug could be obtained.

An editorial in the Journal of the American Medical Association cautioned the practitioner to take extreme care in prescribing the proprietary derivatives that "will inevitable appear on the market. Even though the formula of such derivatives closely approximates that of sulfanilamide, the new drug may be many times more toxic."[123]

As it turned out, the American Medical Association was prophetic. In late 1938, the Massengill Company began to manufacture an over-the-counter drug they called Elixir Sulfanilamide. The solvent they used, diethylene glycol, is toxic. Before the drug was recalled, 107 people had died. In the resulting panic and indignation, physicians' voices were heard. The medical establishment piously pointed out that medical miracles—"magic bullets"—were indeed potent drugs, far too powerful to be left in the hands of lay people. In this new age of scientific medicine, only doctors were trained, competent, and capable of

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[122] "Sulfanilamide," *New England Journal of Medicine*, November 1937, vol. 217, no. 19, 757.

[123] Editorial, *Journal of the American Medical Association*, vol. 109, October 1937, 1128.

translating powerful chemicals, the mysterious products of the laboratory, into safe therapy.

With the introduction of sulfa drugs, many of the efforts at reform in the training of physician in prenatal care were abandoned. The new technology of anti-infectives seemed to solve the problem. But sixty years later, maternal mortality rates have not declined, though a smaller number of those deaths are the result of septicemia. Once again, the question of the training of physicians and adequate systems for delivering prenatal care has been raised. This time, perhaps, the solutions will rely less on technology and more on systemic change. That, too, may be one of the impacts of sulfa drugs.

The Depression exacerbated these issues of physician authority. Citizens simply could not afford doctors. Instead, they were more likely to spend their limited funds on over-the-counter medication. Between 1929 and 1933, physicians had a 60% drop in income.[124] The story quoted earlier from Ladies' Home Journal, "Private Duty," which described the old general practitioner adored by patients and resented by young doctors, explained that the younger men disliked him because "his house calls remained at two dollars, and his office visits at one. Old Bronson, they grumbled, took the bread out of their mouths."[125]

In 1926, an independent body of economists, physicians and public health specialists began to meet, funded by private foundations, calling themselves the Committee on the Costs of medical Care. Their focus was the issue of the cost

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[124] Davis G. Johnson, *Physicians in the Making*, (San Francisco: Jossey Bass Publications, 1983), 14.

[125] Faith Baldwin, "Private Duty," 120.

and distribution of medical care.[126] The Depression raised even more concerns among New Deal reformers about the abilities of Americans to obtain health care. In 1932, the committee made its final report. Many of the committee's recommendations did not please organized physicians. Several of the physicians on the committee refused to sign the final report.[127] "We have been reading a great deal about this iniquitous report" by the Committee on the Cost of Medical Care, "which would turn over the medical profession to a group of laymen and would...introduce the Russian system of the practice of Medicine."[128]

Some doctors, like R. G. Leland, director of the Bureau of Medical Economics of the American Medical Association, reminded his colleagues:

> We ought to admit that there are groups in this country which are not able always to take care of the costs of medical care...[for whom] even the physician's charges are exceedingly hard to meet, but I am firmly convinced that if we will search far enough, we will find that inability to pay for medical care does not lie in the cost of medical care...as much as it lies in some of the other industrial social, and commercial relations of these people.[129]

Other physicians tied their opposition to the report directly to their support of capitalism and their opposition to Roosevelt and the New Deal. Charles Whalen, the editor of the Illinois State Medical Journal, reminded doctors that

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[126] Paul Starr, *The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry* (New York: Basic Books, 1982), 260.

[127] Ibid.

[128] Dr. H. Sheridan Baketel, "Proceedings of the 1933 Annual Meeting of the American Pharmaceutical Manufacturers Association" 169.

[129] R. G. Leland, "The Economics of Medicine," Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association, (1933), 184.

their allies might not necessarily lie with science, but rather with those who were fighting on many fronts to preserve the American way of life:

> the future of medicine depends upon the degree to which our national conscience rouses to fight the imminent menace of socialist usurpation...the fate of medicine is bound to be the common fate of all...the same communistic tendencies striving to disrupt medicine today are so engaged with the destruction of all existing order...So medicine asks of industry this question, we have let you look into this crystal, do you fight with us or stand idly by?[130]

Organized medicine could serve as a model in many ways; "the medical method of approach to problems is quite as applicable to social, business, or national affairs as to the bedside."[131] Many doctors agreed, pointing out that "physicians must run their practices as business...state medicine is the American way."[132]

Even doctors who identified themselves politically with the left agreed with the basic AMA position. One non-physician reformer complained that though the Daily Worker, "organ of the Communist Party of the United States," ran a daily health column written by Communist Party member physicians, "the professional patterns which obtain among conservative physicians are accepted uncritically" without any regard to the underlying economic issues that shaped

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[130] Charles J. Whalen, "The Future of Medicine," Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association, 1933, 170-178.

[131] James Warbasse, *The Doctor and the Public*, 386.

[132] Baketel, "Proceedings of the 1933 American Pharmaceutical Manufacturers Association." Dr. Baketel went on to add that it might in fact be necessary to provide some kind of health care for the poor, using physicians who "for one reason or another would be to work effectively under salaried conditions" 199.

many of those patterns. Communist doctors are so "conventional in their treatments that it is clear that their 'political radicalism' doesn't overcome their medical training."[133]

The public continued to stubbornly focus on certain health issues, among them essentially unchanged maternal and infant mortality rates. The Department of Labor Children's Bureau, scorned by opponents during the Congressional debate on Sheppard-Towner, continued to collect statistics. In 1933, they published "Maternal Deaths—A Brief Report of a Study Made in 15 States."[134] The study reported maternal mortality rates of 67 per 10,000 live births. Furthermore, the Children's Bureau findings determined that 40% of those deaths were the result of puerperal septicemia, defined as "obvious and unmistakable sepsis, and the number of deaths attributed to this cause is the minimum."[135]

In 1933, the New York Academy of Medicine Committee on Public Health Relations published a study of maternal mortality in New York. They, too, found the leading cause of maternal death to be septicemia.[136] The committee

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[133] J. B. Matthews, *Guinea Pigs No More* (New York: Couici, Friede, 1936), 45.

[134] U.S. Department of Labor, Children's Bureau Publication, no. 221, *Maternal Deaths "A Brief Report of a Study Made in 15 States*, U.S. Government Printing Office, 1933. The states included in 1927 were Alabama, Kentucky, Maryland, Michigan, Minnesota, Nebraska, New Hampshire, North Dakota, Oregon, Rhode Island, Virginia, Washington, and Wisconsin. In 1928, California and Oklahoma were included as well.

[135] Ibid., 37.

[136] The New York Academy of Medicine Committee on Public Health Relations, Ransom S. Hooker, M.D., Director of the Study, *Maternal Mortality in New York City: A Study of All Puerperal Deaths, 1930-1932* (New York: Oxford University Press, 1933), 36.

examined each death to determine if the death was "inevitable" based on the criterion of "the best possible skill, both in diagnosis and treatment, which the community could make available." Interestingly, the study went further and determined "where responsibility of preventable death should be lodged on the attendant, whether physician or midwife, or on the patient herself."[137] Of the septicemia deaths, 75.1% were considered preventable, and 81.7% were ascribed to physician error.[138]

> It has been a reproach to obstetrics that the high incidence of deaths from puerperal septicemia has not materially lessened during the antiseptic and aseptic era, as it has been in surgical practice...[139]

The report concluded regretfully that "in the majority of puerperal infections, especially in the fatal ones, the infecting organism has been introduced from without."[140]

The Children's Bureau convened a conference on "Better Care for Mothers and Babies" in 1938, and announced that there seemed to have been almost no reduction in the maternal mortality rate during the twenty-two years for which records were available. The percentage of maternal deaths caused by septicemia remained about the same as well.[141] The conference was focused on

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[137] Ibid., 19.

[138] Ibid., 32-33. The blame for the other deaths was apportioned as follows: 3.7% were ascribed to midwives and the remaining 14.6% to patients.

[139] Ibid., 72.

[140] Ibid., 74.

[141] Beulah Amidon, "Women and Children Last," *Survey Midmonthly*, 74, (February 1938), 34.

finding solutions for those deaths that had been judged as preventable. Perhaps not surprisingly for a government agency, they felt that the best solution was a massive government program to improve maternal and infant health. The conference also expressed concerns over medical training:

> It was brought out that while a medical student ought to attend at least fifty confinements if he is to handle such cases in practice, many Grade A medical schools do not require the student to be present at any deliveries before graduation and others require only two to fifteen cases...[142]

Some members of the medical profession agreed, recommending better obstetrical training.[143] They accepted responsibility for their role in the problem:

> It is futile to educate the public to recognize and demand certain minimum standards of the medical standards if the medical profession fails to make these standards available. Any such practice...tends to undermine the confidence of the lay public in the medical profession.[144]

The establishment in 1930 of the American Society of Obstetrics and Gynecology was also part of the movement to improve training and care. The American Committee on Maternal Welfare, made up of "elite Practitioners and Institutions," was formed to write an extensive booklet, Maternal Care: The Principle of Antepartum, Intrapartum and Postpartum. The committee made recommendations about proper care, including a lengthy discussion of septicemia. The authors concentrated on prophylactic measures. The text warned doctors not to contaminate a patient by going to a labor from treating scarlet fever, to sterilize

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[142] Ibid., 39.

[143] Hooker and Miller, *Maternal Mortality*, 219.

[144] Ibid., 49.

sheets and towels if possible, etc. If infection did occur, these elite practitioners recommended fresh air, sunshine, blood transfusion and nursing care. At the end of an eight-page section on care of the infected mother, there is one paragraph referring to sulfanilamide. "Recently, sulfanilamide has been strongly advocated in streptococci puerperal infections...like all new preparations it has found friends and critics." What is critical to note is that this booklet was published two years after the Lancet articles reporting on the use of Prontosil in queen Charlotte's Hospital in London. It was also two years after Newsweek ran a story, "Reddish Dye Comes to the Aid of Women in Childbirth," which described the drug and its successful clinical trials to the general public.[145]

The New York Academy of Medicine report advised doctors to take the lead in this issue, because 'there are not lacking among lay writers those who are eager to inform or misinform their readers as to the proper conduct of the physician."[146] There was no question that physicians were genuinely concerned about the high maternal mortality rate, but they were also enraged by the public attention and outcry around the issue.

The Ladies' Home Journal published a four-part study of the problem in 1936. Written by Paul de Kruif, it began:

> To the mothers of America: Every 14 seconds some mother brings into being a new life - and for each 175 new lives some mother

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[145] "Reddish Dye Comes to the Aid of Women in Childbirth," *Newsweek*, June 1936, 42.

[146] Hooker and Miller, *Maternal Mortality*, 217.

> trades her own. Is this necessary?...NO! Can it be prevented?...YES![147]

The article goes on to assure women that maternal mortality rates can be lowered, but that the mothers themselves must become active in that fight. "Protest now! Protest to your Physician, to your Mayor, to you Congressman, to your President—NOW!" De Kruif went on to lay the responsibility firmly on doctors: "Many physicians, not knowing it, have carried death from sick women to healthy and more often than not this unwitting murder does not out."[148] De Kruif also explained that part of the problem was that doctors had not considered childbirth an illness, so medical students were not adequately trained.

Many of these criticisms were the same ones that members of the medical profession had essentially agreed upon among themselves. De Kruif's solutions, however, were quite different from those of the New York Academy of Medicine. He ended his series (which ran from March to December 1936) with the assertion:

> A band of women, nation-wide, is going to inquire why all our powerful science isn't used to guard every last mother who now runs needles risk of dying to give the world new life...Their fight will not be an easy one. In the beginning there may be individual doctors, even societies of physicians, who will not want our mothers as soldiers in this battle. Medicine is a proud and ancient profession, and does not easily admit plain, nonmedical people into its fight with death.[149]

Not surprisingly, the American medical establishment was not pleased with De Kruif's articles. At a 1936 meeting of the American Medical

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[147] Paul de Kruif, "Forgotten Mothers," *Ladies' Home Journal*, March 1936, 16.

[148] Ibid.

[149] Ibid., December 1936, 12.

Association, mention of "blatantly emotional" and sensational magazine articles provoked comments from the floor. Time reported that obstetricians were stirred to angry outbursts. One physician, Dr. Buford Garvin Hamilton, protested, "American obstetrics seems to be becoming a competitive practice to please American women in accordance with what they read in lay magazines."[150]

Of course, not all magazine articles were as critical of doctors. Some certainly gave physicians more authority and respect and most definitely did no encourage consumer activism. An interesting example is a very long piece that ran in the June 1936 issue of Good Housekeeping, called "Two Out of Three Can Be Saved." The article began by recounting the story of a woman who has just died in childbirth. Her husband overhears the doctor say to a nurse that the wife could have been saved with proper prenatal care. The text goes on to admonish husbands that even if their wives die in a hospital, "the causes of her final tragic failure will have begun, perhaps many months before, in the home where you are lord, master, and protector." The main focus is clearly an appreciation of and advocacy for doctors (presumably, male doctors) and medical progress. The issue of gender is extremely relevant, in that, essentially, the writer of the article proposes a negotiated sharing of authority. Husbands must make the right decisions for their wives, and that decision included acknowledging the doctor's superior expertise. Leaving aside the question of why an article theoretically addressed to men was published in a magazine read primarily by women, husbands were promised that in exchange for properly respecting and following

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[150] "Nature v. Drugs," *Time*, May 1936, 34-36.

the doctor's advice, they would be able to properly take advantage of the gifts of modernity. "Modern medical science is pointing...down a highway leading to normal, happy motherhood," but the only way to travel on that road is with a doctor.[151]

The article goes on to warn husbands of the many mistaken decisions they might make by recounting stories of the preventable death of women. For instance, one woman's doctor had advised her to avoid rigorous exercise, but her husband wanted to go hiking. "Say, who's running this family?" [her husband] quizzed. She died of over exertion.[152]

Another man bragged about his large family. He had had nine children in thirteen years. The family's doctor advised against more children, but the husband was adamant: his family wasn't large enough. His wife died of "functional exhaustion." As the doctor sadly said, "she tried but just couldn't make it." The article instructs husbands that "skilled medical advice can be the only guide."[153]

Skill is an important criterion. Another cautionary tale was that of Nellie, who was attended by Old Dr. Phipps, "...who had a beautiful, long, white beard. The kind birds nest in." Nellie, a modern woman, wanted a 'younger medical

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[151] "Two Out of Three Can Be Saved," *Good Housekeeping*, June 1946, 60.

[152] Ibid., 220.

[153] Ibid., 221-222. What the article does not mention is precisely how the doctor might have advised the couple in question to avoid adding to their family. Contraceptives were legally available in the 1930s to married women if their doctors felt that further childbearing would risk their health.

man," but her husband and mother-in-law insisted on Dr. Phipps. She died of "septic poisoning." While "we can only honor those fine older men of the medical profession, the pioneer practitioners whose lives have been spent in almost Christian devotion to their task of alleviating human suffering," it is time to move on. It may be time to find a new doctor. "Only you husbands can decide that question."[154]

The article concludes that the medical profession is not without "a share of the responsibility" for having held to "good old-fashioned ideas and resisted the newer knowledge issuing from or scientific laboratory, modern hospitals, and medical schools."[155]

Physicians felt pressured from all sides; the public was making demands, government threatened to seize control of public health, and the maternal mortality figures were indisputably high. What doctors did not do, however, was embrace sulfanilamide as a solution. Doctors felt threatened and de-skilled by laboratory science, and over-the-counter drugs seemed to make their expertise unnecessary. According to the Committee on the Costs of medical care, less than one-third of the drugs and medicines consumed annually were used at the order of physicians. When sulfa drugs first appeared, they were over-the-counter drugs. Although a physician could—and some did—prescribe sulfa drugs, a prescription was not legally necessary. Anyone could go into a drug store and buy them. As sulfa drugs began to be considered to be a cure for sexually transmitted diseases,

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[154] Ibid., 222-223.

[155] Ibid., 218.

particularly gonorrhea, many people did take advantage of the privacy of "self-medication."[156]

Of course, much of the caution shown by doctors was more than reasonable, even if not based entirely on medical reservations:

> The physician's conservativism is intensified by his desire to guard against the tremendous influence of mass suggestion on the part of physicians and the general public. It is further heightened by his fear of losing his professional status by being classed as a 'quack' or 'faddist' thus suffering economic loss.[157]

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[156] There are numerous articles in medical journals discussing the drug as a cure for gonorrhea. In 1937, when the toxic solvent used in Massengill's over-the-counter drug, Elixir Sulfanilamide, caused more than 100 deaths, the Secretary of Agriculture's investigation included lists of victims. They were children or men who purchased the drug to cure sexually transmitted diseases (Report of the Secretary of Agriculture).

[157] Stern, *Social Factors in Medical Progress*, 25.

[158] In "Remembering medicine's Past," *Annals of Internal Medicine*, (15 September 1998) 12(6): 515-516, physician and historian Baron Lerner used sulfa drugs as an example of the problems that could occur when doctors used drugs before there was adequate information about side effects and possible toxicity. Lerner was discussing drugs that were used in treating HIV/AIDS, which were used before testing was completed, because without the use of those drugs the patient would die. He argued that in treating fatal diseases, it was still necessary to have this information before prescribing these medications. His article was in rebuttal to the argument that since there were no alternative treatments, the benefits outweighed the risks. In the case of puerperal septicemia,

In June 1936, in their article in the British medical journal Lancet, Leonard Colebrook and Maeve Kenny wrote, "Early in 1935 a startling chemotherapeutic success was announced by Domagk in Germany." The two went on to describe the results of their experimental use of Prontosil at Queen Charlotte's Hospital.[159] In June, the Newsweek article "Streptococci: A Reddish dye Comes to the Aid of childbirth," describing the Queen Charlotte Hospital trials and promising an end to the terror of childbirth, was published and created enormous interest among the lay public.[160]

There was much less excitement in medical journals. In October 1936, an article appeared in the prestigious New England Journal of medicine called 'Hospital Puerperal Sepsis." This was not an article about sulfanilamides, despite the fact that the title and date might suggest at least a mention of that new technology. Quite to the contrary, the article concerns a movie. The author explained, "[W]ithin the past few months we have had the opportunity of seeing, in a really worthwhile moving picture, the life of Louis Pasteur."

The movie tells the story of Pasteur's successful efforts to inoculate sheep against anthrax, and the later developments of his germ theory, with many references to the work of his contemporary, Lister. The film focuses on the lack

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while prophylactic measure could in part protect against infection, once infection had occurred, there was little that could be done.

[159] Leonard Colebrook, Maeve Kenny, "Treatment of Human Puerperal Infections and of Experimental Infections in Mice with Prontosil," *The Lanced*, 6 June 1936, 1279.

[160] "Streptococci: A Reddish dye Comes to the Aid of Childbirth," *Newsweek*, June 1936, 42.

of support for Pasteur from the French medical establishment. The final drama of the film involves Pasteur's daughter's baby to wash his hands and instruments. The local doctor agrees to follow Pasteur's instructions if Pasteur will publicly recant his germ theory. Pasteur, a loving father, agrees. The local doctor delivers the baby safely and then tells Pasteur that he is now convinced, not by scientific proof, but by Pasteur's paternal passion, of the validity of germ theory. The article did not comment on that aspect of the movie. It does mention that there was a current problem in the United States with high septicemia rates; but it does not propose sulfa drugs as a solution, nor dies it recognize that sulfa drugs came from the same essential source as Pasteur's discovery—the laboratory.[161]

A New England Journal of Medicine editorial published two months after Dr. Shipton's article discussed sulfa drugs, acknowledged the publicity, and issued a warning:

> The newspapers are crediting "Prontylin" and "Prontosil" with the power to overcome the effects of the invasion of the human body by streptococci...Published clinical results are far from convincing to one that is inclined to be skeptical...There is no report of consideration of the efficacy of these compounds by the Council on Pharmacy and Chemistry of the American medical Association at the present time, and it would be well for the medical profession to leave further trials of them to competent observers even though statements of reputable physicians are impressive.[162]

The New England Journal of Medicine editorial was published on December 31, 1936, just a few weeks after Franklin Roosevelt, Jr.'s illness had

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[161] George M. Shipton, "Hospital Puerperal Sepsis," *The New England Journal of Medicine*, 215, no. 18 (29 October 1936).

[162] "Prontylin and Prontosil," *New England Journal of Medicine*, 215, no. 27 (31 December 1936), 1311.

been treated with Prontosil, with attendant publicity. The Journal may have tried to restrain enthusiasm for sulfa drugs until further testing, but the same week that the above editorial was published in the New England Journal of Medicine, Time ran a story entitled, "Prontosil: Cure for Streptococci Infections."[163]

In April 1937, the New England Journal of Medicine printed and editorial, "Prontolyn and Prontosil," reminding its readers that the effectiveness of these drugs "can only be determined by exhaustive experimental and clinical trials in trained hands." Eventually, the editorial concluded:

> it must be acknowledged that a number of astonishing "cures" through the use of these drugs have been reported, both in the literature and by word of mouth; and there seems to be a certain amount of justification for their trial by the practitioner in certain cases.[164] [emphasis N.E.J.M.]

The same issue carried a letter to the editor from a physician who complained:

> There is no question about the over-enthusiasm of the medical profession for "sure cure' remedies. I do not see how this remedy gained such quick recognition, but it goes to show that doctors are just as gullible to exploitation of cures as the laity. In the future I shall consign all ultra scientific literature to the wastebasket and I hope that a great number of other physicians will do likewise.[165]

In the May 1937 issue of the Journal of the American Medical Association, the Council on Pharmacy and Chemistry reported that "the Council decided that it

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[163] "Prontosil: Cure for Streptococci Infections," *Time*, 28 December 1936, 21; other publications ran similar stories, for example, "New Drug Arrests Roosevelt Jr.'s Sinus Trouble," *Newsweek*, 26 December 1936, 8.

[164] "Prontolyn and Prontosil," *New England Journal of Medicine*, 216, no. 16, (April 1937), 706.

[165] Ibid., Paul Nettle, "Letter to the Editor." 711.

was advisable to issue a report on the present status of sulfanilamides." They reported that seven major drug companies had submitted drugs for inclusion in New and Nonofficial Remedies.[166] The Council felt that the "toxic effects of the drugs have not been particularly alarming," and that they would include sulfanilamide as the therapeutic agent and planned to proceed with "determining the acceptability of the various brands that have been submitted."[167]

It is clear from several articles in prestigious journals that sulfanilamide drugs were being used by the lay public. These drugs were available over the counter. In some cases, doctors prescribed them; in other cases, patients were self-medicating. The Journal of the American Medical Association somewhat reluctantly moved forward in establishing "standards for identity and purity" after acknowledging that the products were in use anyway. The setting of standards for drugs, and for many other products, was part of the American Medical Association's work. The July 1937 issue that included a brief discussion of sulfanilamide in the "New and Nonofficial Remedies" column also included another column on the same page, called "Council on Foods," which discussed which baby foods, cereals, syrup, evaporated milk, and pineapple juice would be accepted.

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[166] "Report of the Council on Pharmacy and Chemistry," *Journal of the American Medical Association*, 108, no. 22 (May 1937), 1888. The companies listed were Calco Chemical Co; Lederle Laboratories; Eli Lilly and Company; Merck and Co. Inc.; Parke, Davis and Company; E. R. Squibb and Sons; Winthrop Chemical Co.

[167] Ibid., 1889.

In the summer of 1937, the Journal of Pediatrics devoted an issue to a major symposium of sulfanilamide. Pediatricians reacted to the advent of sulfa drugs with significantly more enthusiasm than did other medical specialists:

> No therapeutic agent has appeared on the medical horizon for many years which has attracted so much attention and interest as sulfanilamide. The few brief published preliminary reports of its use are literally amazing.[168]

The editorial board of the Journal explained that it was clear that whatever the official position, sulfa drugs were being used "experimentally in a large number of conditions in practically every pediatric clinic...it is being used widely and indiscriminately in private practice." For that reason, the editorial board had decided that it would be a service to provide a forum for exchanging "experience to date." Therefore, they had invited a group of clinics to report their anecdotal "experience with sulfanilamide up to June 10, 1937."[169]

Sulfanilamide was not a narcotic, and unless mixed with alcohol it was not regulated by the Food and Drug Administration. The law did not permit any other regulation. The agency was aware of its use, however, and was deeply concerned about irresponsible dosages and toxic side effects. At the direction of J. J. Durrett, chief of the Drug Division, Food and Drug officials met with the American sulfa drug expert, Perrin Long, and an associate from Johns Hopkins to discuss the drug. They estimated that 25,000 pounds of sulfanilamide was being

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[168] "Symposium on sulfanilamide Therapy," *Journal of Pediatrics*, vol. 11, no. 2, August 1937, 157.

[169] Ibid.

manufactured per week by ten American manufacturers and sold to two or three hundred distributors. Further, the FDA officials reported:

> Both physicians agreed that this chemical is an important medicine of today; that its use is on the ascendancy; and that it is a definite potentially dangerous drug, inasmuch as the dosage is high.[170]

In the journal, Hygeia, published by the American Medical Association for a lay audience, an article appeared in October 1938 called "Magic Bullets," which described the long search for "magic bullets" to destroy "trouble making influences." Announcements from "authoritative medical sources during the last year or two" have suggested that treatment so long dreamed-of showed promise of becoming a reality. The article was very cautious, but concluded that "medicine is able to report to the people of the world a boon to mankind...It augers well for the future of scientific medicine."[171]

The term, "sulfanilamide," appeared in the index of the New England Journal of Medicine for the first time in November of 1937. Up until then, the few articles published had been listed under the name Prontolyn, one of the first sulfa drugs to be introduced, not as a class of drugs or a new therapy. An editorial in that issue stressed, once again, the need for caution in the use of "Prontosil, Prontolyn, and other drugs of the sulfanilamide group." The editorial reminded readers that though articles about the use of these compounds had been published, there was little reporting on "methods of therapeutic procedure for they are

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[170] Memo to J. J. Durrett, Chief Drug Division, from F. L. Wollard, Chief Baltimore Station, 14 October 1937, Food and Drug Administration Central Correspondence Box 93, National Archives, Record Group 88.

[171] Donald B. Armstrong, "Magic Bullets," *Hygeia*, October 1938, 892.

determined by the individual case." This is important to recognize, since this insistence on individual protocols permitted doctors to retain control over the drug.[172]

Articles in professional journals stressed the need for medical supervision. Many suggested that the drug should only be used in hospitals, though that seems to have been impractical considering how easily the drug could be obtained.

An editorial in the Journal of the American Medical Association cautioned the practitioner to take extreme care in prescribing the proprietary derivatives that "will inevitable appear on the market. Even though the formula of such derivatives closely approximates that of sulfanilamide, the new drug may be many times more toxic."[173]

As it turned out, the American Medical Association was prophetic. In late 1938, the Massengill Company began to manufacture an over-the-counter drug they called Elixir Sulfanilamide. The solvent they used, diethylene glycol, is toxic. Before the drug was recalled, 107 people had died. In the resulting panic and indignation, physicians' voices were heard. The medical establishment piously pointed out that medical miracles—"magic bullets"—were indeed potent drugs, far too powerful to be left in the hands of lay people. In this new age of scientific medicine, only doctors were trained, competent, and capable of

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[172] "Sulfanilamide," *New England Journal of Medicine*, November 1937, vol. 217, no. 19, 757.

[173] Editorial, *Journal of the American Medical Association*, vol. 109, October 1937, 1128.

translating powerful chemicals, the mysterious products of the laboratory, into safe therapy.

With the introduction of sulfa drugs, many of the efforts at reform in the training of physician in prenatal care were abandoned. The new technology of anti-infectives seemed to solve the problem. But sixty years later, maternal mortality rates have not declined, though a smaller number of those deaths are the result of septicemia. Once again, the question of the training of physicians and adequate systems for delivering prenatal care has been raised. This time, perhaps, the solutions will rely less on technology and more on systemic change. That, too, may be one of the impacts of sulfa drugs.

Chapter 4 The New Dealers and The New Medicines: The Role of Sulfa Drugs in the Reform of Pharmaceutical Regulation

The American pharmaceutical industry was reshaped in the interwar years through a particular combination of changes in the science of pharmacology and organic chemistry, and in the nature of the business climate as it developed, first in the 1920s and then the 1930s. In one sense, the pharmaceutical industry must be seen as an important sector of the chemical industry, which was an expanding and successful sector of the economy. As such, the industry was effected by the relationship of the business community with the federal government, the Republican administration of the 1920s, and later the particular political, social, and regulatory climate of the New Deal administration.

In order to understand the pharmaceutical industry, it is necessary to recognize that pharmaceuticals are also part of the healthcare industry. For that reason, some of the changes in the drug industry resemble those of the medical profession as much as those of the industrial sector. As in the case of physicians, scientific technology and scientific rhetoric played a critical role in this transformation. The "business" of pharmaceuticals evolved within the context of the changing nature of American capitalism, but it was also shaped by the rapidly developing scientific discipline of pharmacology, which emerged as an important academic discipline during the end of the nineteenth and beginning of the twentieth centuries. Furthermore, the relationship between academic and industrial pharmacology changed significantly in the interwar years, which had a

profound effect on the shape of the emerging drug business.[1] This peculiar combination of influences, including the myriad of technical and economic lessons learned through the seizing of German patents during the war, contributed to the development of a peculiar industry, which was both business and medicine, at a time when each was undergoing a major transformation.

The pharmaceutical industry, like doctors, used language of science to legitimize itself. This is not to deny that the scientific developments of the 1920s and 1930s were not of critical importance, but rather to emphasize that for many drug companies the rhetoric of science was also important, as a way of redefining pharmaceuticals, and repositioning and legitimizing many pharmaceutical companies. This reflected a change in marketing strategy as well as changes in the product. In this context, it is perhaps understandable that academic pharmacologists in the United States distanced themselves from the pharmaceutical industry, fearing commercial exploitation. Eventually, however,

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[1] For a detailed description of the relationship between academic and industrial pharmacology, see John Swann, *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth Century America*, (Baltimore: Johns Hopkins University Press, 1988); For a more historically extended general description, see Jonathan Liebenau, *Medical Science and Medical Industry;* Tom Mahoney, *The Merchants of Life: An Account of the American Pharmaceutical Industry*, (New York: Harper and Brothers, 1959); John Parascandola, *The Development of American Pharmacology: John Abel and the Shaping of a Discipline*, (Baltimore: Johns Hopkins University Press, 1992). Several studies have examined the relationship between economics and the drug industry. See Walter Measday, "The Pharmaceutical Industry" in *The Structure of American Industry*, 5th Edition, Walter Adams, ed., (New York: Macmillan, 1977); Harlow N. Higinbotham and Fred Weston, *Economics of the Pharmaceutical Industry*, (New York: Praeger, 1982). Milton Silverman and Phillip Lee, *Pills, Profits and Politics*, (Berkeley: University of California Press, 1974).

the need for funding, combined with assiduous courting from industry, broke through their resistance.[2]

In Europe, by the late eighteenth century, small but well-equipped commercial chemical laboratories were established as part of the metallurgical engineering industry.[3] In the 1770s, other less laboratory-oriented European companies began manufacturing drugs.[4] By the later half of the nineteenth century, these interests had been combined and a research oriented pharmaceutical industry began to develop, based primarily on coal-tar products.

Paul Erlich's work perhaps best exemplifies this new era of laboratory pharmaceuticals. In the 1880s, he developed the idea of using stains to track substances in the body, recognizing that "different dyes show characteristic differences in their distribution and location."[5] In 1886, he completed his important study "On the Methylene-blue reaction of the living nerve-tissue," in which he explained that different cells were affected differently by various substances. Using this information as the basis of his experiments, Erlich

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[2] Swann, *Academic Scientists and the Pharmaceutical Industry*, 18. The pragmatics of the situation are important. For example, in the relationship between Waksman, Rutgers, and Merck, mentioned earlier, Waksman stressed the fact that he could not have done his work without Merck's support, since he received very little funding from Rutgers, only limited funding from private foundations, and none from the National Institutes of Health.

[3] Swann, 19-20. Swann suggested that European interest in alchemy may account for these laboratories.

[4] Ibid.

[5] Paul Erlich, "Dedication Speech at the Opening of George Speyer House" in 1906, quoted in Hubert LeChevalier and Morris Solotorovsky, *Three Centuries of Microbiology*, (New York: Dover Press, 1974), 446.

proceeded to direct his energies to what he considered the "foremost task of medicine," which was to "achieve remedies which...will sterilize the infected organism and thus break the neck of the disease." He called these imagined substances magic bullet, "which seek their target of their own accord."[6] He began to experiment on the effects of various dyes on parasites in mice, finding that their effects were heightened when combined with arsenic. He methodically examined the effects of organic arsenical compounds on the spirochete of syphilis, which had been identified in 1905. The 606th drug he tried proved effective. It was named Salvarsan, and in 1910, it became commercially available. In 1912, a water-soluble version, neo-salvarsan, was developed. Salvarsan was the most effective antisyphilitic drug of its time—and the formula was protected by copyright. I. G. Farben, which had supported Erlich's research, profited substantially. A modern industrial model for pharmaceutical research and manufacturing had emerged.

Erlich's importance to science and medicine went well beyond the commercial success of Salvarsan. He was a critical force in the shaping, or reshaping, of pharmacology as a new scientific discipline. He criticized pharmacologists for concentrating on the investigation of the effects of drugs on healthy animals. He maintained that it was necessary to study the action of these drugs on animals who had been deliberately infected with the disease that the drug was intended to cure. He called this system "experimental therapeutics," and after Erlich won his Nobel Prize in 1909, the idea gathered many adherents,

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[6] Ibid., 448.

significantly altering and expanding the scope and practice of pharmacology.[7] This was a bolder, more practical role for science, as well as a potentially profitable one.[8]

After Erlich's success, the scientific and medical community optimistically predicted that more magic bullets would rapidly be developed. The enthusiasm petered out when most of these attempts at discovering anti-infective agents failed, and it became a generally accepted belief that only disease caused by protozoa could be successfully treated with Erlich's magic bullets.[9] Some research continued, however, Azo dyes were suspected to have anti-bacteriostatic qualities, though these were not apparent in in-vitro experiments.[10] Scientists at the I. G. Farbenindustrie laboratories prepared azo dyes combined with sulfonamide as early as 1909, and continued to develop more compounds until World War I interrupted their work.[11]

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[7] Parascandola, *The Development of American Pharmacology*, 131.

[8] It is clearly not coincidental that during these same years the issue of animal experimentation and vivisection attracted significant social concern. For an excellent overview of the public response to this question, see Susan Lederer, *Subjected to Science: Human Experimentation in America Before the Second World War* (Baltimore: Johns Hopkins University Press, 1995).

[9] For an excellent background view of German industrial chemistry in this area, see John Lesch "Chemistry and Biomedicine in an Industrial Setting: The Invention of the Sulfa Drugs" in Seymour Mauskopf, ed. *Chemical Sciences in the Modern World*, (Philadelphia: University of Pennsylvania Press, 1993).

[10] Azo dyes are compounds in which two nitrogen atoms are linked by a double bond, and numerous ones had been developed, particularly by German dye companies in the late nineteenth century. The fact that they worked so well on wool and silk suggested to many scientists that somehow the agents reacted with bacterial protoplasm.

[11] Perrin and Bliss, *Clinical and Experimental Use of Sulfanilamide*, 2.

After the war, work at I.G. Farbenindustrie resumed, and the company appointed a young scientist, Gerhard Domagk, as the director of research at its laboratory for pathology and bacteriology. Domagk was instructed to find bacteriostatic compounds. He began work targeted at streptococci, which were known to be the causative agents of childbed fever, endocarditis, blood poisoning, and other diseases. He designed a series of animal experiments, systematically testing the various azo dyes that had been developed at Farbenindustrie.[12] One, which he called Prontosil, proved to be an effective anti-infective agent when used in vivo, as Erlich had suggested. Domagk began animal studies in 1932, and in early 1935 he published his work in a paper now considered to be "a masterpiece of careful and critical evaluation of a new therapeutic agent."[13]

In 1938, Domagk was awarded the Nobel prize for his discovery.[14] Almost immediately after Domagk published his work, researchers at the Pasteur Institute in Paris isolated the active ingredient in Prontosil. It was sulfanilamide, a compound first synthesized in 1908 and patented in 1909. By 1932, the patent had expired. The French scientists quickly developed their own compound, which was as effective as Prontosil.[15] In the next decade, 5,400 compound

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[12] Lesch, "Chemistry and Biochemistry," 179.

[13] Erick Posner, "Gerhard Domagk," *Dictionary of Scientific Biography*, vol. 4, Scribners ACLS (1972), 154.

[14] Hitler did not allow Domagk to accept the prize. The Peace Prize had been awarded to German anti-Nazi dissidents, and an incensed Hitler declared that Germans would no longer accept any Nobel Prizes awarded in any category.

[15] J. Troufoel, Mme Trefouel, F. Nitti, and D. Bovet, *"Activite de p-amino-phenylsulfamide sur infections streptoccocciques de las souris et du lapi"*

substances were synthesized and studies.[16] Sulfa drugs were found to be effective therapeutic agents. Furthermore, the process for manufacturing them was so similar to that of the coal-tar dyes on which the drug had been based that they were easily manufactured by dye companies, which already had the equipment and necessary technical knowledge.

Pharmaceutical companies in the United States developed differently. American industry did not have the same research tradition. Those few drug companies that even had laboratories used them primarily for standardization of ingredients and quality control.[17] With the passage of the 1906 Pure Food and Drug Act, which required truthful labeling, those laboratories took on a new importance. In order to comply with the law, assaying of chemicals became necessary.[18]

Of course, the standards of "assay" were somewhat flexible. Dr. Squibb, the founder of the drug company bearing his name, was "one of the great pioneers in drug standardization methods." A technique with which "the name of Squibb is permanently linked" was that of testing aconite root on the human tongue. Squibb "determined the value of different preparations...by finding that particular

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translated and republished in Holmstedt and Liljestrand, *Readings in Pharmacology*.

[16] Louis S. Goodman and Alfred Gilman, eds. *The Pharmacological Basis of Therapeutics*. (New York: Macmillan, 1970), 1177.

[17] Parascandola, *The Development of American Pharmacology*, 103.

[18] James Harvey Young, "Federal Drug and Narcotic Legislation," *Pharmacy in History*, 37, no. 2 (1995), 60.

dilution which caused perceptible tingling...when approximately one teaspoonful was held in the front part of his mouth for exactly one minute."[19]

The intellectual roots of pharmacology were also somewhat different from those in Europe. Though a few American universities did establish medical research centers in the 1870s, there was little of the cooperation between academic centers and industrial research that existed in Europe. Furthermore, only a small number of academic institutions even had these departments, and those that existed had very little funding.[20] Students frequently traveled to Europe for their postgraduate training. Because of the relatively late development of pharmacology in the United States, what little American research existed was based on European, primarily German, science until after World War I.

When pharmacology emerged as an academic discipline, it did so at a moment of rapid expansion of American industrial capitalism. It developed as much in response to the demands of an important, emerging industry as improved training or scientific knowledge. Robert Kohler has suggested that there are several ways to examine the development of a new scientific discipline. The first of these is the appearance of academic teaching positions, which shows a degree of official recognition. The second is the appearance of journals and professional societies. Third, he suggests that an examination of the disciplinary and

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[19] John C. Krantz, Jr., ed., *Fighting Disease with Drugs: The Story of Pharmacy* (Baltimore: Williams and Wilkins, 1931), 169.

[20] Swann, *Academic Scientists and the Pharmaceutical Industry*, 10.

institutional affiliation of contributors to research journals helps to complete the picture.[21]

After the Flexner report, elite medical schools emphasized their scientific credentials. They presented themselves as research institutions pursuing projects in experimental sciences like physiology and bacteriology, and supported the work of clinical investigators, as well as researchers. This did not necessarily benefit the scientific discipline of pharmacology, however, since many medical educators felt that pharmacology was so interwoven with disease that medical education, as opposed to a laboratory science doctorate, was necessary in order to understand the discipline.[22]

As a result, pharmacology was dominated by physicians for a much longer period than were other pre-clinical medical sciences. Many doctors opposed the establishment of Ph.D. programs in pharmacology, maintaining that it was only a medical discipline.[23] In 1901, though the Rockefeller Institute had provided funds to encourage the "conversion of the medical profession to the view that the mysteries of human illness needed to be explored...by the use of scientific techniques," physicians remained resistant.[24] Furthermore, the situation was

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[21] Robert Kohler, "The History of Biochemistry," *Journal of the History of Biology* 8 (1975), 273-318.

[22] Parascandola, *The Development of American Pharmacology*, 73-75.

[23] Ibid., 87.

[24] A. McGettee Harvey, *Science at the Bedside*, 115.

complicated, since many scientists, particularly biochemists, feared that clinicians were trying to dominate their activities and limit their research.[25]

Pharmacologists felt hard pressed. They insisted that few students were being adequately trained in their discipline and that, as a result, there was a shortage of pharmacologists.[26] They reminded medical school administrators that there were practical consequences to the problem "[T]he complaint is often made...by state boards—that students do not know how to write prescriptions and only know proprietary preparations."[27] A 1936 report published in the Journal of the Association of American Medical Colleges states that "In many schools in this country, the subject [of pharmacology] is still in leading strings."[28] Thus, the limited resources of pharmacology departments could have serious consequences on the practice of medicine.

In 1907, to strengthen their discipline, pharmacologists and biochemists held the first meeting of what would become the American Society for the Advancement of Clinical Investigation.[29] In 1919, the name was changed to the American Society for Clinical Investigation. Its purpose, as stated in its 1916 Constitution, was "the cultivation of clinical research by the methods of the

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[25] Kohler, "The History of Biochemistry," 218.

[26] C. W. Edmunds, "The Teaching of Pharmacology," *Journal of the Association of American Medical Colleges* 11 (1936), 83-93.

[27] Ibid., 88.

[28] Ibid., 86.

[29] J. Harold Austin, "A Brief Sketch of the History of the American Society for Clinical Investigation," *Journal of Clinical Investigation* 28, no. 2, March 1949, 401.

natural sciences, the unification of science and practice of medicine."[30] This society was meant for junior investigators—in fact, "active members who have reached the age of forty-five years prior to the annual spring meeting of the society; shall automatically become emeritus members."[31]

The Journal of Biological Chemistry was founded in 1905. The next year, the American Society of Biological Chemists was formed.[32] In 1908, the American Society for Pharmacology and Experimental Therapeutics (ASPET) was founded, and in 1908 it began publishing the Journal of Pharmacology and Experimental Therapeutics.[33] ASPET's bylaws included the explicit proviso that no member could be in the permanent employ of a drug company. Though sentiment to remove this restriction began to build during the 1920s and 1930s, and was modified to permit members to work as consultants to drug companies, the restriction was not removed until 1941.[34] The ban was established because the society's organizers felt that pharmaceutical companies did not do fundamental

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[30] Ibid., 402.

[31] Ibid., 404. The quote comes from "1930 Amendment III. Overriding Amendment I (1924)."

[32] As a further reflection on Kohler's point on scientific institutionalization, this organization is now the American Society of Biological Chemists and Molecular Biology.

[33] Parascandola, *The Development of American Pharmacology*, 116. Swann, *Academic Scientists and the Pharmaceutical Industry*, 54.

[34] John Parascandola discusses this restriction at length in "The Preposterous Provision: The American Society for Pharmacology and Experimental Therapeutics' Ban on Industrial Pharmacologists 1908-1941," George Higby and Elaine Stroud, eds., *Pill Peddlers: Essays on the History of the Pharmaceutical Industry* (Madison: American Institute for the History of Pharmacy, 1990).

research and were only interested in "applied" pharmacology. Furthermore, drug companies were associated with patent medicines, secret nostrums, and unscientifically proven claims. Many pharmacologists felt that a connection with such institutions would do nothing to advance the discipline. The profit-making aspect of commercial pharmacy was disturbing to the champions of pure scientific research, and ASPET, like the American Medical Association, opposed the patenting of medical discoveries.[35]

ASPET grew slowly. There were 50 members in 1909, 200 in 1938, and 300 in 1945.[36] In an effort to maintain the separation from industry, the initial editorial policy of the Journal of Pharmacology and Experimental Therapeutics permitted no advertisements from pharmaceutical companies. Eventually, economic reality demanded a modification of that policy, and advertisement for proprietary drugs approved by the American Medical Association Council of Pharmacy and Chemistry were permitted.[37] Another institution, the American Society of Clinical Investigation, was formed in 1915. By 1924, it began to publish its journal, the Journal of Clinical Investigation. Biomedical research had begun to free itself from a strictly medical school context while still remaining separate from the drug industry.[38]

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[35] The proviso was included in the original bylaws.

[36] Parascandola, *The Development of American Pharmacology*, 134.

[37] Ibid., 137.

[38] McGettee Harvey, *Science at the Bedside*, 120.

From the point of view of consumers, these changes initially had little impact. Drug companies and pharmacology did not converge in the United States until well into the twentieth century. Until the middle of the nineteenth century, most Americans used drugs that were either mixtures of botanical drugs and chemicals compounded by pharmacists and/or physicians and advertised only to the medical profession, or they used so-called "patent" medicines.[39] Patent medicines, or proprietary drugs, were manufactured according to secret formulas and were advertised to the general public, as opposed to "ethical drugs," which were advertised only to the medical profession. Most of the drugs purchased by Americans were patent or proprietary drugs.[40] As late as 1939, well past the beginning of the era of scientific medicine, $148,500,000 of domestically produced ethical drugs were manufactured, as opposed to $152,400,000 of proprietary drugs.[41]

It is obvious that physicians would feel professionally threatened by a situation in which so many people were self-medicating or buying medicines on the advice of druggists or pitchmen. Doctors also had legitimate concerns about the safety of many of these nostrums and commercially produced medicines. As professional medical societies organized in the nineteenth century, they began to

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[39] There are several excellent studies of the patent medicine industry in the United States. Among them see Sarah Stage, *Female Complaints: Lydia Pinkham and the Business of Women's Medicine*, (New York: Norton, 1979); James Harvey Young, *The Toadstool Millionaires*, (Princeton, N.J.: Princeton University Press, 1961).

[40] Young, *Toadstool Millionaires*,

[41] *Census of Manufacturers*, (Washington, D.C.: U.S. Government Printing Office, 1939).

advocate the passage of state poison control laws that would protect consumers as well as enhance their own professional status.

Doctors preferred to prescribe their own formulas, as opposed to recommending patent medicines.[42] Sometimes the doctor compounded the medicine, or else the patient took the prescription to a pharmacist who would mix up the formula. If the formula proved to be efficacious, the patient could refill the prescription and medicate his or her family and friends. The pharmacist, noting the success of the formula, could market it himself. Unless the formula contained opium, there were not restrictions on its sale.[43]

In 1820, a group of physicians and pharmacists and representatives of state and national pharmaceutical societies, led by Dr. Lyman Spalding, compiled and privately published the first United States Pharmacopoeia (U.S.P.), listing ethical products and formulas that they considered to be safe and that were frequently prescribed by physicians. They also established the United States Pharmacopoeial Convention to revise and update the publication every ten years.[44] This marks the first effort of pharmaceutical interests to institutionalize.

In the later part of the nineteenth century, physicians began to demand standardized drugs for use in prescriptions. German chemical companies met

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[42] Jan R. McTavisit, "What's in a Name? Aspirin and the American Medical Association," *Bulletin of the History of Medicine* 61, no. 3 (Fall 1987).

[43] Peter Temin, *Taking Your Medicine*, 20-22.

[44] Parascandola, *The Development of American Pharmacology*, is a complete picture of the early years of the American drug industry. See also *The American Chemical Industry*. For the early development of the Pharmacopoeia, see also Walter A. Bastedo, "The Pharmacopoeia and the Physician," *Journal of the American Medical Association* 108, September 1936, 780-782.

much of this demand; but in 1854, Edward Squibb developed a process for distilling ether of uniform purity and strength. He abandoned his medical practice in order to produce ether in quantity. Thus Squibb became the first American manufacturer of "ethical" drugs.

In 1856, the American Pharmaceutical Association was formed to share with its members the scientific and professional developments in pharmacy. As part of its ethical code, it stated that the "primary object [of pharmacy is] the service which it can render to the public in safeguarding the handling, sale, compounding and dispensing of medicinal substances."[45] The group began to collect and circulate drug formulas, and in 1888 it began publishing the National Formulary, a book of formulas, substances, and preparations that were too new to be included in the Pharmacopoeia, or that had been dropped by the Committee of Revision but were still in demand. The Formulary was written by pharmacists as a supplement to the Pharmacopoeia, but it contained only ethical drugs by definition, since they were listing the formulas.

Proprietary drugs, made by secret processes out of secret ingredients, were excluded by these directories. In 1881, patent medicine companies organized themselves into the Proprietary Medicine Manufacturers and Dealers Association. Doctors and ethical drug companies may have opposed them, but the public relied on them. These companies did not just produce the quack patent medicines of the medicine show, but wide varieties of tonics, elixirs, and formulas. One such company was S. E. Massengill, founded in 1897 by a medical doctor who never

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[45] Parascandola, *The History of American Pharmacology*, 45.

practiced. Instead, he set up a manufacturing company that manufactured drugs, including the production of private formulas for physicians and druggists—in other words, proprietary or patent medicines.

All of this changed when, in the 1880s, German coal-tar drugs began to emerge. The most effective and popular was aspirin. Aspirin, however, was a patented drug that created further confusion between American drug categories. Until the First World War, American ethical drug companies generally bought fine chemicals from German chemical companies, made active drug ingredients from those chemicals, and sold those ingredients to wholesalers. Wholesalers, in turn, sold bulk powders and crystals to pharmacists and doctors who filled capsules, prepared liquid suspensions, and compounded ointments for individual patients.[46]

In the course of their efforts to reform medicine, the American Medical Association established the Council on Pharmacy and Chemistry in 1905. The purpose of the Council was to encourage doctors to move against the forces that resisted the advance of "rational therapy." It was also intended to discourage the use of patent drugs by physicians. The Council provided standards that would allow physicians to proscribe ethical drugs with confidence.

This was also an attempt on the part of the American Medical Association to gain some degree of disciplinary control over the pharmaceutical industry.[47] In

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[46] Walter Measday, "Pharmaceutical Industry," in *The Structure of American Industry, 5th Edition*, Walter Adams, ed. (New York: Macmillan, 1977).

[47] Burrows, "The Prescription Drug Policies of the AMA," 114.

1906, the AMA established its own chemical laboratory with the cooperation of the American Pharmaceutical Association. It established its own definitions of acceptable drugs, as well as appropriate drug analysis and assay standards.[48] The American Medical Association began to publish another directory, the New and Nonofficial Remedies, which listed non-patented drugs. Only those drugs that had been accepted for inclusion could be advertised in professional medical journals. In 1912, the American Medical Association also established a Committee on Therapeutic Research to investigate non-proprietary drugs.[49] In 1906, with the passage of the Pure Food and Drug Act, the standards of the Pharmacopoeia and the National Formulary took on the force of law.[50]

The 1906 Law was supported enthusiastically by ethical drug companies. It enhanced their status and made them part of Progressive Era regularization. To comply with the law, and to be included in these directories, drugs had to be accurately assayed and labeled as to identity and contents. This requirement, therefore, made—at least assay laboratories—a necessary expense for all ethical drug companies. They accepted the necessity as a way for them to distinguish themselves from the manufacturers of patent medicines.[51]

Pharmacists also moved to improve the status of their profession and distinguish themselves from hawkers of nostrums. In the spirit of the Progressive

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[48] Ibid., 115.

[49] McTavish, "Aspirin and the AMA."

[50] Young, "Federal Drug and Narcotic Legislation," 63.

[51] Ibid. See also Burrow, "The Prescription Drug Policies of the AMA."

era, they formed the American Pharmaceutical Association and developed licensing criteria, moving to establish that state boards enforce them.[52]

Despite these efforts, drug companies remained tainted by association with quackery in the eyes of many in the medical profession and much of the public. For these reasons, drug companies looked to science and the laboratory both for new products, and for a way to change their image. Despite the prohibition against ASPET members working for industry, pharmaceutical companies began to try to tempt academic pharmacologists into working for them. Spurred on by their acquisition of German patents and significant financial resources, in the 1920s drug companies began to build dedicated research institutions. As the history of the Chemical Industry, commissioned by the Chemical Foundation, put it, "the imperative necessity of manufacturing here many medicinal chemicals and pharmaceutical preparations previously imported...acted as an exhilarating ferment upon the manufacturing drug industry."[53] In fact, the movement of research scientists to industry did work to ameliorate at least partially the negative image of the industry.[54] In 1925, the first paper from an industrial laboratory was published in The Journal of Pharmacology and Experimental Therapeutics.[55] ASPET remained afraid that its organization might be dominated by industrial employees who might corrupt the ideals of its best scientists by "constant

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[52] Temin, *Taking Your Medicine*, 22.

[53] Haynes, *The American Chemical Industry*, vol. III, 304.

[54] Swann, *Academic Scientists and the Pharmaceutical Industry*, 41.

[55] Parascandola, *The Development of American Pharmacology*, 119.

association with those who are in business with its insistent demand for financial success."[56] Nevertheless, industry continued to woo ASPET members.

G.D. Searle opened a laboratory in 1924, Smith Kline and French in 1925, and Burroughs Welcome (USA) in 1928. In 1929, Smith Kline and French opened another research facility that was dedicated to the effort to "discover and manufacture new drugs of special interest to the medical world."[57]

The management at Abbott complained about the expense of research and development, but realized it was the wave of the future and necessary if they were going to exploit the German patents they had received from the Chemical Foundation. In 1925, the new director, Dr. Alfred S. Burdick, further increased the research budget.[58]

In 1931, Mr. Edgar B. Carter of Abbott Laboratories gave a paper at the annual meeting of the American Pharmaceutical Manufacturers Association, called "The Establishment and Management of a Research Laboratory." He explained that he had written the paper for the benefit of "the manufacturer who, not having a research laboratory, anticipates the establishment of one." The first step, he advised, was to find and hire a director of research who need not be a chemist, but who must be able to direct research into appropriate projects because

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[56] Ibid., 122.

[57] John Francis Marion, *The Fine Old House* (Philadelphia: SmithKline Corp., 1980), 117.

[58] It is interesting to note that the next president of Abbott Laboratories, Dewitt Clough, was not a physician but rather the former head of advertising and promotion before taking over the company in 1933. For a complete history of Abbott Laboratories in this period, see *The Long White Line: The Story of Abbott Laboratories*, (New York: Random House, 1963), 122-157.

an academic scientist would not "...be able to produce results of value to an industry. Somebody in the industry must give him the problem." The response to Mr. Carter's paper was so enthusiastic that the Association decided to reprint it.[59]

Other companies with minimal research staffs expanded them in the late 1920s and 1930s.[60] Merck opened its Institute for Therapeutic Research in 1933; Eli Lilly opened a research laboratory in 1934; and Squibb opened the Institute for Medical Research in 1938, the same year the Abbott Research Lab opened its doors.[61] These laboratories were all contributing to mainstream pharmacology, and their staffs attended scientific papers. Research budgets grew. Merck spent $146,000 in 1931 and $906,000 in 1940.[62]

Pharmaceutical companies emphasized this scientific aspect of their industry in their advertising campaigns. Though ethical drug companies could not advertise to the public, they could do so in the professional and trade publication. An advertisement for Searle products in the Druggist Circular in 1935, for example, was headlined, "He Brings a Research Laboratory as an Annex to Your Store." The copy of the ad went on to explain that when a Searle representative, "that enterprising gentleman," comes to call, he is bringing the "new resources of

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[59] Edgar B. Carter, "The Establishment and Management of a Research Laboratory," *Proceeding of the American Pharmaceutical Manufacturers Association (1931), (unpaged).*

[60] Parascandola, "Industrial Research Comes of Age," *Pharmacy in History,* 27 (1985), 14.

[61] Swann, "The Evolution of the American Pharmaceutical Industry," *Pharmacy in History,* 37 (1995), 81.

[62] Ibid., 80.

our research laboratories in producing new products to enlarge your prescription business."[63]

The importance of these laboratories, and of the changes within drug companies, was not all rhetorical. Companies reorganized their product lines. For instance, in 1936 Smith Kline and French discontinued production of 500 standard and proprietary drugs. The next year the company sold 14 products, only eight of which were pharmaceuticals. The company made certain that its reforms received appropriate publicity.[64]

An article in Science Newsletter, intended for lay readers, reported in 1938 that "A new trend in the world of drugs, destined to aid man's search for health is signaled by the dedication...of new medical research facilities of two large drug manufacturing firms." The firms in question were Abbott and Squibb. The writer concluded, "Medicine makers such as these are no longer confining themselves...to drugs. They are undertaking important programs of research on medical matters."[65]

These research institutes were successful. They developed new drugs. Pharmaceutical companies began to patent these drugs to protect their considerable investment. In 1920, Squibb had applied for one patent. In 1940, it applied for 164 domestic patents and 39 foreign ones.[66] As one enthusiastic

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[63] *Druggist Circular*, March 1935, 43.

[64] Marion, *The fine Old House*, 130.

[65] "Medicine Making, Research, Now March Side by Side," *Science Newsletter* (15 October 1938), 245.

[66] Swann, *Academic Scientists and the Pharmaceutical Industry*, 54.

writer explained, "the atmosphere...is a combination of a university and the Pentagon Building." He went on to elaborate, "girl technicians bask in the sun like co-eds...inside are blackboards on which scientists, many of whom have been college professors, write chemical formulas."[67]

Universities were so inspired that they, too, began to patent discoveries made in their facilities, ostensibly to prevent drug companies from controlling too much of the pharmaceutical industry, but also as a source of revenue.[68]

Drug companies had to do more than win over the public. Ethical drugs were only advertised to doctors, so pharmaceutical companies had to convince physicians to use their products.

As early as 1894, Dr. Wallace Calvin Abbott tried to make it clear to physicians how much he respected them and their professional dilemmas. The Alkaloidal Clinic, edited and owned by Dr. Wallace Calvin Abbott, published an article reporting on the protest lodged by the American Pharmaceutical Association about physicians who dispensed drugs while on hose calls. Dr. Abbott explained that he approved of the activities of these fine doctors, who he felt were practicing good medicine and who needed to collect their fees. He remarked that "most of the sickness is among the poorer classes, because there are so many more of them, and too often, when the medicines for sickness are paid

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[67] Tom Mahoney, *The Merchants of Life* (New York: Harper Brothers, 1959), 19.

[68] Swann, *Academic Scientists and Medical Industry*, 54.

for, there is nothing left for the doctor." Abbott concluded that physicians should be practicing medicine (and being paid for it), not the "clerk in the drugstore."[69]

Publications like the Alkaloidal Clinic were useful to drug companies in the efforts to reach doctors. In 1906, Abbott renamed it the American Journal of Clinical Medicine. According to Abbott, the monthly journal was "Devoted to Accuracy, Dependability, and Honesty in Every Department of Medicine and to the Safeguarding of the Doctor." Despite Abbott's public support of physicians, the American Medical Association labeled his publication a house organ and not a legitimate journal. Abbott protested that while Parke, Davis's Therapeutic Gazette, and Merck's Report and Merck's Archives were indeed house organs, his monthly was not.[70]

At the 1910 American Medical Association convention, Abbott was permitted a booth, and he distributed booklets about his company. His corporate position which was to give "the physician means to combat disease of every description more effectively...by furnishing him with weapons only he can wield."[71] This, of course, was the critical point. For many physicians, drug companies represented a threat to their income as well as their professional standing. They had good reason for their feelings. Even as late as 1932, the Committee on the Costs of medical Care's final report included the statement that manufacturers and vendors of drugs and medicines are in many ways "engaged in

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[69] Kogan, *The Long white Line*, 178.

[70] Ibid.

[71] Committee on the Cost of Medical Care, *Final Report*, 28.

the healing arts."[72] Americans continued to use over-the-counter drugs. According to historian Peter Temin, "At the retail level, patent medicines still accounted for half of all drug sales in 1929."[73]

Abbott concluded his 1910 affirmation of his company's principles by assuring doctors that the company was well aware of their importance. "We have brought the conflict from quackery and self-medication back into the sickroom, in which he [the doctor] reigns supreme."[74]

The American Medical Association took a firm position on the role of pharmacists. The 1912 Principles of Medical Ethics of the AMA explicitly stated:

> By legitimate patronage physicians should recognize and promote the profession of pharmacy; but any pharmacist, unless he be qualified as a physician, who assumes to prescribe for the sick should be denied such countenance and support.[75]

This definition was calculated to please doctors, and certain consumer groups took exception. Activists pointed out that patent and proprietary medicines were advertised everywhere and that physicians were effected as much, if not more, than any other group. "Side by side with the high pressure

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[72] Some health-care reformers pointed out that though the American medical Association had done "notable working exposing the frauds of the patent medicine racket," there could be no significant change in the situation unless the Association retracted its opposition to the socialization of medicine, as their position was one of "the chief causes of the continuance of the racket." The logic behind this was that the poor had no alternative but to use over-the-counter drugs. J. B. Matthews, *Guinea Pigs No More.*

[73] Temin, *Taking Your Medicine*, 38. See also Sarah Stage, *Female Complaints; Lydia Pinkham and the Business of Women's Medicine*, 252.

[74] Kogan, *The Long White Line*, 81.

[75] "Principles of medical Ethics of the American Medical Association," (Chicago: AMA, 1912), Chapter III, sec. 4.

bamboozling of the common people, a special campaign is unremittingly directed at the 150,000 doctors practicing the mysteries." Outraged consumer advocates pointed out that "drug-peddlers know the oracular power of the Rx...the compelling power of the pig Latin prescription."[76] The power of the prescription lay in the idea that the patient had paid for and received a compound prepared individually for him. Even if the prescription was for a patent medicine, in the eyes of the patient, the prescription itself made the medicine more potent. This is a critical point in understanding the evolution of pharmaceutical medicine, especially in the 1930s. Even ethical drugs were compounded individually, for each patient, according to the prescription written specifically for that patient. This was an important part of medicine as it had been practice, especially by elite physicians. One of the ways in which "regular" physicians distinguished themselves from sectarian practitioners was that they were not committed to one particular therapy; instead, using their training and clinical experience, they chose the specific therapy that was appropriate.[77]

The ability to write a prescription was important therapeutically as well as culturally. Prepared compounds did not require the same kind of professional expertise on the part of the physician. In this context, prepared medicines such as sulfa drugs were perilously close to nostrums and patent medicines. Aware of

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[76] "Drug Prescription Racket," *American Mercury*, 45, November 1938, 299.

[77] As an illustration, at one point the American Medical Association opposed the over-the-counter sale of vitamins as self-medication. They particularly opposed multivitamins, which they considered a "shotgun" approach, as opposed to a specific therapy. Elmer Bobst, *Bobst: The Autobiography of a Pharmaceutical Pioneer*, 190.

this, drug companies worked to make clear the distinctions between prepared compounds and over-the-counter medications. For these reasons, there was significant opposition to pre-formed tablets or pre-filled capsules.[78] Ethical drug companies were as interested as physicians in making this clear. They wanted to make certain that doctors understood that their authority was not undermined, but rather enhanced by the use of ethical medications, and that using these drugs, as opposed to patent medicine, was a professional privilege and responsibility. To help clarify the issue, the Chairman of the Committee of Revision of the Pharmacopoeia of the United States, E. Fullerton Cook, wrote an article published in the Journal of the American Medical Association. He explained that the Committee for the XI Revision had decided to list only basic substances precisely in order to insure that each physician would be free to "exercise skill and judgment in the selection and combining of each medicine, that it may exactly meet the needs of his individual patient." In fact, Cook gently suggested, on occasion doctors themselves showed a "lamentable tendency to order drugs instead of prescribing them." He felt that it was important that physicians be mindful of the suggestible nature of patients, if only for the patients' own good. He reminded doctors that "belief in the physician and his treatment is a powerful influence for relief and cure." Specifically, a prescription provides "evidence of professional skill and is not a product with which the patent is already familiar."

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[78] Pharmacists were also affected by this issue. The skill involved in counting out a required number of manufactured tablets was clearly less than that involved in compounding medicines according to the doctor's prescription. Physicians were not the only professionals threatened with de-skilling by modern pharmacy.

Lest his point be missed, Cook finally came right out and said that "patients are reluctant to pay a doctor if patent medicine is prescribed."[79] The ethical drug companies wanted to make it very clear to physicians that it was in their mutual interest to do what they could to limit patent and proprietary medicines.[80]

In order to solidify the relationship between ethical drug companies and doctors, the officers of the United States Pharmacopoeia announced that they had been consulting with the editors of the Journal of the American Medical Association. As a result, the Journal would publish a series of articles every two weeks for at least a year, articles that would present the "therapeutic side of specific diseases." These articles were intended to extend information to physicians "concerning the use of official medicines."[81] As the president of the Pharmacopoeia Committee on Revision explained, a new therapeutic era had begun "about a generation ago," inspired in part by the fact that physicians had decided that most of the drugs then available were useless, since their action cold not be demonstrated biologically or chemically. This scientific opposition could

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[79] D. Fullerton Cook. Ph.M., "The Importance and Advantages of prescription Writing in Medical Practice," *The Journal of the American Medical Association*, 107, September 1936, 965-967.

[80] There were contradictions, however, and doctors were aware of them. For example, a Johnson & Johnson ad, which ran in the April 1936 edition of *Druggist Circular* (6), was headlined "Remember the J & J slogan publicized throughout the world **Your Druggist more than a merchant"** (emphasis in the original copy). The copy goes on to explain, "The more you recommend and sell the products of known and reputable concerns the more you justify the public trust."

[81] National Archives, Record Group 88, Records of the FDA, USP Circular, Box 23, Circular #717, September 1936. All the archival material from the National Archives comes from Record Group 88. Hereafter, only the specific type of FDA record will be listed.

not be ignored, even though some of these physicians had gone too far in their criticism. The situation had been corrected, and because drug companies now had better trained investigators, "the research laboratories of a few of our pharmaceutical and chemical manufacturing firms give much promise for the future."[82] The Committee for Revision was proud that the USP had kept pace with these changes. The XI Revision reflected the recognition that many doctors used more or less standard combinations of drugs prepared by skilled pharmacists. Therefore, official preparations would now be included in the Revision.[83]

The USP further pledged that it would include all new medicinal agents as soon as their value had been proven. The patent issue, however, was a major stumbling block. By definition, as well as by policy, the USP could not include patented medicines. It only listed ethical drugs. However, there was "an increasing tendency for universities and manufacturing firms to patent or trademark new medicinal products." That made preparing the USP difficult. Insulin, fore example, could not be included in the XI Revision, as it was protected by copyright. As soon as the patent expired in 1942, it would be listed.[84] The Committee on Revision raised the point that the policy might have to be changed sometime in the near future so that all important drugs could be included. This redefinition was made necessary by developments in organic chemistry. Pharmaceutical companies had to establish laboratories, and they had

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[82] *USP Circular*, Box 23, Circular #668 (1936), 2701.

[83] Ibid.

[84] Ibid.

to find a way to pay for them. Patenting products provided a solution. This new kind of "patent" medicine would not be nostrums sold by quacks, but rather the most scientific kind of medicine, to be used only by the most skillful of practitioners.

To make sure that doctors were comfortable with these changes, the first of the Journal of the American Medical Association articles—written by Walter Bastedo, M.D. and president of the United States Pharmacopoeial Convention—began with the assurance that "fundamentally the physician is a therapist" and that the purpose of the articles and of the Pharmacopoeia was to "direct the physician's attention to the high quality of drugs...and their ability to meet his most exacting needs."[85]

Pharmaceutical companies tried to reach doctors in other ways. They made extensive use of salesmen, or detail men, who traveled around to doctors, giving them samples and explaining the value of the drugs their companies produced. Ethical pharmaceutical companies also advertised widely in medical journals. In addition, they sent out mailings to doctors, often enclosing samples. These mailings were "masterpieces of color printing," which was necessary because "physicians were highly educated and artistically discriminating."[86]

Most of the drug companies published newsletters or, as the American Medical Association put it, "house organs." The companies maintained that these

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[85] Walter A. Bastedo, M.D., "The Pharmacopoeia and the Physician," *Journal of the American Medical Association* 107, September 1936, 780-782.

[86] Mahoney, *The Merchants of Life*, 26.

were "a valuable source of data on modern treatment methods."[87] In their publication, Therapeutic Notes, Parke Davis and Co., in addition to informing physicians abut new drugs, also discussed at considerable length the success of their six-year-old advertising campaign called "See Your Doctor," which they were running on behalf of the medical profession. These advertisements were intended to remind the lay public of the "idea of the practitioner's supremacy...not...by high pressure methods but in a way which appeared to be in keeping with the dignity of a learned profession."[88] An advertisement that had a wonderful response, both from patients and doctors, was one which was "intended to encourage the payment of old accounts owning to physicians—obviously a delicate topic."[89]

Another of these advertisements featured a child siting up in bed writing a letter. The headline read, "Dear Santa, please can I be well for Christmas?" The child's reply was written not by Santa Claus, but by the family doctor. The copy included statements like, "the one person who...knows [about the gifts of medical science] is your physician...Keep in touch with him." In fact, the advertisement promised that the family doctor could "bring into your home a new peace and a

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[87] National Archives, Advertising Materials, Patent Medicine, Acc. #243, Box 11, *Therapeutic Notes*, published by Parke Davis and Co., January 1935.

[88] Ibid.

[89] Ibid.

new tranquility."[90] Parke Davis offered an "attractively bound" portfolio of these advertisements free to any doctor who wanted one.

Elmer Bobst, president of Hoffman-LaRoche, developed his own plan, which caused some controversy. He suggested that organized medicine sponsor a national radio program that would be 'designed to develop a greater public appreciation of the services of the physician." Bobst estimated that the program would cost $400,000. He pledged $100,000, provided that other "pharmaceutical concerns of acceptable ethical standing" would raise the rest. The money would be given to the American Medical Association, and the names of the contributors would not be made known to the public.[91] The plan was never carried out, as there was concern that it would demean the medical profession.

In December 1936, the New York Times printed a report of a paper given by Perrin H. Long and Eleanor Bliss of Johns Hopkins University. The two described their success in treating streptococcal infections with Prontosil and Prontolyn. The Times referred to Long and Bliss as "merely clinical verifiers of a discovery made by Professor G. Domagk," a chemist in the employ of a chemical company. The article suggested that "the lesson Domagk...teaches is one the medical profession and the public should take to hears." The point of the article was that chemists, "not...trained physicians" who were employed by a commercial company, have discovered a drug that appears to be responsible for "the probable conquest of streptococci and a dozen afflictions to which they give

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[90] National Archives, Advertising Material, Patent Medicine; Acc. #243, Box 11.

[91] *Druggist Circular*, LXXI, no. 1, January 1937, 39.

rise."[92] Commercial science was at last able to provide products that were both humanitarian and profitable.

The introduction of sulfa drugs is critical in that it served to focus much of an ongoing debate within both the pharmaceutical and medical professions, one that included more than issues of the morality of patenting and profiting from medicine. As the above quote suggests, the fact that these drugs did come from a commercial corporation that paid for their development was relevant. Equally important was the context of the re-negotiated relationship between the pharmaceutical industry and doctors.

The American Medical Association Council on Pharmacy and Chemistry was part of this change. In order to continue to exercise control over pharmaceuticals, it had to make some kind of statement or take some kind of official position about sulfa drugs. Yet, for all the reasons discussed above, many doctors and members of the Council were reluctant to endorse a product already heralded in the lay press as a medical miracle but one that could be purchased in any drug store.

In May 1937, the Council on Pharmacy and Chemistry decided that it was necessary to "issue a report on the present status of sulfanilamides." At that point, Calco Chemical Company, Lederle Laboratories, Eli Lilly and Company, Merck and CO., Inc., Parke, Davis, and Co., E. R. Squibb and sons, and Winthrop Chemical Co. had all submitted sulfanilamide products for acceptance by the American Medical Association. The Council decided that sulfanilamides should

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[92] Editorial, *The New York Times*, 18 December 1936, 24

be included in New and Nonofficial Remedies, as a therapeutic agent; but the Council had yet to determine the acceptability of the various brands that had been submitted to it for consideration.[93] It had yet to determine standards for identity and purity. A month later, according to the New England Journal of Medicine, the Council had accepted tablets made by Calco, Lederle, and Abbott.

Nomenclature proved a relatively uncontroversial way of dealing with taking control of the issue. The Council explained that the drug was "apparently first introduced in the United States under the proprietary name Prontolyn."[94] Since the product (actually, the active ingredient) was not patented and "as other firms were privileged to make it," the Council on Pharmacy and Chemistry had an obligation to come up with a "non-proprietary name." The Council decided on "sulfanilamide."[95] Despite, or perhaps because of, the enormous interest in the lay press, the Journal of the American Medical Association reported on the drug's progress through its acceptance system. The Journal continued to display much less enthusiasm, however, than pediatric journals. Even through many of the initial European publications emphasized the use of the drug in treating puerperal septicemia, obstetricians responded even more slowly.

The first substantial article on sulfa drugs to appear in an American clinical journal was published in the Journal of Pediatrics. It dealt, in part, with

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[93] "Report of the Council on Pharmacy and Chemistry," *Journal of the American Medical Association* 108, no. 22, 29 May 1937, 1888.

[94] "The Chemical Laboratory," *Journal of the American Medical Association* 109, no. 5, July 1937, 358.

[95] Ibid.

therapeutics. "It is evident that the clinician has at his disposal a new drug, with undoubted value in the treatment of many infectious conditions of a hitherto most refractory nature."[96] The article addressed other issues as well. It concluded with a plea for general usage of the American Medical Association's approved term—sulfanilamide—rather than the numerous trademarked names, "some of which are already in common usage."[97] If sulfa drugs were going to play an important therapeutic role, then the medical community should establish what control they could over the situation.

Even as all of these debates raged on, the drug was being used by practitioners, especially pediatricians. The fact that the drug was in use was made clear in a lengthy discussion, the "Symposium on sulfanilamide Therapy," published by the Journal of Pediatrics, as part of the previously mentioned first major analysis of sulfa drugs in an American medical journal. Since it was evident that there was widespread use of sulfa drugs among both pediatricians and the lay public, the editors of the Journal of Pediatrics decided to publish what they called "a service by exchanging the 'experience to date' of a group of pediatric clinics, making this information available to all pediatricians and hospitals for children." The Journal pointed out that "the few brief published preliminary reports of its use are literally amazing."[98] The American Medical Association

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[96] Arnold Welch, "The Pharmacological Basis for Sulfanilamide Therapy," *Journal of pediatrics* 11, no. 2, august 1937, 65.

[97] Ibid.

[98] "Symposium on Sulfanilamide Therapy," *Journal of Pediatrics* 11, no. 2, August 1937, 157.

was much more temperate in its reporting. "Since there is adequate evidence that sulfanilamide is an effective drug for the treatment of grave hemolytic streptococcus infections, which are often fatal, its use in such cases appears to be justified."[99] "Often fatal" was something of an understatement. The mortality rate varied from 92% to 100%. Initial reports of sulfa drug therapy reported a 12.5% mortality.[100] The American Medical Association warned members that the drug should be regarded suspiciously, and that it was not a panacea.[101] In his book The Clinical Use of Sulfanilamide, Perrin Long wrote that while the drug should not be used indiscriminately, physicians should also not hesitate to use it where indicated. Long felt that, on occasion, "infections are permitted to advance to a dangerous stage because the physician was afraid to use sulfanilamide."[102]

Drug companies quickly developed—and began enthusiastically advertising—their own sulfanilamide preparations. Winthrop Chemical published two physician information booklets in 1937 describing their products, which were being marketed under the familiar names Prontolyn and Prontosil. (The chief difference between the two is that the first was an oral preparation; the second

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[99] "Report of the Council of Pharmacy and Chemistry," *Journal of the American Medical Association* 108, no. 22, May 1937, 1889.

[100] Joseph Millet, M.D., "Hemolytic Streptococcus Meningitis," *New England Journal of Medicine* 217, no. 14, September 1937, 556.

[101] "Report of the Council of Pharmacy and Chemistry," *Journal of the American Medical Association* 108, no. 22.

[102] Long and Bliss, *Clinical Use of Sulfanilamide*, 148.

was administered by subcutaneous injection.)[103] A competing company published a similar booklet, calling its drug Sulfanilamide, and suggested that it "is more effective than its chemical derivatives."[104]

As the medical profession feared, the lay public was less ambivalent about using the drug. Over-the-counter preparations were extensively advertised. Sulfa drugs were publicized as cures for countless diseases, including gonorrhea. There was some evidence in medical literature that the disease responded to sulfa drugs, and drug companies enthusiastically promoted it for that use.[105] Over-the-counter sulfanilamide products that were intended to cure gonorrhea sold briskly. Drug companies also produced "ethical" products to be used to cure sexually transmitted diseases; one such drug was "Phythrees Gonorrhea Cure." Although this drug was advertised only to doctors and was therefore an ethical product, its label was designed to attract lay users.

These drugs were perfectly legal. Except for narcotics, the 1906 Food and Drug Act did not restrict sales of drugs. Individual states, however, could pass legislation that would restrict the sale of over-the-counter drugs. There was considerable pressure for drug regulation from many directions, including medical and consumer groups. Some states did outlaw the over-the-counter sale of

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[103] National Archives, Advertising Material, Patent Medicine, Acc. #243, Box 11.

[104] Ibid., Millenckrodt Chemical Co.

[105] Lyman Stewart, M.D., "Treatment of Urogenital Tract Infections with Sulfanilamide," *Bulletin Sagamon Country Medical Society*, October 1937, 106-109; "Report on Sulfanilamide," *Journal of the American Medical Association*, May 1937, 108.

sulfanilamides. The California State Board of Health issued such an order in September 1937.[106]

The Food and Drug Administration was actively trying to extend its regulatory power during the 1930s through new legislation. One of its particular concerns was the over-the-counter use of sulfanilamides, particularly as a cure for gonorrhea. Food and Drug Administration Chief, William Campbell, wrote to his senior staff, the chiefs of districts, expressing his particular concerns about two products that were about to come onto the market. He explained that new drugs were continually appearing and that the Administration needed to be kept informed as they developed.

> Sulfanilamide is no doubt attaining a most remarkable volume of distribution...we are anxious to confine its use to legal preparations. We are not yet in position to proceed to investigate sulfanilamide preparations in general.[107]

Though the Food and Drug Administration may not have been in a position to investigate, it did as much as it could. It surveyed the wholesale drug companies to determine how extensively the drugs were being marketed, and to whom. It discovered that only four companies were making the basic ingredients, though the number of "concerns who make preparations therefrom, appears to be rapidly increasing."[108]

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[106] *Journal of the American Medical Association*, vol. 109, no. 21, November 1937, 1729.

[107] National Archives, FDA General Subject Files, 510-520; Letter from W. G. Campbell, Chief, to all Chiefs of All Districts, 20 October 1937.

[108] National Archives, FDA Central Correspondence, Box 93, Memo to Chief, Eastern District from Charles Hyack, Acting Chief, New York Station, 7 August 1937. The four firms in question were Abbott, Burroughs Welcome,

The question of the regulation of the pharmaceutical industry was of concern to drug manufacturers as well as to the Food and Drug Administration. Their positions, however, differed. Just before the passage of the 1938 Pure Food, Drug and Cosmetic Act, Eli Lilly wrote to the Honorable Clarence F. Lea that "it is come to our attention that the name of Eli Lilly...has been mentioned as being in favor of a federal licensing system for new products...we are unalterably opposed..."[109]

The pharmaceutical industry, as were many other industries, was not eager for government regulation. To combat such a possibility, it identified itself with the medical profession, which prided itself on successful self-regulation. The American Pharmaceutical Association pointed to its own efforts to establish educational qualifications for pharmacists and licensing laws. It took credit for state poison-control laws, as well as laws restricting the sale of narcotics. It insisted that all such legislation had been copied or adapted from laws formulated and disseminated by its organization.[110] The group felt strongly that the production of drugs and medicines, as well as their distribution, was the province of the pharmaceutical profession.[111]

Calco, and Merck. In *The American Chemical Industry* (vol. V, Appendix XXIV, 519), the figure is given as 10 firms in 1937 and five in 1938.

[109] National Archives, Records of the FDA, Office of Committee on Legislation, Acc. #52a-86, Box 10, Letter to Hon. Clarence F. Lea from Eli Lilly, 15 March 1938.

[110] Krantz, *Fighting Disease With Drugs*, XVIII.

[111] Ibid., 182.

Like physicians, some felt that intrusion into the regulation of drugs represented the interference of laymen with professional privilege. Like other successful businessmen in New Deal America, drug manufacturers resented interference in their activities by government, considering it an impingement on their freedom and an attack on capitalism, if not an actual Communist plot.

The first formal protest about possible restrictions came from the American Pharmaceutical Manufacturers Association in December 1931, even before Roosevelt took office. The Association complained that there had been suggestions of modifications of "the revision methods of the Pharmacopoeia by the establishment of a Government Commission to perform the same service." The Association had no intention of relinquishing control over the Pharmacopoeia. It stated that it had successfully carried out revisions for many years "on the highest professional plane." At the urging of the Chairman of the Revision Committee, the organization pledged, "as American pharmacists...[to] stand together to correct any defects but at the same time maintain this pharmaceutical service as one of our most prized birthrights..."[112]

At the 1933 meeting, the president of the organization, John G. Searle, recognized that there was the distinct possibility that the Roosevelt administration would try to impose some kind of government regulation on the pharmaceutical industry. In his presidential address, Searle acknowledged that there was an economic crisis. He applauded the government for trying to correct the problem,

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[112] "Report of the Committee on Revision of the United States Pharmacopoeia," *Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association*, December 1931, (unpaged).

"radical as many of the suggestions have been..." He told the members that it was time to admit that logically there was no way the drug industry would be spared government intrusion, and "it appears quite likely that we will be working with an entirely new plan of marketing goods in the proposed new Food and Drug Act." He reminded his audience that theirs was "a two billion dollar industry and, as such, ranks fourth in size in this country." He recommended that the industry act to shape any government regulation as much as they could. To that end, the Association had formed the Drug Institute of America in order to "rationalize the industry," and he was sure that all members would cooperate with the national effort.[113]

The implication that the industry would resist to the extent that it could and that it was mindful of its economic power was not enough for some of the other speakers at the meeting. In his address, "The Future of Medicine," Charles Whalen, M.D., editor of the Illinois State Medical Journal, linked drug company concerns to broader issues. He cautioned, "[In] common with the future of all national professions and industries, the future of medicine depends on the degree to which our national conscience rouses to fight the imminent menace of socialist usurpation." He sharply warned against any incursion by government on any aspect of medicine, including pharmaceuticals. He pointed out that "the future of medicine hinges more upon the economic than upon the scientific."[114]

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[113] John Searle, "Presidential Address," *Proceedings of the Annual Meeting of the American Pharmaceutical Manufacturers Association* (1933), 145-147.

[114] Whalen, M.D., "The Future of Medicine," *Proceedings of the American Manufacturers Association* (1933), 170-177.

William Campbell, chief of the Food and Drug Administration, also addressed the meeting. He assured his listeners that he knew that "you have approached this problem sympathetically and with an appreciation of the difficulties which are ours in the administration of the law." He went on to remind the meeting that the purpose of Food and Drug Laws was to prevent poisons from being added to food and to prevent a "vast field of pure cheat, of fraud, misbranding, adulteration..." which, presumably, his listeners were just as eager as he to suppress. Apparently believing in a philosophy of divide and conquer and appealing to proprietary drug manufacturers, he explained that although perhaps some doctors would like to eliminate self-medication, "I have no interest in the outlawry of self-medication...The only concern that I have is to make possible the safety of self-medication."[115]

Early attempts at government regulation were unsuccessful, due in part to the strenuous efforts of the industry to prevent them. As will be discussed in the next chapter, after trying to prevent any law at all, the industry changed tactics and decided to try to shape proposed legislation to suit its own purposes. In 1935, Dr. Robert Fischelis, the president of the American Pharmaceutical Association, suggested a reorganization plan for the industry. He proposed building an "all inclusive" organization of pharmacists, manufacturers, wholesalers, teachers, and "law enforcement officials." If these efforts were successful, and the Association was "representative of the majority of practicing pharmacists, its power of moral

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[115] Ibid., 21-28.

suasion will be great enough to make demands for laws to control trade practices unnecessary."[116]

The Proprietary Drug Association had similar plans. It organized an advisory committee on advertising to censor commercial announcements since the organization felt itself to be "beleaguered."[117]

These efforts at self-regulation were not enough to stem consumer concerns over the safety of food and drugs; nor did the Food and Drug Administration accept them as sufficient. Despite all efforts to the contrary, Pure Food and Drug regulation refused to disappear. In October 1937, when more than one hundred people died from the toxic solvent used by the Massengill Company in their Elixir Sulfanilamide, the passage of some form of drug regulation was all but inevitable.

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[116] "Reorganization of the American Pharmaceutical Association Urged by President Fischelis," *Druggist Circular*, January 1935, 20.

[117] *Time*, May 1936, 35.

Chapter 5 The World That Sulfa Drugs Made—Short Term

It is not surprising that during the New Deal, a period of political reform that included significant government control over many aspects of life, legislation to regulate the food, drug, and cosmetic industry would be submitted to Congress. In that sense, the 1938 Pure Food, Drug, and Cosmetic Act is reflective of what historian Harry Marks has defined as a period when federal authorities refashioned themselves and regulatory power took on a new critical political meaning.[1] Peter Temin sees drug regulation as an essentially Progressive impulse to support social values in the face of purely market driven ones.[2] It can certainly be seen as part of the New Deal effort of "experts" and fledgling bureaucrats to structure society from within the government.

The first version of a bill for drugs quickly became known as the Tugwell Bill, named for Rexford Tugwell who, as the Assistant Secretary of Agriculture, was the major political advocate for the legislation. The impetus for the law came from Food and Drug Administration staff members who had long held concerns over unsafe patent drugs, inadequately tested ethical medicine, and adulterated food products. Tugwell's support of the law brought with it considerable political opposition, and Ruth DeForest Lamb, a member of the Food and Drug staff, explained that the work was done by the Food and Drug Administration. Tugwell had never "written a line of any one of the many drafts of the bill, nor dictated the

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[1] Harry M. Marks, *The Progress of Experimental Science and Therapeutic Reform in the United States, 1900-1990* (New York: Cambridge University Press, 1997).

[2] Temin, *Taking Your Medicine.*

substance of any provision." What Tugwell did to contribute was "the winning of presidential approval for the undertaking, and his own sympathetic support."[3]

The legislation was submitted to Congress in 1933 by Senator Royal S. Copeland of New York, and quickly became known as the Copeland Act. It was not passed until five years later, by which point, like much legislation of its type, the bill had been significantly weakened despite the efforts of the Food and Drug Administration.[4]

By 1936, Ruth DeForest Lamb described the bill as "battered almost beyond recognition;" but despite its considerable flaws, the 1938 law is a key piece of consumer legislation.[5] One lawyer who worked on the legislation remarked in 1939, "it is curious that this bill, significance to every citizen, never was the object of widespread public attention."[6] He suggested that the lack of

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[3] Ruth DeForest Lamb, *American Chamber of Horrors: The Truth About Food and Drugs*, (New York: Farrar and Rinehart, 1936), 285.

[4] In addition to the general works on the history of American pharmacology already cited, all of which touch on this legislation, there are several studies of the effort at legal regulation of the pharmaceutical industry. See H. Welch and F. Marti-Ibanezea, *The Impact of the FDA on Our Society*, (New York: MD Publications, 1956); John B. Blake, ed. *Safeguarding the Public: Historical Aspects of Medicinal Drug control* (Baltimore: Johns Hopkins University Press, 1970); Charles O. Jackson, *Food and Drug Legislation in the New Deal*, (Princeton: Princeton University Press, 1970). For two very specific points of view, see a history of the first years of the legislation struggle written by a member of the Food and Drug Administration staff, Ruth DeForest Lamb, *American Chamber of Horrors*, (New York: Farrar and Rinehart, 1936). For an alternative view, see *The Druggist and the Federal Food, Drug, and cosmetic Act* (National Association of Retail Druggists), 1939.

[5] DeForest Lamb, *American Chamber of Horrors*, 287.

[6] Carvers, "Food, Drug, and Cosmetic Act of 1938," *Law and Contemporary Problems* 6 (winter 1939), 3.

consumer activism had permitted the bill to languish in committee for so long and blamed the phenomenon on a lack of interest on the part of the press. This lack of attention may not have been an oversight, but a reflection of the fact that patent drug companies were heavy advertisers and the media did not wish to offend them.[7] Furthermore, despite Tugwell's involvement, Roosevelt apparently didn't consider drug legislation reform to be a priority until after the Elixir Sulfanilamide debacle.

More than anything else, the delay in the passage of the bill demonstrates the power of the drug companies. Pharmaceuticals were a big business. Because the industry was decentralized, there were numerous forms of local and national political pressure that the industry could bring to bear. This political pressure, especially in the south where many drug companies, including Massengill, were located, proved useful in mobilizing opposition behind the scenes. Perhaps as a result of the complex politics involved, despite the consumer aspects of the bill, the consumer interest in the bill, most of the critical battles over the details took place behind closed doors or in committee meetings and hearings.[8]

Sulfa drugs played a critical part in the fight for the passage of this legislation in several ways. The most dramatic is that the scandal surrounding the deaths of 107 people from Elixir Sulfanilamide was the immediate catalyst for the passage of the stalled legislation. Another, and perhaps more important, role that sulfa played was the way in which it embodied the major changes that were

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[7] Morell, *Poisons, Potions and Profits: The Antidote to Radio Advertising* (New York: Knight Publishers, 1937), 5.

[8] Ibid., 7.

occurring in the drug industry. Sulfanilamides were not just efficacious "miracles;" they were sophisticated, scientific, laboratory-produced therapeutics with the potential to generate enormous profits. The appearance of such a powerful drug suggested that the public could look to pharmaceuticals for protection. In turn, the public needed to be protected from the potential immorality of the very businesses that produced it.

The third aspect of sulfanilamides, which heightened the controversy surrounding them, was the drug's German origin. Gifts from Germany, a once and future enemy, made some Americans suspicious. On the other hand, because the drug was so efficacious, adequate supplies were crucial to national security. By the late 1930s, the political situation in Germany was a source of considerable concern. The drug and its American producers were therefore that much more valuable. Chemical companies worked hard to make certain that the problems caused by the embargo of German drugs and dyes during World War I were not forgotten. The memory of those shortages emphasized how critical American chemical and pharmaceutical companies were to the nation. While consumer and political reform voices had to be satisfied, a legislative solution had to be found that was acceptable to the industry as well as the good of the country.

The first significant piece of federal legislation that regulated the food and drug industries was passed in 1906 as part of the "trust busting" reforms that characterized Theodore Roosevelt's administration.[9] Dr. Harvey Wiley, the head

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[9] Between 1879 and 1906, 140 bills to provide the government with regulatory power over the drug industry had been submitted to Congress, and each had failed. T. Swann Harding, "Why a New Food and Drug Law?" *American Medicine*, New Series, Vol. XLI, No. 8, (Aug. 1935).

of the Bureau of Chemistry, had fought for the bill; after its passage, he and his agency were charged with its enforcement. Dr. Wiley viewed the law as "corrective and educational rather than strictly punitive"[10] and relied, to a great extend, on "gentlemen's agreements among manufacturers to voluntarily discontinue their illegal activities."[11] Actually, Wiley had little choice. His staff was small and his powers were extremely limited.

Under the 1906 law, pharmaceutical companies were not required to prove either the efficacy or the safety of their drugs; but they did have to label their products accurately as to their identity and content. While drugs could not be seized simply because they were dangerous, the Bureau could impose fines on the producers of mislabeled products. In extreme circumstances, the Bureau could order a product destroyed. The 1906 law also established the United States Pharmacopoeia and the National Formulary as official standards against which drugs were measured.[12] To some extent, the ethical drug industry had supported the legislation, despite the fact that it forced the industry to assay its products because the law seemed to target proprietary medicines.[13]

In fact, the 1906 law actually provided very little control over patent medicines. The act permitted the government to fine a drug company up to $200

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[10] The Past and Future of Food and Drug Legislation," *American Medicine*, New Series, Vol. XXIX No. 6, (Sept. 1934).

[11] Ibid.

[12] Young, "Drugs and the 1906 Law" in *Safeguarding the Public*, 150-151.

[13] For example, Abbott had supported labeling and standardization, with criteria set by the American Medical Association and administered by the government. Herman Kogan, *The Long White Line*, 187.

for violating the law, but in fact the fines were almost always much lower, often $1 or $2. In those few cases where high fines were imposed, they were remitted by the courts.[14] The American Medical Association recognized the law's weakness. Its solution was increased reliance on physicians rather than patent medicines, but the Association wanted to find an alternative method to persuade the public without relying on government regulation. Doctors were uncomfortable with the idea of any kind of government regulation of any aspect of medicine.[15]

The chemical industry took the position that though it believed the law was motivated by the concern for the common good, nevertheless it set a pattern of lawmaking that "threatened an economic system of free enterprise."[16]

In 1913, the Supreme Court ruled that the false and misleading strictures of the 1906 bill applied only to the quality and the identity of drugs, not to their therapeutic claims. In response, Congress passed the Sherely Amendment, which provided that action could be taken against a drug for its therapeutic claims, if those claims could be proven to be "false and fraudulent." This meant that the

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[14] Frederick P. Lee, "The Enforcement Provisions of the Food, Drug, and Cosmetic Act," *Law and Contemporary Problems*, 6 (Winter 1939), 72.

[15] James G. Burrows, "Drug Prescription Policies of the AMA," in *Safeguarding the Public*, 115.

[16] Haynes, *The American Chemical Industry*, vol. III, 414.

government could take action against a drug; but first it had to prove that the mislabeling was intentional, which was difficult to do.[17]

Physician concern over government regulation of medicine intensified during the public debate over compulsory health insurance. In 1915, the Association for Labor Legislation had proposed a standard insurance bill for introduction into state legislatures. Its plan provided for free choice of physician, and initially the American Medical Association supported the idea. It even appointed a committee to help draft legislation. By 1920, however, the official American medical Association position had changed. AMA opposition was based firmly on the idea that the government should not regulate medicine in any way.[18] (The American Medical Association opposed the Sheppard-Towner Act on the same basis.)

By the same token, many physicians in the 1920s opposed the Volstead Act because, as the writer of one letter to the editor of the Journal of the American Medical Association explained, "it contained the most drastic legislation affecting the medical profession yet enacted. A physician becomes a criminal by the mere fact of writing a prescription..." The letter concluded, "[T]oday it is alcohol. Tomorrow it may be any remedy which falls under the ban."[19]

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[17] Charles O. Jackson, *Food and Drug Legislation in the New Deal* (Princeton, N.J., 1970), 4; see James Harvey Young, "Drugs and the 1906 Law," 153.

[18] For an overview of New Deal efforts for national health insurance, see Daniel S. Hirshfield, *The Lost Reform: The Campaign for Compulsory Health Insurance in the United States, 1932-1943* (Cambridge University Press: 1970).

[19] Letter to the Editor, *Journal of the American Medical Association*, 76, no. 23 (June 1922), 1593.

As a result of the American Medical Association's opposition to health insurance, many New Deal reformers were suspicious and hostile towards the organization even before attempts at drug legislation began.[20]

In 1926, the drug industry supported a bill that was intended to further restrict the effects of the 1906 Pure Food and Drug Act: it would limit the power of the Food and Drug Administration to carry out multiple seizures of adulterated drugs (separate seizures in all states to which the product had been shipped). Multiple seizures required the company to send representatives to may different jurisdictions and was therefore expensive and time consuming.[21] The Department of Agriculture opposed the bill. The bill was not passed, to the dismay of the pharmaceutical companies. The issue remained one of grave concern to drug companies, and they wanted the law changed despite the fact that multiple seizures were relatively rare.[22]

Wiley's policy of suasion was followed by his immediate successors, Drs. Carl Alsberg and C. A. Browne; but in 1927 Dr. Browne proposed a reorganization plan. The Bureau of Chemistry had initially been organized as a research institution, but because of the demands of law enforcement, much of that work had been neglected. Therefore, Browne suggested that the Bureau of Chemistry combine with the Bureau of Soils and concentrate entirely on research. Under this proposal, the enforcement of the 1906 law would be turned over to the

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[20] Hirshfield, *The Lost Reform*, 50.

[21] Haynes, *The American Chemical Industry*, vol. IV, 280.

[22] Ibid.

Food, Drug and Insecticide Administration.[23] William Campbell, a lawyer who had served as Chief Inspector under Wiley, was appointed Chief of the new administration. Campbell had a very different philosophy about the 1906 Pure Food and Drug Act. He viewed the law as punitive, and he meant to enforce it.[24]

The Committee on the Costs of Medical Care supported Campbell's position. The Committee considered patent medicine as exploitative and called for legislation, on both the state and federal level, to "prevent the sale of drugs and medicines with secret formulas."[25] Physicians and ethical drug companies who were also working to ban patent medicines agreed with this aspect of the Committee's finding. However, the Committee went on to suggest that "all manufacturers of drugs and medicines should be permitted to operate only under licenses granted annually by the Federal Government." The drug companies opposed that idea. Most of them were quite content with the system that was already in place, which gave the Chemical Foundation the authority to grant whatever licenses were necessary, to whichever companies they felt were able to manufacture products safely and economically. The Chemical Foundation did not require the inspections for "equipment, sanitary surroundings, a standardization of finished product" that the Committee was recommending.[26] Doctors also opposed the efforts of the Committee. An editorial in The Journal of the American

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[23] Renamed the Food and Drug Administration in 1931.

[24] Krantz, *Fighting Disease with Drugs*, 170-174.

[25] Committee for the Cost of Medical Care, *Final Report.*

[26] Committee on Costs of Medicine, *Medical Care for the American People*, Publication No. 28, Chicago, 1932.

Medical Association called it an attack led by "public health officialdom...on the organized medical profession of this country."[27]

After Roosevelt became President in 1933, his Assistant Secretary of Agriculture, Rex Tugwell, met with Campbell, who had many suggestions for improving drug regulation. Essentially, he believed that there were so many problems with the 1906 law that it was time for new legislation, as opposed to trying to amend the old law. His staff drafted their version of this new legislation, including provisions supporting Campbell's belief that not only should labeling be technically correct, but it should not be permitted to deceive consumers indirectly or by inference and ambiguity.[28] The Tugwell Bill gave broad powers to the Secretary of Agriculture to promulgate regulations.[29] This proved to be particularly controversial and was quickly moderated, first to give Congress the power to override the Secretary, and then to permit the court system to review any regulations developed by the Department.[30] The Secretary could also prescribe

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[27] Editorial, *Journal of the American Medical Association* (1932), 1950-1952.

[28] Jackson, *Food and Drug Legislation*, 23-27; David Carvers, "The Food, Drug, and Cosmetic Act of 1938," *Law and Contemporary Problems*, 3-6.

[29] The Food and Drug Administration was part of the Department of Agriculture. The Secretary of Agriculture technically would have the powers enumerated in the bill.

[30] This became two separate arguments. The first having to do with congressional versus Executive power. The second part of the discussion was a more direct discussion of authority. Some of the opposition to the idea of the court having the right to review regulations was about balancing the powers of various parts of government, but the argument also raised the question of the role of expertise. Those who argued against court review, including the staff of the FDA, maintained that without scientific knowledge the court could not make decisions. Those who supported the idea of court review did so because they felt

testing or assay methods. The American Medical Association opposed this provision, since it felt that the Committee on Chemistry of the American Medical Association was the appropriate body to make such decisions.

The bill also said that claims must reflect general medical opinion. (This had to be modified, since it was too hard to determine general opinion.) Tugwell also wanted the proportion of active ingredients to be listed which, of course, particularly distressed the patent medicine companies.[31]

The bill was sent to the chairmen of the Committee on Agriculture in both houses, who rejected it out of hand.[32] It was at this point that the supporters of the bill persuaded New York Senator Royal Copeland to sponsor the legislation. Copeland was a physician, so he was a logical choice. He was also known as a political conservative, and it was hoped that his support would mitigate some of the opposition of political grounds. When Copeland read the original bill, he felt aspects of it were too extreme. For example, he did not support the requirement that a label must specify if the contents were palliative, rather than curative. Before agreeing to submit the bill, he demanded that it be modified. His requests were honored, and the bill was submitted to the United States Senate as S. 1944.[33]

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the court's role was to make certain that freedom of enterprise was not threatened. This controversy is alluded to in many ways in the North Carolina journal and can also be seen in the transcripts of the numerous committee hearings held each time the bill was submitted.

[31] Louise Baldwin and Florence Kirlin, "Consumers Appraise the Food, Drug, and Cosmetic Act," *Law and Contemporary Problems*, 6 (Winter 1939), 149; Jackson, *Food and Drug Legislation*, 142.

[32] Carvers, "Food, Drug, and Cosmetic Act," 14.

[33] Ibid.

The patent medicine industry was horrified by the law. The advertising industry was distressed as well, since the new legislation would shift the responsibility for reviewing labels from the Federal Trade Commission, where it had rested, to the Food and Drug Administration. The drug companies suspected that the Food and Drug Administration would be less sympathetic to the commercial and practical aspects of their business. The industries mounted a campaign against what they continued to call the Tugwell Bill, complaining that it was a draconian interference with free enterprise. Opponents called it government by bureaucracy—which verged on communism. They also complained that the bill violated their freedom of speech, since the government would be give the right to decide what advertising was permitted. This would give the government, and the Food and Drug Administration in particular, far too much discretionary power.[34] The industry also suggested that the Tugwell Bill would be unenforceable and that its passage would create a situation similar to the one created by the Volstead Act.[35]

Addressing the annual meeting of the American Pharmaceutical Manufacturers Association, the president of that organization, John Searle, made it clear that the only amendment to the Pure Food and Drug Act of 1906 that his board had endorsed was that "advertising copy should be controlled and regulated in the same manner as label copy." Clearly speaking for attribution, he contended

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[34] Baldwin and Kirlin, "Consumers Appraise the Food, Drug, and Cosmetic Act," 149: "Who Shall Control Advertising? Fight for Control of Food and Drug Advertising," *Business Week* (3 April 1937), 42.

[35] *Milwaukee Sentinel*, FDA Scrapbook (16 October 1933), vol. I.

that rather than opposing changes in the law, "it was legitimate food and drug people themselves that primarily were interested in writing this act." The problem of the law as proposed, however, was that it "allows for the too much interpretation in the hands of one individual or small group of individuals." He also commented that he was glad to see that "President Roosevelt does not consider the revision of the Food and Drug Act as an Emergency Measure."[36]

Searle's remarks clearly show that, at least to some extent, the ethical pharmaceutical industry wanted to distance itself as much as possible from patent medicine companies for all of the reasons discussed in the proceeding chapter. There were, of course, many chemical companies that maintained both ethical and proprietary drug divisions, which made Searle and the American Pharmaceutical Manufacturer Association's position quite delicate. In some ways, it was easier for drug companies to find support in the broader business community. Industrial interests did oppose the bill, but they were more focused on fighting against the passage of the National Recovery Act and the Agricultural Adjustment Act.[37] It is possible that Searle felt that without Roosevelt's support, the bill would stall in committee and there would not be additional drug regulation, which, in fact, is what did happen for several years.

In December 1933, two days of hearings were held to discuss the bill. The drug companies were ready. Dr. James Beal of the National Drug Conference appeared before the Agriculture Committee and testified that the 1906 law was a

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[36] John G. Searle "Presidential Address," *Proceedings of the Annual Meeting of the American Manufacturers Association* (1933), 150.

[37] Carvers, "Food, Drug, and Cosmetic Act," 7.

fine piece of legislation. It was possible that a certain amount of tinkering might be required, but this could take the form of carefully considered amendments. Anything else would be unnecessary.[38] Other witnesses testified that giving so much rule-making power to the Secretary of Agriculture would allow him to become the "czar" of the industry. Furthermore, they suggested that the American people had a right to self-medication, one that Congress simply could not take away. Congressmen more friendly to drug companies made it clear that they would be introducing much milder legislation as an alternative.[39]

By law, the Food and Drug Administration could not lobby Congress but Ruth Lamb, and information officer with the agency and an ardent supporter of S. 1944, organized a traveling exhibit called "Chamber of Horrors," displaying the damage caused by unregulated and unsafe food, drugs, and cosmetics. She mounted a huge propaganda effort, which presumably she was able to do in her role as education officer, appealing primarily to women's groups to oppose the drug companies' lobbying efforts.[40]

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[38] Jackson, *Food and Drug Legislation*, 31.

[39] The Beal Bill, which was sponsored by Representative Loring Black of New York, was supported by the proprietary drug industry. It lowered the standards of efficacy to opinion, not fact. It also removed the possibility of criminal prosecution; the only power the government would have would be a cease-and-desist order. The other, the McCarran-Jenckes Bill, was a more serious threat. It had enforcement procedures, but they were so complicated they were almost impossible to carry out. Jackson, *Food and Drug Regulation in the New Deal*, 68-70.

[40] Carvers, "Food, Drug, and Cosmetic Act." There are numerous memos written by Lamb in FDA correspondence files that testify to the energy with which she organized women's groups and consumer groups. She also dedicated her book to "The Gallant Group of Women Who Have Been Holding the Front-Line Trenches in the Consumers' War for Pure Food, Drugs and Cosmetics."

Women's organizations were important supporters of S. 1944, though many felt that the bill had been very much weakened. Home Economics Clubs were particularly well organized. They felt the 1906 law was much too limited for a variety of reasons that they were glad to enumerate, ranging from a lack of control over advertising to the fact that there were no provisions for cosmetics. They believed firmly that the penalties mandated by the 1906 law were much too light.[41] They also, in the best New Deal tradition, saw the debate over the law as an unusual opportunity for "students of home economics today to take an active part in a dramatic battle for social justice."[42] They took their responsibilities seriously indeed. The defeat of S. 1944 did not stop them or appreciably weaken their determination. They were well aware that the industry was not slackening its efforts to defeat strong legislation. They were quite cynical about the "sudden devotion of manufacturers and advertisers to the old Pure Food and Drug Law whose passage they had fought so bitterly."[43] They felt that they were in a leadership position and one that they were obligated to use. "so many voices are now claiming to speak for consumers, or to condemn us as ignorant and indifferent, that a congressman might be impressed and heartened to meet a few intelligent consumers face to face."[44]

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[41] Harriet R. Howe, "Food and Drug Legislation and Home Economics Clubs," *Journal of Home Economics*, 26 (November 1934), 559.

[42] Editorial, "Go to It, Home Economist," *Journal of Home Economics*, 26 (October 1934), 520.

[43] Howe, "Food and Drug Legislation and Home Economics Clubs," 558.

[44] Ibid., 560.

Other consumer groups, led by Consumers' Research, did not support the bill. They accused Copeland of having deliberately weakened the bill and suggested that because he had given talks on a radio program that advertised Fleishman's yeast—which opposed the legislation—he had a conflict of interest.[45]

The rife between physicians and the drug companies put physicians in a curious position. They were so opposed to patent medicine, and so eager to control it, that they did not actively oppose the Copeland bill. On the other hand, they were so opposed to government regulation of medicine that any support they offered for the bill was at best half hearted. Nevertheless, they were attacked as sponsoring the bill by those who considered the medical profession to be a "racket." These critics maintained that only doctors opposed the ill because they were threatened by the packaged medical industry. The members of this opposition believed that the only thing that the "medical chamber of commerce" wanted to do was stamp out self-medication. Thee advocates believed that while it was necessary to control false advertising, it "should not be confined to products which will increase the 'take' of the American Medical Association."[46]

The Tugwell Bill failed to pass for many reasons, but one of them may have been a question of timing. In 1933, the country was concerned with economic recovery, and the bill did not further that goal.[47] In fact, Drug Trade

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[45] Carvers, "Food, Drug, and Cosmetic Act," 11.

[46] Morris A. Bealle, "Open Letter to Mrs. Franklin D. Roosevelt," *Plain Talk Magazine*, vol. 9, no. 12 (December 1933), FDA Scrapbook, vol. XIV.

[47] Jackson, *Food and Drug Legislation*, 33.

News, an industry publication, attacked the bill by claiming it worked against the National Recovery Act.[48]

The sponsors and drafters of the bill recognized that they had to make concessions. A still further-weakened bill was introduced into the Second Session of the 73rd Congress in January 1934 as S. 2000. Among other modifications, this bill released the publisher from responsibility for false advertising claims. As with S. 1944, many consumer groups immediately objected, stating that the law had been too diluted and that they should fight for a stronger one.

Many women's groups took the stand that any bill was better than nothing; but that was not the majority position among advocates of drug law reform. The Federal Trade Commission submitted an amendment requiring that false advertising claims should be brought to it instead of to the Food and Drug Administration. The Commission insisted that the advertising clauses of the bill interfered with its jurisdiction. This issue would remain a critical issue in the struggle to formulate and pass an acceptable bill.

The attack on the American Medical Association was more direct this time, and the organization was accused of having drafted the bill for its members' benefit. The American Medical Association denied the charge. Physicians did openly support S. 2800, however.

The rift within the pharmaceutical industry itself widened. The American Pharmaceutical Association officially supported the bill, thus clearly distancing itself from manufacturers of proprietary medicines.[49]

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[48] *Drug Trade News* (30 October 1933), FDA Scrapbook, vol. I.

Hearings were held before the Commerce Committee, and they reported the bill out favorably. It never came to a vote, however. In January 1935, Copeland introduced S. 5, which was an only slightly modified version of the previous drafts of the bill. Many of the combatants had accepted that some form of legislation would be passed. The question was now what the bill would specifically contain. The National Drug trade Conference supported the idea of a "revision" of the 1906 Food and Drug Act. It established a committee to study a "number of questions of special interest to its members."[50] The National Drug Trade Conference explained that this was a compromise bill rather than "the original draft prepared by Undersecretary Rexford G. Tugwell."[51]

Among the changes that pleased retail druggists was the elimination of the requirement that the formula of patent drugs be printed, in favor of a requirement that only the names of active ingredients would be listed on the label.[52] The question of multiple seizures remained a critical issue. The Proprietary Drug Association particularly opposed this provision. The fight was led by the Vicks Chemical Company of North Carolina and the Lambert Pharmaceutical Company of Missouri, the makers of Listerine. The senators from those states argued on behalf of their constituents' concerns.[53]

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[49] Jackson, *Food and Drug Legislation*, 152.

[50] "NRA Studies Price Provisions," *Druggist Circular*, (January 1935).

[51] Ibid.

[52] Henry D. Ralph, "Future of Drug Code in Hands of Congress," *Druggist Circular*, (March 1935).

[53] Carvers, "Food, Drug, and Cosmetic Act," 13.

Another controversial point remained the question of jurisdiction. The Federal Trade Commission had regulatory power under the old law, but the only enforcement power that the Commission had was the right to issue a cease-and-desist order and demand that an advertisement be removed. In practice, however, this had little effect, since advertisements were changed regularly anyway. The Food and Drug Administration argued that only it had the technical expertise to regulate drug advertising. Not only did the Federal Trade Commission lack expert knowledge; according to the Food and Drug Administration, when the Administration had brought violations to the attention of the Federal Trade Commission, the Commission had done nothing. The Federal Trade Commission, in return, declared that it would not allow its power to be eroded. It was joined in its effort to maintain its position by the Proprietary Drug Association, which wanted to simply continue the status quo.[54] As one member put it in a letter to the editor in Drug Trade News, "We are unalterable opposed to vesting the control of advertising in the Food and Drug Administration. We prefer to take our chances with the Federal Trade Commission."[55]

The other major political argument was the issue of whether or not there would be a judicial review permitted, or required, of the regulations promulgated by the Secretary of Agriculture. This was an intense battle, since the Food and Drug Administration had recently decided to decrease the permissible levels of lead arsenate in fruit, much to the dismay of the apple growers, who customarily

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[54] Jackson, *Food and Drug Legislation in the New Deal*, 87-92.

[55] Mr. Albion L. Page, *Drug Trade News*, (14 October 1935).

sprayed lead arsenate on their trees. The apple growers, who had "almost twice as many senatorial friends as there are apple growing states," objected strenuously to allowing the Food and Drug Administration unrestricted authority to set such levels.[56]

In March 1935, Roosevelt sent a message to Congress calling for a new law to regulate food, drugs and cosmetics. The bill reached the Senate floor in April. Senator Bailey and Clark, representing the drug interests in North Carolina and Missouri, submitted amendments that protected patent medicines from multiple seizures unless the Food and Drug Administration had probable cause to believe that the goods were imminently dangerous to health. The bill, thus amended, passed the Senate in May.[57]

Once the bill arrived at the House Committee on Interstate and Foreign Commerce, it was immediately bogged down on the question of which agency would have jurisdiction over advertising. The bill the House was considering resembled the one drafted by the drug industry, which definitely wanted to see the Federal Trade Commission in charge. Tugwell himself became an issue. Southern Congressmen—in particular, McReynolds of Tennessee, a center of proprietary medical manufacturing—were reluctant to give Tugwell that power. Instead, they preferred to "leave it with the Federal Trade Commission with...men from this House on the Commission." Presumably, that meant men who

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[56] Carvers, "Food, Drug, and Cosmetic Act," 17; Jackson, *Food and Drug Legislation*, 175-190

[57] Carvers, "Food, Drug, and Cosmetic Act," 17; Jackson, *Food and Drug Legislation*, 95.

understood the needs of McReynolds' constituency, among other things. That proved to be an apparently overwhelming appeal, and the bill was defeated 190 to 70.[58]

Only the battle had been lost. The war was by no means over. Physicians and the American Medical Association were not publicly committed to reform. Doctors were directly attacked by the proprietary drug companies, who accused them of promoting the legislation because they wanted to put an end to self-medication.[59] In this context, the public professions of caution around Sulfanilamide by the American Medical Association take on a new significance. Physicians were concerned that it be made very clear that sulfanilamide was not a panacea, and could not be administered without consulting a doctor on the assumption that it would cure all ills. At the same time, it was far too potent to be left in the unregulated hands of pharmacists, let alone the lay public. Despite whatever feelings physicians may have had about government interference in the practice of medicine, they had no choice but to support drug regulation, both from conviction and convenience.

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[58] Carvers, "Food, Drug, and Cosmetic Act," 15; Jackson, *Food and Drug Legislation*, 123.

[59] Physicians countered that the use of patent medicines often meant that patients did not seek regular medical care and, as a result, were deprived of treatment that could have helped them. As J. B. Matthews put it: "Patent medicines are not always themselves concocted of poisonous or harmful drugs. Quite as often they constitute a menace to health by reason of their fraudulent claims. Their victims are thus persuaded to rely on useless preparations when medical science might have been able to give relief." Matthews, *Guinea Pigs No More*, 148.

The pharmaceutical industry was divided over the issue of the bill into two factions, namely ethical and proprietary drugs. There was, of course, overlap between them, but ethical drugmakers were essentially forced to call for some kind of legislation. The American Pharmaceutical Association, for example, did support the legislation, or at least some form of legislation. This fragmented the forces trying to block the passage of the bill. The Proprietary Association, recognizing that some kind of legislation was inevitable, threw all its resources into backing the weakest bill possible. It particularly wanted to make sure that provisions for multiple seizures would not be included, and that control over advertising would be left in the hands of the Federal Trade Commission.

Agitation for more radical reform continued with the 1936 publication of Guinea Pigs No More by Joseph Matthews, who wrote, "It has not been a 'new deal' for consumers under FDR and this can be proven by the history of the Copeland-Tugwell Bill, which was not a major concern of the Administration."[60] One reason for Roosevelt's indifference may well have been his political antipathy to Copeland.[61]

The Food and Drug Administration announced the results of a survey of U.S.P. and N.F. listed products, which had been sampled for their adherence to the approved standards. One-eighth of all samples examined failed to conform to either set of specifications. In the eyes of many consumer groups and the Food and Drug Administration, the stalled legislation had by now been dangerously

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[60] Matthews, *Guinea Pigs No More*, 257.

[61] Jackson, *Food and Drug Legislation*, 139.

weakened. "It is unnecessary to analyze the defects in S. 5 in order to demonstrate that it is a betrayal of consumers; it is sufficient to show that it has the support of the Proprietary Association."[62]

The National Association of Broadcasting, on the other hand, supported the amended bill, though it had opposed Tugwell's version. In trade publications, it reminded members that the food and drug industry spent $30,000,000 a year in advertising. As long as the bill didn't affect that, the group was in favor of reform, especially since Tugwell had resigned from the Department of Agriculture. "His departure from the Washington scene will remove one of the key protagonists of drastic legislation."[63]

The bill spent the year 1936 bottled up in committee. Supporters of reform thought the bill was too weak and were divided among themselves as to how much they could support it, and opponents of the bill were certainly not going to rush it along. The American Medical Association complained that the bill favored proprietary manufacturers. It explained that, because the law would not require patent medicines to reveal their formulas, "an invalid who resorts to self-medication is being kept in the dark."[64]

In 1937, Copeland submitted the bill again as S. 5. The multiple seizure provision had been slightly strengthened to allow for more consumer protection,

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[62] Ibid.

[63] "Revival of Food and Drug Bill Is Expected in Next Congress," *Broadcast Advertising* (December 1936), 52.

[64] "Food and Drug Bills Faulty, says AMA," *National Consumer News* (February 1937), 2.

though the provisions were certainly weaker than the original bill. Copeland addressed the issue of advertising in an attempt to come up with an acceptable compromise. Recognizing that previous bills went too far for some members of Congress, the revision tightened the definition of false advertising so that it would not "lend itself to unnecessary and unjustified governmental interference."[65] However, he did leave control over advertising in the hands of the Food and Drug Administration.

The Senate passed the bill. The House took no action. The Federal Trade Commission took preemptive action to retain its position. An amendment to the bill was submitted to the House Interstate Commerce Committee that insured that the FTC would continue to control drug advertising. The Bailey amendment, (Representative Bailey came from Greensboro, N.C., the home of Vicks,) was supported by Representative Vandenberg of Detroit, home of Parke Davis; and Representative Clark of St. Louis, home of Lambert Pharmaceuticals, restricted the government's right of seizure of misbranded goods, removed all penalties for false advertising and left the supervision in the hands of the Federal Trade Commission.[66] It became clear that any law that was going to pass the House would be a very weak one.

In his 1937 muckraking book, Poisons, Potions, and Profits, Peter Morell laid the blame for stalled food and drug legislation on the media, which made

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[65] A Statement by Royal S. Copeland, *National Consumer News* (10 January 1937), 7, FDA Scrapbook, vol. XIV.

[66] Jay Franklin, "We, the People," *Philadelphia Record* (6 March 1937), FDA Scrapbook, vol. XV.

enormous amounts of money in advertising patent medicines. He deplored the fact that "radio is being used to peddle dangerous drugs or outright poisonous nostrums."[67] In the acknowledgments of the book, he complained that his research had been hampered because network radio officials were uncooperative, and it had been extremely difficult for him to get copies of advertising claims. In fact, they "most emphatically refused the author's request." He had assumed there would be a record of these advertisements at either the Federal Trade Commission, or the Federal Communication Commission, but that turned out not to be the case. Apparently, no records were kept.[68]

The situation was further complicated by the budgetary limitations of the Food and Drug Administration. Enforcement of even the weakest legislation would be impossible without more money and more staff. As an illustration of the budgetary constraints, the chief of the St. Louis Station sent a memo to the chief of the Central District, explaining that he had received a phone call from a Monsanto executive telling him about the sulfanilamide issue of the Journal of Pediatrics, "since possibly due to its nature and comparatively high price this publication does not regularly or promptly reach the Drug Division..."[69]

Sulfanilamide was causing considerable concern in Food and Drug Administration circles. It was evident that the drug was being widely used in a variety of forms. There was considerable interest on the part of the lay public,

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[67] Morell, *Poisons, Potions, and Profits.*

[68] Ibid.

[69] FDA Administration Central Correspondence File, box 93 (3 September 1937).

particularly in the drug's possible use as an over-the-counter cure for gonorrhea. The agency began to conduct its own studies on the drug on the basis that "there seems to be general agreement that sulfanilamide is a potent drug which is likely to be a danger unless administered...under close medical supervision."[70]

The American Medical Association agreed. An editorial in the Journal of the American Medical Association acknowledged that "seldom has any new drug introduced in medical practice aroused the enthusiasm that has developed for sulfanilamide." The Journal editorial warned, however, that the "indiscriminate use" of the drug was dangerous. "Premature publicity for this drug, has, as usual, been unfortunate."[71]

Almost simultaneously with the publication of the Journal editorial, the American Medical Association received telegrams from both the Tulsa County Medical Association and the Springer Clinic in Tulsa, reporting six deaths among patients who had been treated with a Massengill Company product called Elixir Sulfanilamide. The doctors who had sent the telegrams wanted to know if the AMA knew the composition of the Elixir. The AMA responded that it did not, since the drug had not been evaluated or accepted by the Council on Pharmacy.[72]

While there is no way of knowing if the Massengill company intended to submit the Elixir to the Council, the company certainly had not had time to do so

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[70] Memo to Food and Drug Administration, FDA Administrative Files, Central Correspondence, Box 93.

[71] *Journal of the American Medical Association*, 109, no. 14 (October 1937), 1128.

[72] Young, "Sulfanilamide and Diethylene Glycol," 109; see also Jackson, *Food and Drug Legislation*, 151-170.

by early October 1939. The drug had been developed very quickly. In June, Massengill salesmen reported that they believed that there was a demand for a liquid sulfanilamide. The drug was frequently used for children, and a pleasant-tasting solution would no doubt be profitable. The company's chief chemist, Harold Cole Watkins, undertook to solve the problem himself. Sulfanilamide is insoluble in many liquids, but after many attempts, Watkins succeeded. The solvent he used was diethylene glycol. The drug was tested for taste and appearance and the formula was then sent to the company's Kansas City manufacturing plant on August 28, 1939, only a few months after Watkins began working on the problem.

The drug was first distributed on September 4, 1937. It was not tested for toxicity. This was perfectly legal. The Food and Drug Act of 1906 did not require that new drugs be tested for safety before being placed on the market.[73] It was unfortunate in this case, however, since diethylene glycol is toxic. Apparently, nobody at Massengill had read a January article in The Journal of Pharmacology and Experimental Therapeutics that described the toxic effects of diethylene glycol when tested on animals.[74]

On October 14, a New York physician who worked for a pharmaceutical company called the Food and Drug Administration to report the rumors that he had heard concerning deaths in Tulsa. The Kansas City station of the Food and

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[73] Report from the Secretary of Agriculture, 1937, 1-2.

[74] H. B. Haag and A. M. Ambrose, "Studies on the Physiological Effect of Diethylene Glycol," *Journal of Pharmacology and Experimental Therapeutics*, vol. 59, no. 1 (January 1937). The article cites other studies as well.

Drug Administration was immediately told to investigate. An inspector arrived in Tulsa on October 15. On October 16, he reported to the Food and Drug Administration that there had been nine deaths—eight were "children with streptococcal sore throat," and one was an adult with gonorrhea. All of them had taken Elixir of sulfanilamide, which had come from the Massengill plant in Kansas City. Inspectors were immediately sent there, as well as to the Massengill headquarters in Bristol, Tennessee.[75]

By the time the inspector arrived, Massengill, having received word of the poisonings, had already sent out 1,100 telegrams to its distributors requesting the return of shipments of the Elixir at the company's expense. The telegrams explained that the product had been withdrawn. None of these telegrams indicated that this was an emergency situation, and therefore little effort was made by distributors to reach salesmen or doctors. The Food and Drug inspector insisted that a new set of telegrams be sent that included the phrase, "Product may be dangerous to life."[76]

On October 18, 1939, a Food and Drug inspector and Dr. Theodore Klumpp, Acting chief of the Drug division, met with Dr. Samuel Massengill, sole owner and proprietor of the Massengill Company. Klumpp reported that Massengill "looked worried and agreed to cooperate," assuring the FDA officials that they had done "all that was humanly possible to recall outstanding stocks of the drug." Massengill explained that sulfanilamide had been so "exploited" by

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[75] Report from the Secretary of Agriculture, 4.

[76] Ibid., 5.

physicians and the press that everyone in the country was "going wild for it" and now "the disastrous effects were coming out." He insisted that the cause of death was not the Elixir itself, but rather that everyone who had died was taking other drugs while taking the Elixir. The drug interactions had been fatal. Klumpp wrote in his report that while he disagreed, he felt it was not appropriate to argue. Klumpp asked Massengill if any toxicity tests had been performed on the Elixir. He was told that they had performed those "which are ordinarily made for all their drug products." Under further questioning, Massengill admitted that it ordinarily did no tests at all, since "they make well-known drugs."[77]

Two hundred forty gallons of the Elixir had been manufactured. The American Medical Association held a press conference warning the public and its members about the danger. Virtually the entire force of 239 Food and Drug inspectors and chemists was assigned to track down every ounce of it. They checked shipping records and sales records. They tried to determine which salesmen had distributed samples of the drug. Their task was particularly difficult, because some of the drug had been sold over the counter, and the druggists had no record of to whom they had sold the product. In other cases, doctors had prescribed the drug, but had not written the names of the patients on the prescriptions and could not remember who they were.

> At East St. Louis, Illinois, 49 prescriptions, all for colored people, were filled from two shipments. The only identification on some of the prescriptions were such notations as "Betty Jane, nine months old," "Mrs. Jackson" with no address...One prescription

[77] Report of Massengill factory inspection by Dr. Theodore Klumpp, acting chief of the drug division, and Inspector William Ford (18 October 1937), FDA Central Correspondence Files, Box 93.

> was for "Willie Smith" who was known to be on the relief rolls. There were six colored "Willie Smiths" on the relief rolls but the remainder of this prescription was obtained.[78]

One doctor in New Orleans wrote to the Food and Drug Administration of his distress at the realization that six people died from medicine that he had prescribed for them. Fortunately, the other six patients to whom he had given the drug had survived. "I have spent hours driving to see every one of them, white and Negro. I have lost track of how many miles I have driven..."[79]

Other doctors were less cooperative. One in south Carolina insisted that he "had dispensed the drug to three white patients and two Negro patients whose names he wouldn't reveal." Other sources in the community said that he had given it to seven patients and that three—one white girl, and two Negro men—had died. The inspector managed to track down the sister of one of the deceased men, and asked to see the medicine. When he was informed that it had been left on the grave, as was the local custom, the intrepid inspector went to the grave and retrieved the bottle, which still bore the label and the doctor's name.[80]

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[78] Report from the Secretary of Agriculture, 6.

[79] Ibid., 7.

[80] Ibid., 8. These references make it clear that at least some southern doctors treated both white and black patients with identical medication. The Secretary of Agriculture's report included a geographic breakdown of the Elixir deaths. St. Louis was the most northern point. Essentially all of the deaths took place in the South.

Of the 240 gallons manufactured, 228 gallons and two pints were seized. Half of the eleven gallons and six pints that had been sold were recovered. Half had been consumed.[81]

What was most significant to those fighting for new food and drug legislation was the fact that the Elixir had not been seized because it was poisonous. The Food and Drug Administration did not have that power. It was able to recall the drug only because it had been mislabeled. It was not technically an "elixir" because, by definition, the solvent in an elixir was supposed to be alcohol. Massengill had used diethylene glycol, and the company had not so labeled its product. Under the law as it stood, had the drug been called a mixture, it would not have been subject to any action by the Food and Drug Administration. One hundred three people died from Elixir Sulfanilamide before the drug could be recovered.

Samuel Massengill spoke to the press approximately a week after the first death had been reported. While to some extent he took responsibility for the drug, he explained, "I deeply regret the factual results, but there was error in the manufacture of the product." He went on to maintain, "I do not feel there was any responsibility on our part." He defended his company, pointing out that "sulfanilamide had been approved for use and had been used in large quantities in other forms."[82] Quite firmly, Massengill told the American Medical Association,

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[81] Ibid., 1.

[82] "Deaths Due to Elixir of Sulfanilamide-Massengill," *Journal of the American Medical Association*, 109, no. 24 (December 1937), 1987.

"I have violated no law."[83] Actually, he had—that of misbranding—but the American Medical Association responded to the heart of the matter. "There was prior evidence of toxicity of diethylene glycol...[and] simple tests would have shown the 'lethal properties' of the Elixir."[84]

It turned out that the Massengill Company had run afoul of the Food and Drug Administration before. In 1932, and again in 1934, it had been cited for adulteration and misbranding of Elixir Terpinhydrate and Codeine. The product fell significantly below the standard in the United States Pharmacopoeia and eventually was destroyed. In 1934, the company had been fined $150 for another product that didn't match the standard, and in 1936 it had been accused of the misbranding and adulteration of Tablets of Tincture of Aconite, for which it had been fined $250.[85]

Ruth Lamb could not resist commenting on the situation when sending out press releases warning about the Elixir. She wrote to Bruce Bliven of the New Republic, "No doubt you remember that it was the Tennessee medicine makers who did so much to hold up passage of the Food and Drug Act."[86] The agency did all it could to publicize the Elixir disaster, both in order to warn consumers

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[83] Report from the Secretary of Agriculture, 9.

[84] "Deaths Due to Elixir of Sulfanilamide-Massengill," 1987.

[85] Ibid., Appendix Massengill was hardly unique. Another source accused the firm of McKesson and Roberts, Inc., of having been involved in 28 cases of selling misbranded, adulterated, and substandard drugs between 1928-1938. *The Pressure Boys*, 72.

[86] Ruth Lamb to Bruce Bliven (19 October 1937). FDA General Administration, Central Correspondence, Box 93.

and to highlight the need for improved legislation. "Permit me to take the liberty of expressing...delight on seeing at one of the large movie houses here the 'Elixir Sulfonamide' news reel...It was the feature of the 'News of the Day.'"[87]

Food and Drug officials were quoted as saying they:

> Deplore the possibility, under existing legislation for pharmaceutical companies and retail druggists to sell over-the-counter to laymen powerful drugs that are apt to be very dangerous unless used under a physician's direction.[88]

In turn, the American Medical Association congratulated the Food and Drug Administration for its "conspicuous service in the present circumstances, even though our present laws are so woefully inefficient as to hamper its authority."[89] Citing literature on the toxicity of diethylene glycol, the Journal remarked that there could also have been errors in the manufacturing process. "Indeed the possibilities are unlimited," given that the product was "semi-secret in composition and apparently hastily rushed in the market to meet an over-enthusiastic reception of a new remedy."[90]

The American Medical Association Chemical Laboratory carried out its own animal studies to clarify what had actually happened. One group of animals was dosed with the Elixir, one group received pure sulfanilamide, and one group

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[87] Letter to William Campbell from Morris Wolfson, Eastern District (29 October 1937), FDA Central Correspondence, Box 93.

[88] "Report of Elixir Deaths," *Science*, 86 (29 October 1937), 10.

[89] *Journal of the American Medical Association*, 109, no. 18 (October 1937), 1456.

[90] Editorial, *Journal of the American Medical Association*, 109, no. 17 (October 1937), 1367.

was treated with diethylene glycol. The remaining animals were given a water placebo. The Elixir group died and the diethylene glycol group died; but the sulfanilamide group and placebo group did just fine.[91] The Food and Drug Administration carried out similar studies, adding another group of animals, which received a batch of medicine prepared by the laboratory according to the Massengill formula. That group died, as did those receiving the Elixir and diethylene glycol.[92]

The Food and Drug Administration followed up on all tales of sulfanilamide poisonings, but found little else in the immediate weeks following the elixir disaster.[93] It used the situation for its political advantage as much as it possibly could. Typical is a letter written by William Campbell to a Texas lawyer who had requested information about the manufacturing of the Elixir. Campbell explained that the current Food and Drug act "makes no provision for the

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[91] Paul Nicholas Leech, "Special Article from AMA Chemical Laboratory," *Journal of the American Medical Association*, 109, no. 19 (November 1937).

[92] Report of the Secretary of Agriculture, 4.

[93] There are numerous letters in the FDA files reporting on investigations of reputed sulfa-drug poisonings. For example, one letter reports an aborted investigation of the death of one Alvin Blackstone, 'a tramp' who couldn't be tacked down, and one Joseph Merwald, who turned out not to be dead at all. Both had taken a sulfa drug manufactured by Winthrop Chemical Co. (letter to chief, Los Angeles Station, 28 October 1937). Another reported an investigation in Oregon following a report by the State Medical Association that a doctor claimed one of his patients had died but he couldn't remember the patient's name. An intern remembered the patient but maintained that the patient died from mengicocci meningitis. The inspector believed that the original doctor was probably right, as he was more experienced. The inspector vowed to check for more cases (report to chief, Seattle Station from Inspector George Smith, Jr., 23 October 1937). FDA General Correspondence files.

exercises of preventive measure by the Government against the production and marketing interstate of harmful drug products." Piously, Campbell continued, "contrary to the belief prevailing extensively in certain quarters," the Food and Drug Administration has no powers to "anticipate and prevent tragic results from the consumption of unfit products." The Texas lawyer had clearly not written out of academic interest, since the letter concludes, "[A]ny attempt to give advice regarding civil suits for the recovery of damages would exceed the limits of our authority."[94]

Groups ranging from the American Association of Public health to the League of Women Voters demanded action. The League of Women voters also called for the restoration of those parts of the proposed new drug laws that would require approval from the Food and Drug Administration before a product could be sold.[95] Campbell did all that he could to emphasize this issue. He explained over and over again that unless the Food and Drug Administration was given regulatory powers to restrict the sale of products until they had been proven safe, not only was there no way to guarantee that there would not be another tragedy like that of the Elixir, it was almost inevitable. Campbell wrote to Senator Copeland that the bill, in both the Senate form and in that "made public by the

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[94] Letter from William Campbell to J. K. Baker, Baker & Baker, Coleman, Texas (3 November 1937), Central Correspondence, Box 93.

[95] FDA Scrapbook, vol. XVII.

house subcommittee just before Congress adjourned," simply was not strong enough.[96]

Local governments decided not to wait for federal action. The state of California had already limited the sale of sulfanilamide.[97] To protect its citizens, the New York City Board of Health prohibited the sale of sulfanilamide without a physician's prescription.[98] This was an extremely important piece of legislation for physicians. By law, at least in New York City, these new powerful drugs would now only legally be available to the sick through a doctor's intervention. The American Medical Association position, while applauding these efforts, made the point that not only did the sick die from using drugs that were too potent to be used except under a doctor's care--they died because they relied on false claims instead of seeking rational treatment.[99] Those who accused the medical profession of supporting legislative reform because they wished to outlaw self-medication had some basis for their suppositions.

On November 15, 1937, one month after the first reported deaths from the Elixir, President Roosevelt called for a special session of Congress to consider proposed Food and Drug legislation. At the request of Congress, the Secretary of

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[96] Letter to Senator Royal Copeland from W. G. Campbell (29 October 1937), FDA Central Correspondence, Box 93.

[97] *Journal of the American Medical Association*, 109, no. 21 (November 1937), 1729. By the spring of 1938 three states had passed their own drug laws, and 12 more states had bills under consideration. Jackson, *Food and Drug Legislation*, 176.

[98] *Journal of the American Medical Association*, 109, no. 23 (December 1937), 1915.

[99] "Deaths Due to Elixir of Sulfanilamide-Massengill," 1987.

Agriculture prepared a report on Elixir Sulfanilamide-Massengill, which was presented on November 26. The document included a heart-wrenching letter to Roosevelt from Mrs. Maise Nidiffer, whose six-year-old child had died from the Elixir. While blaming the doctor, she also wrote, "[I]t is my plea that you will take steps to prevent such sales of drugs that will take little lives and leave such suffering behind." She ended, "Enclosed is a picture of the baby I grieve for day and night."[100]

The Secretary's report concluded with recommendations for further legislation. The Department of Agriculture requested a law that would keep all new drugs off the market until clinical tests proved that they were safe. "It is the Department's view that no other form of control will effectively safeguard the public." The Department also wanted a law that would require that drug labels bear appropriate directions and warnings against misuse and prohibit the use of secret remedies and ingredients. (In the case of the Massengill drug, the label did not mention the name of the solvent.)[101]

In the aftermath of the Elixir poisonings, amendments in both Houses of Congress were submitted to pending food and drug legislation, which provided that manufacturers had to submit records of their testing, a list of the drug's components, an explanation of manufacturing processes, and any labels and samples that the Secretary of Agriculture might request.[102] Provisions similar to

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[100] Report of the Secretary of Agriculture, 8.

[101] Report of the Secretary of Agriculture, 10.

[102] Jackson, *Food and Drug Legislation*, 168.

this had been included in the first Tugwell Bill in 1933, but had been immediately dropped.

The other controversies around the bill had not disappeared, however. The issue of whether the Food and Drug Administration or the Federal Trade Commission would have control over advertising remained. At the hart of the argument was the assertion that the cease and desist powers of the Federal Trade Commission simply were not an effective deterrent. The House decided to ignore this concern, or, more accurately, to honor the objections to allowing the Food and Drug Administration control over advertising; and at the same time, the House passed legislation to give regulatory power to the Federal Trade Commission. During the conference over the bill, it was obvious that the House would never budge, and Copeland bitterly commented that "[T]he consumers of this country are being raped."[103] The Food and Drug Administration was outraged. The American Medical Association complained that the Federal Trade Commission was so "slow and ponderous that all the damage would be done to the consumer long before any action was effected." Interestingly, at this juncture, the American Medical Association enjoined the lay public to become involved. Not traditionally advocates of lay-public activism, they warned the American people not to be lulled into a false sense of security."[104]

A pharmaceutical industry spokesperson tried to calm consumer concerns, or at least direct the concerns away from drug companies. He explained to the

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[103] Jackson, *Food and Drug Legislation*, 173.

[104] "Food and Drug Act," The National Federation of Business and Professional Women's Clubs (March 1938), FDA Scrapbook, vol. XVII.

National Federation of Women's Clubs that there were so many versions of the bill around that it was very confusing; but these problems were hardly the fault of the industry. The drug companies had cooperated for the last four years in efforts to produce a satisfactory law, and in the interval had policed themselves. "All sensible people, however, will agree that it would be unwise to hamstring an entire industry" in an impossible attempt to draft a perfect law. After all, there would always be risk, because no drug could be perfect. A law that suggested otherwise was itself a mistake.[105]

Finally, a separate piece of legislation, the Wheeler-Lea Law, was passed, giving jurisdiction over advertising to the Federal Trade Commission. By doing so, the question of advertising was no longer part of the Food and Drug law debate.

Public pressure for drug law reform continued unabated. One article, "Death Takes No Holiday," quoted Mrs. Nidiffer's letter and concluded that the government was responsible for the child's death, at least in part. "[F]or years the puissant Congressional drug block had battled successfully against the passage of an...effective control of commercial drugs." The article also pointed out that since the Elixir had been available both with and without prescription, "it was freely sold in large cities to youth attempting self-treatment for venereal disease" and warned that "drugs you buy may contain...poisons."[106]

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[105] Ibid.

[106] James Christopher Farley, "Death Takes No Holiday," *Independent Woman* (January 1938, FDA Committee on Legislation, Acc. No. 521-86, Box 4.

Another writer pointed out, "[T]he loot goes on, depression proof, juicier every year." For drug companies, money spent in lobbying to keep the bill from passing was "well invested." There were consequences; "now and then a few dozen trusting citizens are sped to limbo by some especially timely remedy," but given the profits involved and the fact that "the goose that lays the gold eggs is a prolific fowl," as far as the pharmaceutical industry was concerned, the legislation could languish indefinitely.[107]

The controversy continued when the House passed on amendment that permitted any manufacturer to enjoin the Secretary of Agriculture not to carry out regulations until the Courts had reviewed them. Furthermore, the amendment provided that the manufacturer, importer, distributor or dealer could enter the suit in any of the 83 federal district courts. The court could then review the regulations.[108] This process would clearly slow down the implementation of any regulations, and would also put district judges in the position of deciding about food, drug or cosmetic regulations, an area in which he or she might have limited expertise. A manufacturer only had to find one judge anywhere in the country who would issue an injunction. The Secretary of Agriculture said that the amendment would so cripple the bill that the 1906 law would be better.[109]

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[107] *The Drug Prescription Racket*, 302.

[108] "Federal Food and Drug Bill Condemned," *Journal of the American Medical Association*, 110 (April 1938), 1492; "Capitol Stuff," *New York Daily News* (25 April 1938).

[109] "Food and Drug Bill condemned," 1492.

Consumer groups reacted with outrage, and put such pressure on Roosevelt that he stated that he would veto such a bill.[110] Eventually, a compromise was reached, which limited the circumstances under which the Secretary could e enjoined and directed that cases could only be taken to one of ten circuit courts.[111] Other compromises were worked out as well. Almost as important for sulfa drugs and other pharmaceuticals as the requirement to prove safety before a drug could be manufactured, were the powers given to the Food and Drug Administration to regulate labeling. As will be discussed later, the decision to remove all product information from any medicine that required a doctor's prescription had enormous impact on the practice of medicine. By removing that information, self-medication became all but impossible.

Public pressure for some kind of law mounted, and eventually a compromise bill was accepted. On June 25, 1938, the bill was signed into law. Copeland did not live to see it. He had collapsed on the floor of the Senate a few days before the end of the session and died.

An article in Business Week, describing the participants in the fight over the Pure Food, Drug and Cosmetic Act of 1938, suggested:

> In this distribution of honors industry lawyers who able influenced the course of the legislation...expect no accolade. They content themselves with the knowledge that in five years of unrelenting warfare with rampant idealism they have succeeded in effecting a

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[110] Jackson, *Food and Drug Legislation*, 189; Carvers, "Food, Drug, and Cosmetic Act," 16.

[111] "Food and Drug Bill Passed at Last," *BusinessWeek* (18 June 1938), 36-37

> compromise which will not seriously interfere with the marketing of the great bulk of goods...[112]

The law was scheduled to go into effect on June 25, 1939, to give the Food and Drug Administration time to work out enforcement mechanisms. The power and responsibilities of the agency had been greatly expanded. Its budget was not.[113]

In the aftermath of the passage of the law, attempts were made to evaluate it. Many supporter were disappointed, in varying degrees, with the final legislation. The American Medical Association complained that though the law might effectively regulate food, it was not strong enough on drugs. The Association was concerned that determination of drug safety would be based on information supplied by the applicant.[114] The New Jersey Medical Society felt that the law permitted—but did not demand—enforcement by the Secretary of Agriculture, and that its definitions were too vague. "The public, and women's organizations especially, seems to have been deliberately propagandized into acceptance of the Copeland Bill."[115] A spokesperson claimed that the old law hadn't even been enforced. "Out of 453 cases charging adulteration of cattle feed there were 365 criminal prosecutions..." On the other hand, "out of 537 preferred

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[112] Ibid.

[113] Carvers, "Drug Regulation Under the 1938 Act," *Safeguarding the Public*, 164.

[114] Editorial "Federal Food and Drug Bill Advanced," *Journal of the American Medical Association*, 110 (April 1938), 1370-1372.

[115] *News*, Newark, New Jersey (21 April 1938), FDA Scrapbook, vol. XVII.

charges of adulteration of digitalis...there were only nine criminal prosecutions." The only conclusion, therefore, was that "the Secretary of Agriculture is 100 percent particular whether calves get pure food but almost completely indifferent whether perilously sick humans get pure drugs."[116]

Though disappointed in the outcome, women's groups had clearly gained some degree of political satisfaction. The American Home Economics Association warned that the Secretary of Agriculture was now required to hold hearings before any regulations could be promulgated and that "those in the industries who have opposed any extension of the Food and Drug Act will now oppose its enforcement."" It was very important that consumer groups organize and make certain that they, too, were present at any hearings.[117] Others were less tempered. "The quacks...are fighting its enforcement tooth and nail...[I]n years to come the snake-oil men may find holes in the Copeland Act...as they did in the Wiley law."[118]

The enforcement question was a serious one. The Food and Drug Administration was understaffed and under-budgeted, and the lengthy ballet over legislation, as well as deliberately vague language in the bill, had led to general confusion. As an illustration, a Justice Department official, J. Edgar Hoover, had received several requests for information on a method for the identification of

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[116] Ibid.

[117] "New FDA Law and Home Economists," *Journal of Home Economics*, 546.

[118] Kenneth G. Crawford, *The Pressure Boys: The Inside Story of Lobbying in America* (New York: Julian Messner, Inc. 1939), 89.

diethylene glycol and sulfanilamide. Hoover forwarded the letters to William Campbell.[119]

Pharmaceutical companies wrote to the Food and Drug Administration requesting guidelines, perhaps disingenuously. Some of the letters are surprising. The Westerfield Pharmaceutical Company wrote asking for information about the rules for selling sulfanilamides. Campbell replied that "this administration is of the opinion" that the distribution of sulfanilamide or sulfanilamide preparations "in a manner which results in indiscriminate use by the general public will subject such preparations to legal action."[120]

Another letter, this one from a professor of pharmacy, requested "your interpretation of the possible over-the-counter sale of sulfanilamide...I realize the danger involved in promiscuous use of this drug; however, I understand it is still sold directly to the layman." The writer was aware of an August 1938 notice sent to distributors, but he was still confused.

The Food and Drug Administration replied that the responsibility lay with the retailer as long as the manufacturer put appropriate warnings on the label. Of course, what constituted appropriate warnings was contested ground itself. Campbell also said that "even refilling a prescription for such drugs should be authorized by the physician." The reason for this was the knowledge that frequently the patient might try to renew a prescription "when he is no longer

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[119] FDA General Subject Files, 510-20. The letters in response all explain that the letters have been forwarded to the FDA because this does not fall under the jurisdiction of the Department of Justice.

[120] Campbell to Westerfield Pharmaceutical Company (7 October 1938), FDA General Subject Files, 510-20.

under the physician's observation." This correspondence reflects the myriad of details that the Administration would have to consider.[121]

A physician wrote to complain that "several pharmacists in this city are giving [sulfanilamide] to those afflicted with gonorrhea." The problem, in the physicians' eyes, was that "the patient thinks he is cured, probably gets married, and proceeds to infect his wife." Campbell replied that the Food and Drug Act "does not confer authority upon this Administration to regulate the local practice of pharmacy." Even if the law did provide that authority, with a staff of only 115 inspectors, it would be simply impossible to carry out such responsibilities.[122]

The food and Drug Administration also received many letters from individual citizens with personal queries. "I wonder if you could give us some information about a formula called sulf-anil-amide (sic). Is it safe to take internal for rheumatism?" All these letters received a standard reply: "This drug possesses inherently harmful properties and, in our opinion, should be taken only under the guidance and supervision of a physician."[123] Other letters received more personalized responses. One woman wrote asking for information about sulfanilamide because "I have had chronic gonorrhea for five years or more. I

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[121] Correspondence between A. B. Nichols, Assistant Professor of Operative Pharmacy, Philadelphia College of Pharmacy, and William Campbell (29 March 1939), FDA General Subject Files, 510-20.

[122] O. R. Gregg, M.D., to William Campbell (20 February 1939), FDA General Subject Files, 510-20.

[123] Mrs. William Dershaw to William Campbell, FDA General Subject Files, 510-208. There are numerous such letters in the files, and Campbell's response is pretty much the same to all of them.

have been to at least six doctors. They always dismiss me as cured. Yet I never have been. I just haven't a bit of faith in doctors left..."

The writer explained that she felt that if she "did go to some doctor here for advice I am afraid he would not know enough about how to use it." While she may have had a point, her attack on doctors continued: "[E]ither doctors just want your money or they don't know their business." This received a fairly stern reply. "Enclosed is a press notice bearing on the dangerous character of sulfanilamide..." The Food and Drug Administration's letter concluded, "[W]e know of no better advice than to consult a physician and follow his instructions."[124]

The Food and Drug Administration was concerned with other aspects of the sulfanilamide problem. For example, there was no approved way to assay tablets of sulfanilamide. According to the law, the producer would do the tests, but standards and methods had to be chosen. The method of assay and tolerance level were finally agreed upon by the Combined Contact Committee in March 1938. This committee was made up of representatives of the American Drug Manufacturers Association and the American Pharmaceutical Manufacturers Association. Their decision was included in "pharmaceutical standards" and accepted by the Food and Drug Administration.[125]

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[124] Correspondence between Alvinia Bloomer and the Food and Drug Administration (16 September 1938), FDA General Administrative Files, 510-20.

[125] "Minutes of the Combined Contact Committee Meeting, (March 1938), 28-29; FDA General Subject Files, Box 14.

As early as November 1937, all Chiefs of Districts had been notified that though the seizures of the Elixir had been made without collecting samples, they should proceed to get as many samples as possible "to document the criminal prosecution which is in the course of preparation."[126]

In February 1938, Campbell sent a letter to the solicitor for the S. E. Massengill Company, in which he said that since the firm's business was primarily interstate, it would have to comply with Food and Drug legislation. The company's product, Elixir Sulfanilamide, had caused the "deaths of numerous patients because of the presence of a poisonous ingredient." The specific charges were that the drug was adulterated, since it was not an elixir of sulfanilamide but rather a solution in a mixture of diethylene glycol and water. Because it was not actually an elixir, the product was also misbranded, and the "statement 'quality pharmaceuticals' is false and misleading." Lest the company minimize the charges, Campbell concluded, "[I]t is highly important that the further preparation of the case be expedited, first, because of the extensive public interest in this manner, and, second, because of the gravity of the offense."[127]

In July 1938, a pharmaceutical chemist who was a friend of Massengill's informed a Food and Drug Administration official that the company has "collected 660 or 680 affidavits from people who used the Elixir and are satisfied." The company maintained that when the medicine was used under

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[126] To Chiefs of Districts from P. B. Dunbar (1 November 1937), FDA General Correspondence Files, Box 93.

[127] William Campbell to solicitor, S. E. Massengill Co., Bristol, Tenn. (17 February 1938), General Subject Files, 510-20.

"competent medical supervision," it was not a problem. The company apparently had collected statistics to show that sulfanilamide itself has "adverse results, including deaths" in 15% of patients. Massengill, at least according to the writer, had made $11 million off the drug, which had cost them only $500,000. The individual who furnished the information explained that "while he was a friend of Massengill, he had no respect for Watkins, his chemist, and considered him an unreliable individual."[128]

Massengill did not personally appear at his Food and Drug Administration hearing. His lawyers sent written replies to the citations in which Massengill defended himself, saying that the cause of the deaths was drug interaction and that he had withdrawn the drug promptly. His lawyers maintained that the press had unfairly sensationalized the issue. He did also submit affidavits from patients who said that the Elixir had helped them.[129]

By the time the case came to trial, in October 1938, Massengill had decided to change his pleas to guilty. He was fined $26,000, which the largest fine levied under the 1906 Food and Drug Act. He settled several individual cases out of court for undisclosed sums. Watkins, his chief chemist, committed suicide. As Harry Marks has pointed out, the Food and Drug Administration had the power to regulate what manufacturers said about drugs, but it left the scientific development to others.[130] The problem was that the power and responsibility

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[128] Letter to Drug Division from P. B. Dunbar (23 July 1938), FDA General Subject File, 510-20.

[129] Young, "Sulfanilamide and Diethylene Glycol," 116.

[130] Marks, *The Progress of Experimental Science and Therapeutic Reform.*

given to the Administration was not as simple as issuing a permit. It was still an open question as to how, or even whether, new drug procedures could be formalized. The new act did not state requirements about what kind of analysis would be required before a drug could be marketed.

The Food and Drug Administration relied on various sources for standards. Some of the standards were questionable, and some of the results submitted showed little rigor. Once the Secretary of Agriculture announced methods that the Department considered satisfactory, manufacturers could challenge them in court. How the courts would exercise the authority that they had been granted to issue injunctions against regulation also remained unresolved.[131] There was yet another problem. Namely, there was a real question s to whether or not doctors could actually use new drugs properly. This was not within the purview of the Food and Drug Administration or the Food, Drug, and Cosmetic Law of 1938; but the problem was a real one. As one doctor wrote, sulfanilamide was used "as much as a thermometer." The problem, he suggested, was "nowadays they're giving sulfanilamide to everybody who comes into the hospitals. Only if they aren't cured in four days do they even get a physical examination."[132]

The Pure Food, Drug, and Cosmetic Act of 1938 is a critical piece of legislation, which is not to say that it had significant practical value. The

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[131] For a more detailed discussion, see Marks, *The Progress of Experimental Science and Therapeutic Reform*, Carvers, "The Evolution of the Contemporary System of Drug Regulation," 158-163; Young, *The Medical Messiahs*, 191-202.

[132] Silverman, *Magic in a Bottle*, 304.

difficulties in implementation were enormous. It would take many amendments to the law, and eventually new legislation, before the government had genuine regulatory power over pharmaceuticals. The law, and the battle that surrounded its passage, are nevertheless of historical significance.

Harry Marks believes the law to have been fashioned by the drug industry and then agreed to by the Food and Drug Administration. In his interpretation, the industry continued to have the upper hand well into the 1950s. He examines the 1938 law in its broader context as part of the changing nature of government regulation over biomedical science and the economy as a whole. Peter Temin sees the law as the moment in which there was a more definite change in nature of government regulation, and believes that the law indicates a general willingness on the part of society to substitute government regulation for market control of health care. In The Medical Messiahs, James Harvey Young views the law in the context of the continuing effort to control fraud and "health quackery." Charles Jackson examines the laborious process of pushing the legislation through Congress. He tells the story of a political struggle, acknowledging the role of the FDA, the industry and consumer groups, with particular attention to women's organizations. Indeed, the law did serve the various agendas hat these histories discuss.

All of these interpretations acknowledge that the Elixir Sulfanilamide poisonings had a role, but a symbolic role, one that can be folded into the larger narrative each is exploring. But there is yet another context in which to see the Pure Food and Drug Act, namely that of the changes that were going on in the

practice of medicine and biomedical science. The 1938 law also serves as an acknowledgment of a transitional moment in science, as well as in government regulation. It served the vested interests of the drug industry, but also of medicine and pharmacology, and they are not synonymous. It is as much a marker of the changed position of physicians as it is of government, and in both cases the change is not as substantive, or as permanent as it appeared, as marks shows in his study. The 1938 law gives a legal affirmation of the arrival of a new phase in medicine. It is yet another announcement that the age of "miracle medicine" had arrived.

Chapter 6 The World That Sulfa Drugs Made—Longer Term

In December 1938, Science Newsletter published an article called "Life Giving Dye," about sulfa drugs and the "amazing record of a new chemical in today's warfare against germs." After reporting exultantly about Prontosil's success, the article went on to promise that "the end is certainly not yet in sight...Research goes on in laboratories in the hope of finding a super sulfanilamide."[1]

Colliers ran a featured story called "A Punch in the Spine," about a little Tommy, who was nine years old, and whose earache turned into spinal meningitis. "Now up to not much more than a year ago this strep meningitis was quite a little more than ninety-nine percent fatal." But, luckily for Tommy, "a new drug had turned up called sulfanilamide..." The writer went on to remind readers, "[Y]ou've probably heard of sulfanilamide...and if you're one of the people who are afraid of it because of those deaths caused by Elixir of Sulfanilamide...get over the idea." The problem wasn't the sulfanilamide; it was "the stuff in which it was idiotically dissolved." Tommy was given the largest doses that his doctor thought he could stand, and "it's perfectly true--six days later Tommy felt perfectly well." The article concluded by discussing the "punch in the spine" of the title, explaining that only through a spinal tap could the doctor "tell one disease from another."[2]

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[1] "Life-Giving Dye," *Science Newsletter*, December 1938, 362.

[2] The etiologic agent for meningococcal meningitis had been isolated in 1887, but until sulfa drugs the mortality remained upward of 84 percent despite a serum that had been developed by Simon Flexner in 1913. See Gerald L.

The advice to view the Elixir tragedy as an isolated incident was widespread. In a newspaper interview, "Dr. Perrin H. Long, who is credited with being the first to verify the curative effects of this drug," announced in a public speech that sulfanilamide has "opened up the probability that in the not far distant future all infectious diseases which hitherto have made such heavy inroads upon human life and health will be under control."[3]

Even the fairly restrained periodical Scientific American acknowledged that "great discoveries in chemotherapy are rare," but that one of the great significance had occurred. "We must then regard the recent progress in the development of powerful chemotherapeutic agents as the opening of a new era." The article concluded with a firm warning that "use is restricted-wisely--to the leading medical experts."[4]

Another writer promised "no one need be fearful when sulfanilamide is prescribed by a reputable doctor...Sulfanilamide is among the greatest of blessings when used by those who intimately know its power..."[5]

One of the results of the 1938 Pure Food, Drug, and Cosmetic Act was that prescription drugs such as sulfanilamide emerged as a separate category.[6]

Mandell, "Sulfonamides and Meningitis," *Journal of the American Medical Association*, 251, no. 6 (10 February 1984), 791-794.

[3] "Sulfanilamide – Miracle and Menace," *Norfolk Ledger-Dispatch* (12 January 1940), FDA General Subject File, 511.07.

[4] Barclay Newman, "Sulfanilamide and Sulfapyridine," *Scientific America*, June 1939, 362-63.

[5] "Sulfanilamide – Miracle or Menace," *Norfolk Ledger-Dispatch*, 10.

[6] Carvers, "Drug Regulation Under the 1938 Act," 160.

The existence of these drugs, and the fact that doctors had sole authority over them, changed the practice of medicine in innumerable ways. Section 502 (f) (1) of the law exempted certain drugs from the requirement of labeling them and providing directions for their safe use. Instead, these medications were to be labeled "use only by or on the prescription of a physician." Precisely which drugs would be put into this category was an aspect of implementation still to be worked out when the law was passed; but the very fact of the existence of such a group of non-narcotic drugs marked a significant change.

There were concerns on the part of the medical community about how prepared doctors were to make use of such drugs. Some critics worried that doctors would get their medicinal information primarily from the circulars distributed by drug companies.[7] The Food and Drug Administration was aware of these concerns. One correspondent wrote that the problem with the new laws is "this throws the responsibility back on the medical profession and I must say the prescription surveys do not reveal a particularly encourage situation."[8]

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[7] USP Circular 78 (1939), 3018, Records of the FDA, Box 23.

[8] Theodore Klumpp, M.D., Chief, Drug Division, to Dr. Arthur C. DeGraff (8 December 1939), FDA General Files, 511. From the Flexner report onward, the medical profession assumes that medical school equips doctors to keep abreast of new medical developments and that doctors read medical journals and attend professional meetings. For another perspective, see Mary L. Fennell and Richard B. Warnecke, *The Diffusion of Medical Innovation: An Applied Network Analysis* (New York, 1988). This is a critical issue. For another contemporary discussion, see "Changing Physician Performance," *Journal of the American Medical Association*, 274 (1995), 700-705; also, D.L. Sackett et. al., "How to Keep up with the Medical Literature: Access by Personal Computer to Medical Literature," *Annals of Internal Medicine*, 105 (1986), 810-816.

In order to gain its support, the Food and Drug Administration had assured the American Medical Association that the 1938 law was not meant to regulate the practice of medicine. The intention of the decision about labeling was to assure that creating this category of prescription medicines increased medical authority. The regulations gave the physician complete responsibility for giving patients directions on how to use these restricted medications. The warning allowed the Food and Drug Administration to refuse permission for the marketing of drugs that would facilitate self-medication. Once the patient was advised to see a doctor, it was the physician's job to make certain that the patient understood how to follow the doctor's instructions.[9]

There were some "experts" who were not sure that even these labeling provisions were sufficient to guarantee the safe use of such a potent drug. The Scientific American article quoted above concludes with a recommendation that patients who are being treated with sulfa drugs should be in a hospital; otherwise the patient is "liable to overdose himself against the advice of his doctor."[10] The American Medical Association began to express significantly more enthusiasm for sulfanilamide after the passage of the Food and Drug Act. It is certainly true that the timing may be coincidental--more studies had been done and more evidence collected by the time the legal battle finally ended. But just as the new

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[9] Letter to Paul Leech, AMA Council on Pharmacy and Chemistry, from T. G. Klumpp (10 October 1940), FDA General Correspondence Files 1940, 536.1.

[10] Perrin Long and Eleanor Bliss, *The Clinical and Experimental Use of Sulfanilamides, Sulfapyridine and Allied Compounds* (New York: Macmillan Company, 1939), 363.

law went into effect, an editorial in the American Journal of Gynecology was published, which concluded: "To sum up, it may be claimed that this new drug constitutes a valuable and noteworthy addition to the materia medica." But lest anyone forget, "certain unfortunate results which have accompanied its employment largely in unskilled hands, should call for that caution which is so essential..."[11]

A few months later, in July 1939, the same journal published "A Preliminary Report on the use of Sulfanilamide in Puerperal and Postabortal Infections," which reported a study done at Cook County Hospital in which half the patients with septicemia were treated with sulfanilamide. The mortality of the control group was 7.40%, while in the treated group the rate was 3.09%. In addition, the sulfa drugs reduced the number of days of hospitalization and in less severe cases prevented infection from becoming generalized.[12] This was essentially the same study as had been done at Queen Charlotte's Hospital in London three years earlier, with approximately the same results. The Journal of Pediatrics published an article describing recoveries from Pneumococcus Meningitis, stating that before the advent of sulfa drugs, there had only been 200 recoveries recorded in the literature. The paper discussed recent reports from pediatricians, and presented the cases of 30 recent survivors, all of whom had been treated with sulfanilamide, and pointed out that there were undoubtedly

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[11] R. G. Douglas, editorial, *American Journal of Gynecology*, 37, no. 3 (March 1939), 524.

[12] Theodore J. Morris, M.D., "A Preliminary Report on the Use of Sulfanilamide in Puerperal and Postabortal Infections," *American Journal of Gynecology*, 38, no. 1 (July 1939), 572.

others that had not come to the attention of the author.[13] Another article in The Journal of Pediatrics reported that "sulfapyridine has changed the entire aspect of pneumococcus pneumonia in childhood."[14]

The American Journal of Gynecology published several studies describing the use of sulfanilamide in the treatment of patients suffering from acute or chronic gonorrheal infections. One study concluded that the treatment "indicates a miraculous advance in the management of such infections."[15]

Doctors were not the only health care providers to be affected by the advent of sulfanilamide. Nursing practices were also changed by these drugs. As one article in the American Journal of Nursing explained, "The widespread use of sulfanilamide and its derivatives in the treatment of infectious diseases...places a heavy responsibility upon every nurse." This was because it was "often the nurse who first notices the appearance of toxic manifestations in patients."[16] And there were many toxic manifestations, some of which were sufficiently severe that treatment had to be discontinued. Others were less serious, but still required skilled nursing care. Some of these include "mania and marked depression...[in

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[13] Thurman Gwan, M.D., "Pneumococcus Meningitis: Recovery after treatment with Serum and Sulfapyridine," *Journal of Pediatrics*, 15 no. 3 (September 1939), 450.

[14] Charles Smith, M.D., "The Treatment of Pneumonia with Sulfapyridine," *Journal of Pediatrics*, 15, no. 3 (September 1939), 448.

[15] Edward J. Bonze, Paul G. Fuerstner, and Frederick H. Falls, "Use of a Sulfanilamide Derivative in the Treatment of Gonorrhea in Pregnant and Nonpregnant Women," *American Journal of Gynecology*, 38, no. 1 (July 1939), 78.

[16] Perrin Long, "Sulfanilamide and Its Derivatives," *American Journal of Nursing*, 39, no. 7 (1939), 719.

which case] care should be taken that the patient does himself no harm." Leaving such patients unattended could have serious consequences, since "there is no telling when they may fall out of bed or even jump out of a window."[17]

Less serious but more frequent side effects included nausea and vomiting, and acidosis. Cyanosis was also a common complaint, and though the condition would correct itself, it was "often a source of worry to [the patient's] family, his physician and his nurse."[18] Sulfanilamide toxicity was another significant concern. Nurses were instructed to be on the alert for drug rashes and drug fever, which could indicate that treatment should be suspended immediately.[19]

Sulfanilamides also affected nursing in another way. Much of the work of nurses, whether as hospital staff or, more frequently, as private duty nurses, consisted of providing skilled care for patients who were suffering with, and recovering from, infectious diseases. Such recoveries were lengthy and often difficulty. Sulfanilamides greatly reduced the period of both illness and convalescence and thus had a significant effect on the content of a nurse's practice.[20]

The pharmaceutical business also changed after the Elixir poisonings and the passage of the 1938 law. The requirement to fill out a new drug application and submit data to the Food and Drug Administration before marketing a drug

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[17] Ibid., 723.

[18] Ibid.

[19] Ibid., 721-723.

[20] I am indebted to Joan Lynaugh for this observation and her comments on the effect of these drugs in reference to nursing practice.

gave new importance to pharmaceutical laboratories. One New York University professor of therapeutics wrote to the Food and Drug Administration that he was "besieged by various people...who wish to have toxicity studies made in preparation for reports to your department." At first he was going to say no; but then he realized that "these people might then go some place where these studies might be made poorly and then it might be difficult for you to make an evaluation of the results."[21] The demands of the law eventually led to the development of laboratory facilities, which, combined with the lack of access to German pharmaceuticals once World War II began, provided additional impetus to research programs within drug companies as well as expanded relationships with academic departments of pharmacology.[22]

There were changes in the image of drug companies as well as in the content of what they actually did. For example, until January 1939, the Druggist Circular identified itself on the table of contents page of each issue as "Founded in January 1857 by Dr. Henry Bridgman...Questionable Advertisements Not Accepted." After January 1939, the typeface was changed to a much less ornamental and more businesslike style, and the table of contents described the publication as "American's leading and Oldest Drug Journal. Founded January 1857 by Dr. Henry Bridgman." There was no mention of questionable

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[21] Arthur Degraff to Theodore Klumpp (3 October 1939), FDA General Subject Files, 511.

[22] Swann, *Academic Scientists and the Pharmaceutical Industry: Cooperative Research in Twentieth-Century American* (Baltimore: Johns Hopkins University Press, 1988).

advertising. It was unnecessary, since such advertisements were obviously out of place in a professional journal.

Proprietary drug companies felt besieged. In a formal meeting between Food and Drug Administration officials and the Proprietary Drug Association, requested after the Food and Drug Administration promulgated its labeling requirements, the drug makers complained that they were concerned about the methods of enforcement of the drug act. They felt that the "drastic warnings" on the labels required by the Food and Drug Administration made it impossible for them to sell their products. In fact, as far as they were concerned, the entire purpose of the law was to "outlaw self-medication" and put them out of business. Campbell reassured them, explaining that, in fact, this law legalized self-medication because it insured that the consumer now received complete information. The labels that they found so distressing were only meant to serve as model warning statements, which the Food and Drug Administration had prepared to help manufacturers create their own versions. The Food and Drug Administration had done so at the request of the Proprietary Association, which had asked for the material in order to provide guidance for its members. The Food and Drug staff reminded their visitors that its sole purpose was to protect the public, and that its enforcement of the law benefited the majority of drug manufacturers--who were trying to comply with the law.[23]

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[23] Memorandum of interview: William Campbell, Theodore Klumpp, P. Dunbar, and various members of the Proprietary Association, including James Hoge, their attorney (25 January 1940), FDA General Subject Files, 500.13.

The drug industry was confused about implementation of the law at every level. One wholesale druggist wrote to the Food and Drug Administration, asking for guidance about whether or not he could sell sulfanilamide to registered pharmacists and practicing physicians. The Administration replied that it was not trying to "force manufacturers or wholesale druggists to discontinue the sale of a product, which is recognized as a valuable drug." It did, however, want to be sure that the "retail distribution will be made only under conditions which will guarantee administration under adequate professional supervision." The problem, the Food and Drug Administration admitted, was that the new law did not allow it to say exactly how this should be done. It was "not unmindful" of how hard this was on wholesalers and manufacturers; but the industry itself would have to decide how it was going to avoid the "promiscuous distribution of a kind that would constitute a violation of the statute."[24]

Retail druggists had their own set of problems. According to a 1940 pamphlet published by the National Association of Retail Druggists, the Food and Drug Administration said that the retail druggist had the responsibility of "legal delivery," which meant that he could not sell adulterated or misbranded products, nor ignore manufacturers' warning labels intended to restrict indiscriminate distribution of "drugs to the laity."[25] In an answer to a 1940 query about the legal responsibilities of the retail druggist from the Department of Pharmaceutical

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[24] Correspondence between J. W. Edgerly and William Campbell (8 September 1939), FDA General Subject Files, 510-20.

[25] "Food and Drug Act," National Association of Retail Druggists (February 1940), FDA General Subject Files, 510.

Jurisprudence at the Massachusetts College of Pharmacy, the Administration admitted that there was as yet no definite answers on many points of implementation of the 1938 law. These questions would have to be decided by the courts. The Food and Drug Administration also explained that it simply did not have the facilities to supervise all retail druggists, and much would have to be left to state or local authorities.

One point made by the Food and Drug Administration was significant. The law made it clear that in order to protect consumers, all drugs except prescription ones had to be labeled. Therefore, a retail druggist could not buy in bulk unless he was willing to label everything himself. Otherwise, the druggist would have to buy prepackaged drugs. This was a significant change in the nature of retail pharmacy. Previously, pharmacists had sold the patient what the patient wanted, not a prepackaged amount. Many pharmacists believed that the rights and obligations of their profession "included more than the marketing of ready-made, sealed package drugs."

The Food and Drug Administration explained that it had not compiled a list of drugs that were dangerous to health, because they didn't have the authority to do so. Furthermore, all drugs were dangerous unless used correctly. "The law makes it the responsibility of the distributor to determine whether or not any particular drug under any particular circumstances is safe to use." Of course, the law didn't say how that should be done.[26]

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[26] Correspondence between Joseph H. Goodness, Department of Pharmaceutical Jurisprudence, Massachusetts College of Pharmacy, and P. B. Dunbar (March 1940), FDA General Correspondence, 500.67.

Retail druggists remained confused, however, in part because of the changing definitions of a "dangers drug." Barbiturates were not supposed to be sold over the counter, but The Kansas Pharmaceutical News ran an article informing the state's retail druggists that under some circumstances they might do so. The suggestion made was that, "Your judgment should guide you as to whether or not you are contributing to the delinquency of anyone." The notice ran despite the fact that according to the Chief Food and Drug Administration Inspector in Kansas City, the executive secretary of Kansas Retail Pharmacists had been explicitly told that barbiturates were "potent...and may be a menace to health when used for self-medication." After receiving a stern letter from the Chief of the Food and Drug Administration Division of State Cooperation, the executive secretary of the Kansas Retail Pharmacists Association, Mrs. C. B. Miller, wrote, "[D]o you know you have given me the only concrete information I have been able to get for the druggists of this state on dangerous drugs." Though there may well have been a subtext to her letter, there may have been some truth to it as well. Even if the 1938 law had been shaped in part by the "industry," individuals were extremely confused. Mrs. Miller was far from being alone in her confusion--as Food and Drug Administration correspondence files, as well as plethora of internal memos and conflicting directives, make clear. Mrs. Miller concluded, "Maybe we're dumb out here, but so much of this material we can read over and over and still not know what it says."[27]

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[27] FDA General Subject Files, 511.10-67.

Retail druggists felt themselves the most aggrieved by the law. They were directly responsible for complying with a law that nobody understood, and were frequently the object of Food and Drug Administration raids and investigations. The Administration's files are full of inspection reports and complaints about retail pharmacists. One letter, written by a doctor, stated that he had gone into a drugstore and asked for sulfanilamide and "was informed by the clerk that they had plenty for sale." The clerk then displayed a "broken bottle which possessed the mark in pencil '30 cents per dozen.'" The doctor was then asked how many dozen he would like to buy. The outraged physician wrote, "[It] is evident that this drug is being freely and indiscriminately sold to the laity over the counter." He wanted the Food and Drug Administration to put a stop to it at once.[28]

The equally indignant president of the Winston Salem Drug Club wrote to the Food and Drug Administration demanding to know if doctors could dispense barbiturates. He complained that doctors were selling drugs to patients at the same price as pharmacists. "In our opinion the doctors are using this law to further their own remuneration." He pointed out that druggists were struggling to obey the law to the letter and therefore could not see why "the doctor can promiscuously (sic) sell these preparations to the former customers of the Drug Store." He received what must have been a disappointing response. "It is...not within the authority of the Administration to undertake the regulation of the practice of medicine." In an attempt to placate the Winston Salem Drug Club,

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[28] Letter from O. H. Taylor, M.D. (30 September 1939), General Subject Files, 510-20.

however, the local authorities would be instructed to investigate whether or not doctors were "operating merely as drug vendors rather than physicians."[29]

Doctors had other concerns. For example, there were many complaints about a booklet published by Luyties Pharmaceutical called Luyties Family Doctor, which outraged many physicians. Not only was this a clear invitation to self-medication, but the Luyties company was a homeopathic drug company. Doctors felt certain that the labels violated the Pure Food and Drug Act. As it happens, they did not, which may not be surprising, since Royal Copeland was a homeopath. As Campbell wrote, "This administration doesn't see itself as an arbitrator among schools of medicine." Homeopathic remedies were judged by the standards set in the Homeopathic Drug Directory, and they had experts on homeopathy on their staff who were qualified to make decisions about those drugs.[30]

The U.S. Pharmacopoeia may have been the only organization involved in the implementation of the Pure Food and Drug Act that knew exactly what the law meant to them. "[T]he Pharmacopoeia [is] more important than ever because of the 1938 law." With pleasure, the chairman of the U.S.P. Committee of Revision announced, "[T]he foresight and wisdom of those who planned and built the Pharmacopoeial organization has been repeatedly evidenced." The U.S.P. had begun to establish reference standards to be used in bio-assays in the 1930 edition.

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[29] Correspondence, August 1941, FDA General Correspondence Files, 511.90.

[30] Correspondence between Milton P. Duffy and William Campbell, June 1941, General Subject Files, 500.43.

In the 1940 revision they had expanded the list of drugs, vitamins, and hormones for which they provided bio-assay methods. Their duties now included the publication of standards for official chemicals. In a world in which the relationship between the pharmaceutical industry, physicians, and regulation (not to mention patients) had been so altered, or at least placed in such a state of flux, the Committee of Revision knew its place. "...[T]o protect and serve those who are ill...through triple service to the three groups--medicine, pharmacy and the government." Apparently patients didn't enter into this equation, presumably since the Pharmacopoeia was intended for professional use only.[31]

The Food and Drug Administration saw its job as trying to protect the public by ensuring that the drugs they took were safe. The problem was how to define safety. The law did not provide a definition, so the Food and Drug Administration had to do so administratively. Its efforts to do so were laborious and created immense confusion. They were also somewhat ineffectual. There were many aspects to drug safety. Though the agency had no power over advertisements, as that authority had been given to the Federal Trade Commission, it did have control over product labeling and felt that those labels were critical. One aspect of labeling was relatively easy. The Food and Drug Administration decided that there were no cures for certain diseases. Therefore, patent medicines could not promise to cure arthritis, asthma, epilepsy, nervousness, piles, undernourishment, neuritis, biliousness, lumbago, rheumatism or sciatica. Medicines also had to be careful about such claims as "will build

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[31] "Report of the Chairman of the U.S.P. Committee of Revision, 1940," Records of the FDA, USP Circular, Box 23.

resistance" or "always effective." The Food and Drug Administration said that these were false and misleading. Using any of these terms, or promising a cure for any one of the listed illnesses, would constitute a violation of the law.[32]

The Food and Drug Administration did what it could. When a representative of the Joint Committee of the American Drug Manufacturers and the American Pharmaceutical Association came to discuss the issue of names for drug products, the Administration proposed returning to 30-year-old standards. The "visitors" were told that that would not be acceptable in no uncertain terms. "The visitors were further told that an indefinite continuation of the exchange of such communications was not desirable since we had a definite duty to perform." Furthermore, the visitors were reminded "that some preparations which were improperly named were actually continually resulting in deaths."[33]

Dangerous drugs under the law could be distributed only on a doctor's prescription; but it took several years before the Food and Drug Administration came up with a list of exactly what were dangerous drugs. Initially, the Food and Drug Administration made an "informal ruling" and listed sulfanilamide, aminopyrine, cinchophen, neochinchophen and thyroid in this category. Acetanilid and bromides would have to carry warning statements that should say,

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[32] "Food and Drug Act," National Association of Retail Pharmacists, FDA General Subject Files, 510.

[33] Memorandum of interview (2 November 1938). Dr. Charles Vanderleed and Mr. Carson P. Frailey, representing the Joint Committee of American Drug Manufacturers and American Pharmaceutical Manufacturers Association; W. G. Campbell, Dr. J. J. Durrett, and Mr. A. G. Murray, representing the Food and Drug Administration. FDA General Subject Files, Box 14.

for example, in the case of bromides, "Warning: frequent or continued use may lead to mental derangement, skin eruptions, or other serious effects." Barbiturates required a label and a warning that they might be habit forming. Both dangerous and habit-forming drugs had to be used under the medical supervision, and they had to be so labeled. If they were not properly labeled, then the manufacturer was violating the law.[34]

Originally, Campbell decided that the label could simply read "for Professional Use Only"; but then he felt that that would not be a strong enough warning. The wording was then changed, in late 1938, to read, "Caution: To be used only by or on the prescription of a physician." The Food and Drug Administration decided that apparently this, too, was an inadequate warning, since these drugs remained in circulation as over-the-counter products. The Food and Drug Administration concluded that the warning label would have to be much more "conspicuous and impressive."[35]

The Food and Drug Administration sent out a new directive in early 1939, saying that drugs would be considered misbranded if they were not labeled with a properly aggressive label. Furthermore, this applied not only to the specific drugs that were listed, but to all drugs that could be dangerous.[36]

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[34] Charles Wesley Dunn, "Re Dangerous Drugs – Federal Food, Drug, and Cosmetic Act.," American Pharmaceutical Manufacturers Association Bulletin, no. 261, FDA General Subject Files, 100.67.

[35] Ibid.

[36] Ibid.

This was clearly a problematic statement. The attorney for the American Pharmaceutical Manufacturers Association sent out a confidential memo to its members, pointing out that there seemed to be no way to tell what a dangerous drug was. He advocated forming a committee to discuss the problem, and recommended contacting the Food and Drug Administration as quickly as possible.[37]

The General Subject Files of the Food and Drug Administration are full of hundreds of letters written to the agency begging for information as to which drugs were to be considered dangerous. The standard reply from the Food and Drug Administration was that any drug was unsafe if it was mislabeled. There were also drugs that were unsafe for self-medication, such as sulfanilamides and barbiturates. Judging from the amount of correspondence, it would appear that these letters did little to clarify the question.[38]

The Food and Drug Administration found that these warnings were not in any way adequate or effective. The agency had been completely unable to "prevent the indiscriminate distribution and use of such drugs." It was well aware that "not withstanding such labeling, they are reaching the general public in considerable quantities."[39] At one point, the Food and Drug Administration even considered banning these drugs, according to Charles Dunn, the American

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[37] Ibid.

[38] FDA General Subject Files (1940, 1941), 500.67.

[39] William Campbell to the Lane Drug Stores Inc. (2 May 1939), FDA General Subject Files, 510-208.

Pharmaceutical Manufacturers Association lawyer, but then decided that was not the intent of the 1938 law.[40]

The Food and Drug Administration inspected all product labels. In response to the proposed label for Cole Chemical Companies Sulfanilamide, Campbell explained that while the purpose of the 1938 law was not to discontinue sales of sulfanilamide--which was a valuable product--it did require "the adoption of steps which will reasonably insure that retail distribution will be made only under conditions guaranteeing administration under adequate professional supervision." The problem with the label that the Cole Company had sent was that there "is little, if anything, in the labeling you have submitted that would make any material contribution to this end." In the eyes of Campbell and his staff, the "comparatively inconspicuous injunction" that the drug should be used under the care of a physician was unfortunately coupled with "the relatively prominent statement of dosage in terms readily comprehensible by the general public." The label would have to be changed.[41]

The Food and Drug Administration recognized that it would have to rely heavily on local laws and local enforcement to make sure that its directives were carried out; but it continued to try to use its control over labels to protect the public at a national level. The Administration drafted yet more elaborate sample warnings. In the case of sulfanilamide, the label was to read, "Warning: This is a

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[40] American Pharmaceutical Manufacturers Association Bulletin, no. 261.

[41] Campbell to B. L. Cole (13 October 1938), FDA General Subject Files, 510-20.

dangerous drug which may cause serious or fatal injury unless consumed under adequate and continuous medical supervision." Even this was not enough.[42]

According to the system in place, the manufacturer or distributor was responsible for deciding whether or not a drug was dangerous; and then having made that decision, it was responsible for labeling it appropriately. After that point, the retail druggist was responsible for making sure that no drug was sold in violation of its label. The difficulty was obvious. In response to a complaint by the dean of the Purdue University School of Pharmacy, Theodore Klumpp, the Chief of the Drug Division, wrote, "We have always been loath to issue lists of drugs falling into the 'dangerous' category...[since] the amounts present, the directions for use and other circumstances must be taken into consideration." This was just a more elegant version of "any drug can be dangerous." The Food and Drug Administration acknowledged that the situation needed clarification. Klumpp concluded his letter by promising, "We have recognized that the issuance of some kind of guide would be helpful to those who desire to conduct their business in harmony with the purpose of the Act."[43]

In 1941, the Food and Drug Administration formally announced that it was forbidding the over-the-counter sale of rugs that it believed should be used only with a physician's prescription, and that it would publish a list of those drugs they were classifying as dangerous. The labeling on those drugs would only have to say that the drug could not be used without a prescription. The Food and Drug

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[42] American Pharmaceutical Manufacturers Association Bulletin, no. 261.

[43] Theodore Klumpp to Dr. C. B. Jordan (12 March 1941), FDA General Subject Files (1941), 500.67.

Administration expressed its concern that manufacturers might label drugs that they knew would be sold over the counter with the physician-only label, to save themselves the liability issues involved in incorrect product labeling. This was something the agency would not permit.[44] Campbell was quite explicit on this point. The Food and Drug Administration was well aware that the caution statement was "being abused by manufacturers who prefer to avoid any responsibility for providing directions for the use of their drugs." The Administration considered it absolutely essential that manufacturers live up to their responsibilities and to the law.[45]

The publication of a list of dangerous drugs did not correct the matter, and enforcement remained an enormous problem. In some states, local medical associations considered drafting state legislation that would make it illegal to sell drugs over the counter that had been classified as dangerous by the Food and Drug Administration. The head of the Providence, Rhode Island, Medical Association complained to the local Food and Drug Administration inspector that "retail druggists in the state of Rhode Island sell over the counter such potentially dangerous drugs as sulfanilamide."[46]

The State Board of Pharmacy of Louisiana explained to its members that "the Food and Drug Administration...is desirous of having pharmacists in this

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[44] Publication of the New Jersey Wholesale Drug Co., January 1941, FDA General Subject Files, 500.67.

[45] Campbell to Dunn (11 March 1940), General Subject Files, 500.13.

[46] Memorandum of interview (17 January 1941), FDA General Subject Files 511.07.

state refrain from selling habit-forming drugs over the counter..." The board followed this gentle statement with a warning that "government inspectors...will attempt to make purchases of habit-forming drugs...and we hope they will not be successful."[47]

After publishing its lists, the Food and Drug Administration did send inspectors out all over the country to try to buy dangerous drugs over the counter. In almost all places, they had absolutely no trouble doing so. The number of violations was so large that eventually the Administration decided that it simply could not take criminal action against the druggists. It did send citations to the manufacturers of the drugs, warning them that they must label drugs properly.[48] Typical of the reports sent to the Food and Drug Administration was one from an inspector who was sent to Raleigh, North Carolina, to buy barbiturates and sulfanilamide over the counter. He was successful about half the time.[49]

State laws were not always coordinated with federal regulations, and that further exacerbated the problem. A Jacksonville, Florida, group of druggists who had been cited for selling barbiturates over the counter went to the Food and Drug

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[47] Letter from Board of Pharmacy/State of Louisiana to Pharmacists (1 May 1941).

[48] The FDA Correspondence Files and General Subject Files (500.51-500.67) are filled with several hundred letters requesting guidelines, and hundreds of letters from the Food and Drug Administration to druggists clarifying the importance of observing the rules around prescription drugs. It was pointed out to these retailers that if manufacturers were to be forced to label their products in accordance with the law, then druggists must uphold their part and abide by the restrictions. They had to stop selling over-the-counter drugs that were on the dangerous drug list.

[49] Memo to chief, Atlanta Station from E. L. Holmes (30 October 1941), General Correspondence Files, 511.07.

Administration office in Atlanta to complain that the State Inspector had told them that it was perfectly legal to do so. They did admit, however, that they had been warned that the situation would change in the future. The Food and Drug Administration officials made it very clear that barbiturates could not be sold over the counter.[50]

There was another aspect of the labeling issue that concerned the Food and Drug Administration. The Act provided that warnings should appear on medicine if they were written for consumer protection. In the case of prescription drugs, presumably the doctor was already aware of the dangers, so the warnings were not required. Some of the Food and Drug Administration staff felt that as an added precaution, warnings should be included even on these medicines in the interest of public safety. There was, after all, the possibility, particularly in the case of a new drug, that the physician might not yet be aware of the dangers connected with its use. Another difficulty could occur if a new "toxic manifestation" developed with a drug that had already been in use, which the general medical profession might not have been made aware of immediately.

On this point, the American Medical Association was adamant. It did not want there to be any information on labels at all if the product was to be used under a physician's direction. They contacted the American Pharmaceutical Manufacturers Association and made its position clear. "They insisted that

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[50] Report to chief of Atlanta Station from Monte O. Rentz, inspector, Atlanta Station (3 October 1941), General Subject Files, 511.

manufacturers leave directions on use to the physician.[51] One confused pharmaceutical manufacturer wrote to the American Medical Association Council on Pharmacy and Chemistry asking for clarification. The manufacturer explained that his understanding was that the Food and Drug Administration was demanding that there be information on prescription drug labels stating the diseases for which the drug could be used. He was aware that the American Medical Association felt that this was an invitation to self-medication and that, generally, manufacturers agreed. The manufacturers were also concerned that the Food and Drug Administration insisted they add a warning about the side effects of prescription drugs, because they felt that physicians might not necessarily know them.[52]

The American Medical Association's position did not change. Labels should not list side effects, dosages, or the disease the drug was intended to treat. Paul Leech of the American Medical Association Council on Pharmacy and Chemistry wrote to the Food and Drug Administration demanding to know if there was a conflict between the American Medical Association's position and that of the Food and Drug Administration.[53]

Theodore Klumpp wrote back reassuringly that he was sure it will be "feasible to give the information required by the Act...without introducing an

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[51] Charles Dunn to William Campbell (26 January 1940), FDA General Subject Files, 500.13.

[52] Samuel Gordon, vice president, Endo Products, Inc., to Dr. Paul Leech (4 August 1940), FDA General Subject Files (1940), 500.13.

[53] Dr. Paul Leech to Dr. T. G. Klumpp (20 September 1940), FDA General Subject Files (1940), 500.13.

invitation to self-medication."[54] Mainstream medical opinion, which the Food and Drug Administration seemed to accept, saw the dangers of self-medication as something that had to be avoided at all costs. One notable exception to this position was Perrin Long, the American expert on sulfanilamide. He wrote to the American Medical Association that he felt the danger of self-medication to be less of a problem than the dangers of uninformed doctors. He, for one, favored extensive package labeling. Paul Leech of the American Medical Association reprimanded him, pointing out that while it was true that physicians needed information, package labels were not the way to accomplish that goal. After all, he reminded Long, it was the patient, not the physician, who reads the warning label.[55]

As it happened, not all physicians did have all the information they needed in order to use many of the new drugs. A curious example occurred in 1941, when the Pennsylvania State Department of Health established a series of public health facilities under its Pneumonia Control Division. The Chief of Biological Supplies wrote to the Food and Drug Administration asking if he could have permission to have circulars containing dosage and side-effect information included with the sulfadiazine, which would be distributed as part of its program. The Food and Drug Administration wrote that it was their belief that the inclusion of 'therapeutic indications, directions for use, etc.," tended to cause drugs to be

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[54] Klumpp to Leech (28 September 1940), FDA General Subject Files (1940), 500.13.

[55] Dr. Paul Leech to Perrin Long (11 October 1940), FDA General Subject Files (1940), 500.13.

"used by the laity without adequate supervision." However, the agency was prepared to make an exception "based on your assurance" that the drugs will not be used without "medical supervision." In this case, "we will not object to the inclusion in the market package of the descriptive literature."[56]

In the Food and Drug General Subject Files, there is a clipping from a New York Times article on July 16, 1941. The article, "Sulfanilamide is put in Kits for the Army," described special packaging that had been developed for self-administration with one hand. A handwritten comment next to the clipping of the article reads, "This may perhaps be cited in the defense of some future trial involving the issue of safety in indiscriminate sale to the laity of sulfanilamide tablets."[57] Within its mandate and staff limitations, the Food and Drug Administration did the best it could, and it tried to prevent future disasters.

There was still another problem with the drug sections of the Act. Some kind of definition of the term "new drug" had to be agreed upon, as well as the criteria by which that drug was determined to be safe. Initially, the Food and Drug Administration chose to err on the side of caution, declaring even those drugs that were closely related to products already on the market to be new drugs. In that way, the Administration could ensure that tests for toxicity would be done. When queried by the American Drug Manufacturers Association, Campbell explained that "at least for the time being...a safe new way of avoiding the

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[56] J. J. Durrett to Walter F. Heintzelman (30 October 1941), FDA General Correspondence Files 511.07.

[57] Ibid.

consequences of an infraction of the new Act is to resolve all doubts in favor of the product being a new drug within the legislative intent."[58]

Under the "new drug" provisions of the Pure Food, Drug, and Cosmetic Act, an application became effective 60 days after filing with the Food and Drug Administration. Within that 60 days, the FDA could postpone a drug's introduction if the agency felt that there needed to be more research done or if more data had to be supplied. The agency had an additional 120 days in which there could be a further investigation. After that, the only way a drug could be withdrawn was if the Administration could show that it was given false information on the application. There was an exemption for experimental drugs that were used only in clinical investigations.[59] In the first few years, because of the broad way in which the Food and Drug Administration defined new drugs, the agency was overwhelmed with applications. For example, in 1938 and 1939, there were 1,277 applications, all of which were accepted, though many were not really "new drugs" at all. The definition of "new" was narrowed in 1942, with the result that there were only 894 publications in 1941 and 1942.[60]

The next question was how these drugs should be tested and by whom. The degree of confusion is illustrated by a query from the University of Pennsylvania Medical School, which had been enlisted by drug companies to

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[58] J. J. Durrett, Chief, Division of Drug Control, to Carson P. Frailey, Executive Vice President, American Drug Manufacturers Association (18 August 1938), FDA General Subject Files 511.

[59] Carl M. Anderson, "New Drug Section" report submitted to the New York Board of Trade, 1946, 77.

[60] Ibid.

perform studies for them. "We are...interested in the division of responsibility between the manufacturer of a particular drug and the department that is conducting the clinical investigation." Previously, "we satisfy ourselves as to the non-toxicity of a product, but we are naturally dependent at times on the statement of the manufacturer." Clearly, the writer, Donald M. Pillsbury of the Department of Dermatology and Syphilogy, had questions concerning not just scientific responsibility but legal liability.

In his response, J. J. Durrett, Chief of the Drug Division, addressed that issue. Admitting that the regulations were hard to follow, he explained that the main concern of the Food and Drug Administration was that "investigations should be carried out by qualified persons"; but he went on to explain "these persons have no legal responsibility." There were no penalties for poor or incomplete reports, although Durrett was of the opinion that there should be. As to the possibility of dishonest reporting by an investigator for the benefit of the manufacturer, Durrett was sure "no responsible scientific investigators would be involved in such a collusion."[61]

Another physician-investigator wrote that he was besieged by representatives of different firms of drug manufacturers. All of them had new products that they wished to market, but they could not do so without clinical trials. "All were anxious to try this, and that, and the other thing on patients just to get these clinical trials." The purpose of these trials was not to learn about their

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[61] Correspondence between Donald M. Pillsbury, M.D., Department of Dermatology and Syphilogy, and Dr. J. J. Durrett, April 1939, FDA General Subject File, 511.

drugs, but rather to "pass the scrutiny of your department." The writer was apparently less certain about the likelihood of collusion than Durrett was. "Aren't you a little bit afraid of the pressure of haste in these trials, the power of consultant fees for various people?" The concern was that the FDA was putting pressure on the pharmaceutical industry to come up with new materials, and that "this is no good, as far as I can see, for doctors, patients, or anybody. I am worried about it."[62]

Durrett admitted that they had already had some reports of clinical trials of new drugs that "were practically valueless." He admitted further, "[J]ust how tests were secured we are not informed, but I suppose some were secured in the manner that has you worried." The only solution that Durrett could propose, however, was to rely on awareness in the scientific community that they have a "distinct obligation to discharge to themselves, to the profession and to the public at large." Reluctantly, he admitted that "this obligation is not fully realized by the profession as a whole or by certain individuals."[63]

Other pressures were put on the Food and Drug Administration with respect to new drugs. One investigator wrote that he was using a not-yet approved drug, sulfathiazole, with excellent reports and wanted to know why he couldn't use the drug more broadly. Durrett explained that the manufacturer's reports were not yet complete. "We are as anxious as anyone to make available

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[62] Stanley P. Reimann, M.D., Lankenau Hospital, Philadelphia, to J. J. Durrett (24 January 1939), FDA General Subject File 511.

[63] J. J. Durrett to Stanley P. Reimann (26 January 1939), FDA General Subject Files 511.

on the American market without undue delay safe drugs which are effective in combatting disease," but the Administration had an "enormous obligation" to make certain that a preparation was safe before it went into general use. As much as the Food and Drug Administration appreciated the information he had sent, their final decision would rest on the investigations submitted by the manufacturer.[64]

As the number of sulfanilamide drugs rose, so did other kinds of questions. An attorney from the Anti-Trust Division of the Department of Justice paid a visit to the Food and Drug Administration to discuss the distribution of several such drugs. The Food and Drug Administration expressed its discomfort with the conversation because it did not wish to violate the confidentiality of new drug applications, which were protected by law. And it was relying on the Department of Justice "to determine what information is or is not covered by [the] guarantee of confidentiality." The Justice Department representative explained that he was in no way interested in the scientific aspects of these applications, nor of the manufacturing processes involved, except where they might "lend themselves to monopolistic practices." The Department of Justice wanted to know if sulfanilamide could be made by "any well-equipped pharmaceutical house or...only by one of the large chemical manufacturers" (such as the ones who had funded the Chemical Foundation and licensed German patents in the 1920s). The response of the Food and Drug Administration was that "any well-

[64] J. J. Durrett to Dr. Wesley Spink, associate professor of medicine, University of Minnesota (14 May 1940), FDA General Correspondence File, 501.03.

equipped pharmaceutical house could manufacture sulfanilamide." One the other hand, "it might not be commercially feasible for any except the large chemical houses to make the drug."

The Justice Department wanted to know if manufacturers could collude and fix prices. The Food and Drug Administration had no information on that front. When the Department of Justice wanted to know why the price of sulfapyridine was so high, the FDA representative said perhaps the pyridine made it so expensive. The Justice Department representative said that his department thought there was price-fixing going on with pyridine and that chemical firms have "entered into some sort of licensing arrangement with one another..." This conversation occurred in 1941, at the height of the work of the Temporary National Economic Committee, which was investigating anti-trust activities. This did not seem to be a primary concern to the Food and Drug Administration, which assured the "visitor" that the newest sulfa drug, sulfathiazole, was being manufactured by Merck, Calco, Winthrop, and Squibb. Since all of these were major pharmaceutical firms, the Justice Department representative may not have been completely reassured.[65]

Tracking clinical investigations, especially at first when there was no system in place, was extremely difficult. The Food and Drug Administration was uncomfortably dependent on pharmaceutical manufacturing companies. As an example, an internal Food and Drug Administration memo discussed a new drug

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[65] Memorandum of interview (21 April 1941), Mr. Frank de Nunzio, attorney, Anti-Trust Division, Department of Justice; Mr. Frank W. Irish, FDA chemist, FDA General Correspondence File 511.07.

application filed by Schering for a sulfanilamide called sulfacet. The company was told that it had not provided enough evidence. It resubmitted the application, this time under the name sulamyd. "We have been advised by several physicians...that there is probably experimental work completed...which the firm has not submitted to us..." The memo suggested that an inspector be sent to the Schering Corporation to request a list of the names and addresses of the persons to whom the drug had been distributed. The memo also cautioned that "this information should not be limited to distribution under the name 'sulaymd,' but should involve all the names which have been employed."[66]

Clearly, the Food and Drug Administration was not relying solely on the information submitted by drug companies. There is a record of an interview with Perrin Long, "the outstanding authority on sulfanilamide," to discuss sulamyd. Long said that he had been approached "with a generous offer" to perform investigations but refused, because he thought the drug "was of mediocre value" and he "did not consider it worth his time." He did recommend some other experts to evaluate the drug, but "the concern" obtained the services of its own scientists. "Dr. Long appeared dubious as to the qualifications of these investigators."[67]

What is significant about the sulamyd case is that the objections to the drug were not that it was toxic, but that it was not as efficacious as--in Perrin

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[66] Memo to chief, Eastern District, from William Campbell, March 1941, General Correspondence File, 511.07.

[67] Memorandum of interview, Dr. Perrin Long, Dr. Theodore Klumpp, Mr. Fred Irish, Dr. Ernest Q. King (19 March 1941), FDA General Correspondence File 511.07.

Long's opinion, at least--sulfapyridine and sulfathiazole.[68] In a second meeting concerning sulamyd, another expert, E.K. Marshall, Jr., from John Hopkins, also made it clear that he was not impressed with the drug. Furthermore, he explained that he was concerned that "considerable harm would result if the drug was released inasmuch as it would be a precedent whereby we would find it necessary to release a dozen or more ineffective drugs on the market." All of these drugs worked by breaking down to sulfanilamide. The concern was that the confusion, and presumably the pressure from drug detail men, might well mean that physicians would not use proper drugs "known to be of actual therapeutic value."[69] The problem was, of course, that the 1938 Pure Food, Drug, and Cosmetic Act did not set efficacy as a criterion for new drugs.

In July 1940, Winthrop Chemical, which was a subsidiary of Sterling Products, Inc., received permission to begin marketing sulfathiazole tablets. As it turned out, it received the chemicals from Merck and manufactured the tablets on machines adjacent to machines that were producing luminal. In fact, tablet machines were apparently used interchangeably for the manufacture of both drugs.[70]

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[68] Ibid.

[69] Memorandum of interview, E. K. Marshall, Jr., M.D., Ph.D., professor of Pharmacology and Experimental Therapeutics, Johns Hopkins; Ernest A. King, M.D., Ph.D., medical officer, Food and Drug Administration (26 April 1941), FDA General Correspondence File, 511.07.

[70] "Contaminated Sulfathiazole Table Report," FDA General Subject File, 500.23.

In late December, an intern in the Norton Infirmary in Louisville complained to a Winthrop representative that six patients who had been given sulfathiazole tablets had reactions that were indicative of phenobarbital poisoning. The Winthrop representative sent samples taken from the Infirmary to its New York Office. The tablets were sent from there to a plant laboratory in Rensselaer, New York, for analysis. On December 24, 1940, the laboratory reported that the tablets were contaminated.[71]

On December 26, 1940, the company sent telegrams to its branch offices, saying that the tablet did not "disintegrate properly" and that they were being recalled. Further investigations by Winthrop uncovered several cases of "untoward" reaction and possibly one death. The collected tablets were stored at Rensselaer.[72]

Food and Drug files indicate that in February 1941, the Administration was reviewing some of the reports of factory inspections of firms manufacturing sulfathiazole tablets. "Although the project is not yet complete we have noted...such poor and insufficient control systems as to warrant further investigation and close surveillance."[73]

On March 17, 1941, Major Victor Baer from Medical Department of the 101st Engineers contacted the Massachusetts Department of Health, Food and Drug Division, because his daughter had taken sulfathiazole and had had a

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[71] Ibid.

[72] Ibid.

[73] P. B. Dunbar to chief, Eastern District (14 February 1941), FDA General Correspondence Files 511.14.

reaction to the tablets. The Chief of the Boston Station of the Food and Drug Administration was contacted and referred the matter forward. A Food and Drug inspector was sent to the Winthrop headquarters. When visited on March 20, 1941, Winthrop executives explained that they had "assumed that all the tablets had been recovered and there was nothing further to be done." The Food and Drug Administration did not agree and decided to investigate the situation further. In the meantime, they decided to withdraw the product from the market. They also considered revoking Winthrop's new drug application.[74]

The Food and Drug Administration "had definite information that contaminated tablets were still in the channels of trade." The company insisted that none of the contaminated tablets had been distributed but, as it happens, this was not an accurate assertion.[75] What the company had done was decide that it was enough to "try to regain possession of drugs in their distributor and wholesale drug houses," but that it wasn't necessary to "purse the contaminated article into the retail store or the hands of physicians." Two people had died from the drug and 20 were injured. The Food and Drug Administration issued a press release so that the public could be warned.[76]

Winthrop maintained that the tablets had been contaminated accidentally and that the situation had been controlled. "Such an explanation was, of course,

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[74] "Contaminated Sulfathiazole Tablet Report," FDA General Subject File.

[75] Ibid.

[76] Memo of telephone conversation between William Warton, chief, Eastern District, and George P. Larrick (21 March 1941), FDA General Subject File, 500.23.

not satisfactory" to the Food and Drug Administration. Winthrop executives "steadfastly maintained on repeated questioning" that only one batch of tablets had been contaminated. According to the Food and Drug Administration's report, "The confused laboratory records at the plant, however, showed their own analyst had found contamination also in tablets of other batches." Eventually, Food and Drug Administration determined that there were still 94,700 contaminated tablets missing.[77]

In an interview with William Campbell and Theodore Klumpp of the Food and Drug Administration, Dr. F.J. Stock, representing Winthrop Chemical, explained that he was an admirer of the Administration and knew that his firm had "let you down" by not reporting the contaminated tablets. Stock thought that it would be a good idea to make it a criminal offense in the future if a manufacturer failed to notify the Food and Drug Administration in such circumstances. He acknowledged that Winthrop had only recovered 75% of the drugs that they had considered to be enough; but now he saw that was an error.[78]

Among the records of the investigation of the contaminated sulfathiazole tablets is a memorandum of an interview between a Mr. F.I. McGarraghy and Mr. Herbert O. Calvery, about whether or not there were any connections between Winthrop and German pharmaceutical companies. Mr. Calvery said that he knew of no such connections. Some other staff member added a file note to the

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[77] Ibid.

[78] Memo of interview, Dr. F. J. Stockman, representing Winthrop Chemical, William Campbell, Dr. Theodore Klumpp (31 March 1941), General Subject File, 500.23.

memorandum to this effect: "[S]ulfathiazole tablets shipped in error by Winthrop Chemical Company may have been more than error. Closely allied with I.G. Farbenindustrie of Germany."[79]

In a subsequent interview with Campbell and other Food and Drug Administration officials, the chairman of the board of Winthrop Chemical, Dr. W.E. Weiss, explained that the failure to notify the Food and Drug Administration had occurred not because the company was trying to hide something, but simply because of bad judgment.

Campbell said that while the Food and Drug Administration did not have the power to "excoriate the officials" of the firm, it had been "his hope that in view of the well known purposes, motive and scope" of the Food and Drug Administration, reliable manufacturers would have come to the agency as soon as such a contamination had been discovered. The Food and Drug staff could then have helped, and "any necessary publicity" would have shown Winthrop and the Food and Drug Administration as working together to "protect the public following this unfortunate error." As it was, the FDA had no choice but to issue a press release. Weiss said that he hoped that the Food and Drug Administration would not hold it against them, and he was "assured that the actions of this Administration are never dictated by vindictive motives."[80]

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[79] FDA General Subject File, 500.23

[80] Memo of interview, Dr. W. E. Weiss, chairman of the Board of Winthrop Chemical Company; Mr. James Hoge, attorney; William Campbell; T. G. Klumpp; J. Kenneth Kirk (7 April 1941), General Subject File, 500.23.

There was considerable reaction to this latest drug scandal. Some of it took the form of letters to the Food and Drug Administration from concerned consumers. The Administration replied to many of them. For example: "We have your letter...in which you suspect that your dog died following the administration of contaminated sulfathiazole tablets." After consulting with Administration veterinarians, the staff had concluded that "the symptoms which you listed [are] the usual symptoms in the case of a kidney infection..." The letter concludes that the contaminated tablets were not the cause of death.[81]

Other communications in the file make it clear that a system of national food and drug control was slowly emerging. An example is a letter from the secretary of the New Jersey Board of Pharmacy to the Food and Drug Administration, thanking it for the circular announcing the suspension of the new drug application for Winthrop's sulfathiazole tablets. He expressed his hope that he and other could count on the Food and Drug Administration for periodic information, since the state agencies simply did not have the facilities to evaluate new drugs.[82] This changing relationship was not, of course, limited to the Food and Drug Administration, and it must be understood in the context of the changing relationship between the federal and state governments that emerged at the end of the New Deal. Government regulation had changed in countless areas.

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[81] P. B. Dunbar to Miss Rose Keart (14 May 1941), FDA General Correspondence File, 500.23.

[82] Robert P. Fischelis, Secretary, New Jersey Board of Pharmacy, to W. S. Fresbie, Chief Division of State Cooperation, Food and Drug Administration (28 May 1941), FDA General Correspondence File, 511.14.

In the case of drug regulation, those changes were far from complete. The Food and Drug Administration was well aware of that, and well aware of the pressure being brought to bear on the government by drug companies to restrain any expansion of their powers.

In June 1941, Food and Drug officials paid a call on a Mrs. Joseph Casey, who had contacted the Administration because her two-year-old son had taken sulfathiazole and was very sleepy afterward. Theodore Klumpp assured her that the tablets did "not seem to bear the characteristic markings which have appeared on all the contaminated products;" nevertheless, they agreed to analyze them. "During the general conversation, Mrs. Casey expressed interest in the work of the Food and Drug Administration, which arises because of her husband's position as a Congressman and a member of the Appropriations Committee." Both Mrs. Casey and her husband were interested in consumer problems and, in fact, he was about to introduce a "rather comprehensive bill dealing with the subject." The Food and Drug Administration officials invited Mrs. Casey to visit its laboratories. "She stated she would like very much to come and have an opportunity to ask questions concerning our work."[83]

The Administration needed all the political support it could muster. It needed an increased budget. It also needed clarification of many of its regulations. The 1938 law said that prescription drugs did not need to be labeled with warnings for use. As has been discussed, the American Medical Association adamantly supported this position. The problem was that nobody was exactly

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[83] Memorandum of interview, Mrs. Joseph E. Casey, Mr. George P. Larrick, Dr. Theodore Klumpp (18 June 1941), FDA General Subject File 500.23.

sure just what should be considered prescription drugs. The confusion that appeared immediately after the passage of the law was theoretically resolved in 1951, with the passage of the Humphrey-Durham Amendment. This amendment defined the drugs as habit-forming drugs, drugs that were sufficiently toxic that they were unsafe unless used under a doctor's care, and new drugs that required a doctor's prescription because of their unfamiliarity.[84]

The Food and Drug Administration and the American Medical Association continued to work cooperatively through the 1940s; but by the 1960s, when the Food and Drug Administration mandate was extended, it faced organized opposition from physicians. This may have stemmed in part from the generally anti-government regulation sentiment of the 1950s. yet some of it was quite specific. After decades of dispensing medical miracles, doctors had solidified their status. As the issue of efficacy as a criterion for drugs became a political issue, new battle lines were drawn. Though the 1938 law does not contain explicit statements about efficacy, as can be seen from the above Food and Drug Administration documents, the Administration quite clearly considered a drug that did not work as dangerous. The 1938 law did give the agency the right to restrict dangerous drugs. All drugs have inherent risks; but a drug that does not work is dangerous because the patient does not receive other, possibly more beneficial, treatment. Food and Drug officials were able to expand their mandate

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[84] Carvers, "The Evolution of the Contemporary System of Drug Regulation under the 1938 Act," 160-161. Harry Marks' version of this is a bit different. According to him, the Durham-Humphrey Amendment "enshrined" the drug companies' version of how the law should read.

in this direction, even before the 1962 changes in the drug laws that made efficacy an official criterion.

The 1962 amendments to the Food and Drug Act gave the Administration the power to control which drugs doctors could prescribe for particular illnesses. Physicians were denied access to certain drugs; even the information they received from pharmaceutical companies was limited to approved uses of those drugs. It is quite evident why doctors perceived this as interfering in the practice of medicine. Peter Temin suggests that these amendments also removed drug choices further from consumers.[85] Each subsequent change in drug laws raises once again these issues of who will have control over increasing powerful therapeutic agents. In addition to the forces of the pharmaceutical industry, physicians and government that have been discussed in this study, consumers, usually as patients, are also a factor in deciding the use, and even future development of therapeutic drugs.

The issues of methodology for clinical trials is one that has also evolved and changed over the years. The idea of the necessity of double- or triple-blinded testing emerged slowly. For many years historical controls were used instead, as in Colebrook and Kenny's original study on sulfanilamide. In 1952, an article called "The Clinical Trial" in the New England Journal of Medicine pointed out that while the "blind approach" was not absolutely necessary, without it contrasting one form of treatment with another can only show differences if a treatment has "real and considerable effect." Therefore, though the statistically

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[85] Peter Temin, *Taking Your Medicine*, 9-11.

guided therapeutic trial wasn't "the only means of investigation, the blind trial is one way, and a useful way to determine the safety as well as the efficacy of drugs."[86] This, too, speaks to all the issues raised by sulfa drugs. In the 1930s, drugs were tested very differently. Physicians did much of the testing of new drugs, and results were gathered anecdotally. After the 1938 law, that was no longer the case. With the appearance of sulfa drugs (which is not to say that this is a causal relationship), the testing of drugs changed and had continued to change. First came drugs too powerful and too complicated to be in the hands of the lay person. Soon came drugs that were too complex to be put, unrestricted, into the hands of doctors. Each change also dictated more complex research and development, more expense, and more professional expertise. Finally, of course, pharmaceuticals are big business. Medical advances often mean huge profits. To quote from a 1936 advertisement, "Remember the J & J slogan, publicized throughout the world—your druggist is more than a merchant.[87] We have come to expect medical miracles, and are usually willing to pay the cost.

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[86] A. Bradford Hill, "The Clinical Trial," *The New England Journal of Medicine*, 247, no. 4 (24 July 1952), 118.

[87] *Druggist Circular*, April 1936, 6.

Conclusion In the Aftermath of Miracles

In 1963, the biochemist Albert Szent-Gyorgyi wrote:

> We are living in the middle of the transition from the pre-scientific to the scientific thinking, hence the "tumult." We still have God on our lips and on our coins, but no more in our hearts. If we are taken ill we may still pray, but we take penicillin alongside...We find the new expanding universe a rather cold place and do not dare to abandon the old one...In its own time pre-scientific thinking did build a stable world, but science has irretrievably undermined the acquiescence in misery as the attribute of human existence and has undermined the old hierarchies of gods, princes, barons, haves and have-nots...Science has raised man from stench and dirt, liberated him from the miasmas which decimated him in earlier time. Science has helped us to understand and master nature.[1]

With the advent of sulfa drugs, and then the discovery of penicillin five years later, it seemed to many that a new age had begun for humankind—the age of medical miracles and the conquest of infectious disease. The discovery of these anti-infectives and those that followed so quickly in the 1950s seemed to offer a golden promise of constant medical innovation.[2] Sulfa drugs had not only cured disease; they had convinced a sizable portion of the lay public and medical

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[1] Albert Szent-Gyorgyi, "Lost in the Twentieth Century," *Annual Review of Biochemistry*, vol. 32, 1963, 14.

[2] Actually, it was quite clear that disease would disappear first in the developed world. There was an assumption that eventually medical miracles would be available to other countries, but it was accepted that there regrettably would be a time lag. Given the essentially optimistic orientation of medical research, the possibility that disease might re-conquer the developed world by spreading from other areas did not really seem to be a potent threat; the 1990s' concepts of "disease reservoirs" and the health impact of the ecological exploitation of Africa and South America on Americans were not yet recognized as issues.

practitioners of the potential of the biomedical laboratory. Future discoveries were simply a matter of time.[3]

In the 1960s, Americans questioned and redefined authority on many levels, including the benevolence of science and the power of medicine. With hindsight, it is clear that the age of miracle medicine was not the beginning of a new age stretching endlessly forward, but a finite stage in the history of medicine, science, and pharmacology. By the 1980s, as the AIDS epidemic grew, and—despite campaigns for their cure, some diseases, such as cancer, stubbornly refused to disappear—skepticism about medicine grew. It became clear by the 1990s that disease had not been conquered after all. The method and extent of government regulation of the practice of medicine and of pharmaceuticals would need continuous re-negotiation. The appropriate role of commerce and profit in medicine remained a difficult issue. Physicians found their authority, along with that of other professionals, once again under siege. As the historian Stanley Reiser has put it, in the late 1960s the public began to re-evaluate medical authority, and to question the social implications of technological medicine.[4]

These concerns echo the very social and cultural questions that the development of sulfa drugs addressed but did not resolve. In fact, they continue to shape the dialogue about the role of medicine and pharmacy, and their relationship to science, as well as their place in society. Physicians, too, have re-

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[3] This is obviously not limited to pharmaceuticals. The discovery of the structure of DNA is part of the same scientific conquest of nature.

[4] Stanley Reiser, *Medicine and the Reign of Technology*, (Cambridge, England: Cambridge University Press, 1978)

examined some of the transformations of the age of "miracle medicine." As Reiser has pointed out, many physicians in the 1970s began themselves to reject the "dehumanization" of modern medicine.[5] The question of the source of medical authority and the role of the doctor shifted yet again. Sulfa drugs had provided a way to redefine these issues in the 1930s, but not for all time.

In the middle of the 1960s, Henry K. Beecher wrote an article, "Ethics and Clinical Research," which was published in the New England Journal of Medicine. He questioned the ethics of the direction clinical research was taking, the very direction that had seemed to be such an important step forward in the era of "miracle" medicine and the scientific developments in the 1930s. He expressed his unease with the idea that patients were experimented on not for their own benefit, but for the benefit of others. He felt that there were too many errors that were increasing "not only in numbers but in variety."[6] He worried that medical schools and hospitals were becoming "increasingly dominated by investigators."[7] He was concerned that the emphasis on those new medical disciplines that made research a profession, such as clinical pharmacology, meant that there was an increasing separation between the interest of science and of the patient.[8] These are much the same questions raised by Sinclair Lewis in Arrowsmith thirty years earlier.

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[5] Ibid.

[6] Henry K. Beecher, "Ethics and Clinical Research," *New England Journal of Medicine*, 274, no. 24 (16 June 1966), 1354.

[7] Ibid., 1355.

[8] Ibid.

There were others who expressed apprehension quite specifically about the long-term miraculous nature of antibiotics themselves. The author of an article in the 1952 Annual Review of Biochemistry remarked, "There is to the reviewer an unfortunate resemblance between the growth of the literature on antibiotics and the growth of the microorganisms against which antibiotics are directed: They both multiply logarithmically."[9] A 1995 observation was much more blunt. "[I]n the race between bacterial evolution and human ingenuity, technology appeared to be winning...now...[R]esistant strains may soon outpace the development of new drugs, leaving doctors powerless to treat infections..."[10]

The evolution of drug-resistant bacteria, and then of multiple drug-resistant bacteria, created more than just a health-care crisis, though it certainly did create that. Antibiotics are a big business. Since the 1940s they have been an important sector of the pharmaceutical business, representing 10% of industry sales--$23 billion in 1995. The possibility that they would become less profitable had economic implications for drug companies and their shareholders.[11] They were important to the identity of drug companies in other less tangible ways as well. As one researcher explained, "If the pharmaceutical industry has any real

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[9] T. S. Work, "The Biochemistry of Antibiotics," *Annual Review of Biochemistry*, vol. 21, 1952, 431.

[10] Marc Lipsitch, "Fears Growing over Bacteria Resistant to Antibiotics," *The New York Times* (12 September 1995), C1.

[11] Lawrence M. Fisher, "Biotech Counterattack on Resistant Bacteria," *The New York Times* (26 April 1996), D1.

claim to improving the lot of society, it is the antibiotics, most other treatments are palliatives."[12]

The public imagination had been captured by the fear of strange new organisms emerging from exotic locations.[13] Nobel Prize winner in medicine, Joshua Lederberg, responding to popular concerns, issued a warning that though emerging new viral diseases had captured the public imagination in the 1990s, the odds of a major epidemic were fairly low, which "with antibiotic resistance, the odds are certain and the stakes are just as high."[14] "Miracle" drugs, and the later "wonder" drugs, were no longer working as well as they had. Once cause of the problem was that genetic mutations had made some bacteria resistant to certain drugs. This process of genetic mutation is very efficient among bacteria, and the drug-resistant germs then multiply rapidly.[15] The problem has been much exacerbated by the fact that doctors, especially those in the United States and Europe, used antibiotics for all kinds of illnesses, which are essentially self-limiting. This constant use, as well as the addition of antibiotics to animal feed, gave the bacteria that much more exposure to the drugs, and that many more

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[12] Ibid. The quotation is from a statement by Virn Mehta, a partner in Mehta and Isaly, a pharmaceutical research firm.

[13] One of the earliest books to deal with the subject for lay audiences, other than as a plot device for novels, was Robin Marantz Henig's *A Dancing Matrix: Voyages Along the Viral Frontier* (New York: Knopf, 1993). It was quickly followed by many others.

[14] "Superbugs," *New York Times Magazine* (2 August 1998), 45.

[15] Lederberg's Nobel-prizewinning work revealed that bacteria can exchange genes back and forth, which is why they were so successful at developing resistance.

chances for a successful genetic mutation to occur. In their defense, some physicians point out that patients demanded antibiotics but others said they had no other ethical choice but to use these drugs, because "any potential benefit to the patient, even if it is small, is paramount."[16] Once again, is the appropriate role of the doctor to deal with the individual patient or with society at large?

Furthermore, drug companies encouraged doctors to use antibiotics, rather than advising their patients just to wait the illness out. Their reasons were clear, but they raise, once again, the issue of the profit motive in medicine and the extent to which it shapes the practice of medicine. There were significant doubts as to the accuracy of the information that doctors were receiving from pharmaceutical companies. According to an article in the New York Times, in the 1995-1996 fiscal year, the Food and Drug Administration made more than 150 requests to drug companies that they withdraw physician-directed information that was either false or misleading.[17]

Another controversy has direct bearing on the problem of resistant bacteria, and again echoes many of the debates of the 1930s. It is this: In the late 1980s and early 1990s, relatively little research money was spent in doing basic research, or the pursuit of knowledge for its own sake, as opposed to applied research, or research with a clear, practical and profitable goal. By 1992, the

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[16] Lipsitch, *The New York Times*, C3.

[17] Abigail Zuger, "Drug Companies Sales Pitch: Ask Your Doctor," *The New York Times* (5 August 1997). There are numerous articles in professional journals expressing the same concerns. For just one example, see Michael Ziegler, "The Accuracy of Drug Information from Pharmaceutical Sales Representatives," *Journal of the American Medical Association*, 273, April 1995, 1296-98.

policy directing public funding—at least that supplied by the National Institutes of Health—was explicitly intended to "insure that American medical researchers proceed along lines that keep the United States economically competitive."[18] The announcement of this policy distressed many scientists who felt that it would limit research to what was obviously pragmatic, and that basic research would be neglected, thus limiting innovation. Without basic research, practical applications would eventually suffer as well. For example, Baruch S. Blumberg, winner of the Nobel Prize in 1976, pointed out, "Much of the highly targeted research in the war on cancer in the 1970s was inappropriate because we did not know enough about the basic science of cancer virology."[19] The new policy was intended to encourage scientists to work more closely with industry, which was itself problematic. A gulf had developed between those who did basic research and those who were engaged in commercial projects. Academic scientists often saw themselves as an elite group, because they did not do applied research. While the situation was not as extreme as it had been in the 1930s (when ASPET members could not work for industry), the problem was severe enough to cause problems.[20] When drug-resistant bacteria emerged as a significant problem, it became clear that none of the major pharmaceutical companies had new drugs in development.

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[18] Robert Pear, "U.S. Will Tighten Health-Lab Goals," *The New York Times* (24 August 1992), A1.

[19] Ibid., A16.

[20] Dick Thompson, "Science's Big Shift," *Time* (23 November 1992), 34.

The basic research necessary for the new class of antibiotics that could solve the problem simply had not been done.[21]

Until the development of sulfa drugs, the dividing line between "respectable," or more properly, "ethical" drugs, rested on the issue of patents. Only nostrums were patented; respectable drugs were not. After the introduction of sulfa drugs, those categories were changed. Some patented drugs, particularly those available only by prescription with the passage of the 1938 Pure Food and Drug Act, were considered the modern product of laboratory research. The medical community, including the American Medical Association, was forced to change its definitions of acceptable drugs. Nevertheless, it maintained its own ban on the patents for its members. It was not ethical for a physician to patent a medicine. Realistically, considering the complexity of developing a new drug and the necessity for funding and equipment, few practicing physicians were likely to apply for product patents. But in the 1990s, the debate shifted to the ethics of patenting medical procedures, which was a much more likely scenario. The American Medical Association decided in 1994 that it was unethical for a doctor to do that, too.[22] It condemned the practice, despite the fact that one lawyer

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[21] Drug companies moved to begin that work. Many of the companies that had developed sulfanilamides in the 1930s, including Eli Lily, Abbott Laboratories, Smith-Kline Beecham, Bayer, and Pfizer, announced new research plans. The public announcements were presumably an effort to impress investors. See, for example, "A Biotech Counterattack Against Resistant Bacteria," *The New York Times* (26 April 1996); "Counterattack: How Drugmakers Are Fighting Back," *Time* (12 September 1994); "Drugmakers Are Discovering High Cost of Cutting Costs," ***BusinessWeek*** (17 October 1994); "The New Fight Against Killer Microbes," *Fortune* (5 September 1994).

[22] "A Question of Ethics," *American Medical News*, 1995, 30.

estimated that in 1994 there were 15 such procedures patented per week.[23] The American Medical Association council on ethics and Judicial Affairs explained that it was concerned that patents would create a situation in which a physician could not use a procedure that would benefit his patient.[24] The supporters of patents said that patents promoted innovation. Theoretically, the doctor's reward for developing new procedures was not monetary but came from the satisfaction of successful treatment and publication in prestigious journals. Some doctors argued that their incomes were declining, and they could no longer ignore financial considerations. Other physicians also complained that prestigious medical journals would only publish the work of physicians who attended the best medical schools or who worked in elite teaching hospitals. These doctors said the marketplace was the only venue in which they could distribute their innovations.[25] Furthermore, some physicians had already patented their procedures, which meant increased costs for physicians, for which they could only be compensated by filing for patents of their own. The example cited the most often was that of Dr. Samuel Pallin, who claimed that he had the right to collect royalties on his patented "stitchless" incision for cataract surgery.[26]

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[23] "Just Rewards or Just Plain Wrong." 3.

[24] "The Case for Patenting Medical Procedures," 86; "A Question of Ethics," *American Medical News,* 1995, 30.

[25] Ibid., 32.

[26] Brian McCormick, "Restricting Patents," *American Medical News,* March 1995.

Another distinction between "ethical" and "proprietary" drugs was that ethical drugs could be advertised only to doctors. That distinction, too, has eroded. In 1995, the Food and Drug Administration relaxed the regulations restricting the advertising of prescription drugs to professional journals. Almost immediately, drug companies began to advertise directly to the public. In 1996, they spent $600 million dollars on trying to reach patients over the heads of their doctors.[27] (The justification for the change in regulations was that patients needed to be better advocates for their own health care.) Thus, as doctors feared in the 1930s, pharmaceuticals were undermining their authority. One physician complained that he "once told a patient asking for a specific treatment, 'I am not a waiter in a restaurant,' and after a lengthy discussion, 'She actually smacker her hand on the table!'" The Food and Drug Administration has also moved to change the rules on labeling and package insertions. The information was increased to include recommended dosages, drug interactions and side effects. As was hoped in the earlier legislation, the purpose of these changes is to help patients take more responsibility for their health care and to use medication safely.[28] When sulfa drugs were introduced, some doctors advocated using the drugs only in hospital therapy, because they required strict compliance to treatment times and dosages and because of the possibility of side effects. In the 1990s, the Food and Drug Administration had clearly chosen a very different solution.

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[27] Abigail Zuger, "Drug Companies' Sales Pitch: Ask you Doctor," *The New York Times* (5 August 1997), 17.

[28] Ibid.

Labels on over-the-counter medication have also been reformed. The labels must provide adequate information in an understandable manner. The justification for this is that the Food and Drug Administration is "acknowledging the increasing willingness of Americans to treat their own illnesses." As the commissioner of the agency, David Kessler, explained, "Eighteen billion dollars' worth of nonprescription drugs are sold in the United States each year, and the numbers are going up as the agency shifts more drugs from prescription to non-prescription status."[29]

Not only were patients using over-the-counter drugs, they were increasingly seeking health care from alternative practitioners and were being supported in this activity by their insurance companies. The guiltiest were those providing Health Maintenance Organization coverage, which doctors also opposed, as they had opposed national health care in the 1920s and the 1990s. In 1996, Oxford Health Plans announced that it would begin paying for treatments provided by chiropractors, acupuncturists, naturopathic doctors, massage therapists and yoga instructors. Other insurance plans were permitting the same kind of treatment. The chairwoman of the American Medical Association, Nancy Dickey, said that her organization was concerned only that "patients might turn to unproven therapies and delay getting treatments known to be effective."[30] In her

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[29] David Stout, "U.S. Acts to Simplify Labels on Medicine," *The New York Times* (27 February 1997), 18.

[30] "Oxford Health Plans to Cover Alternative Care," *The New York Times (9 October 1996)*, 11.

statement, she echoed AMA objections to patent medicines and alternative practices voiced in the 1930s.

Physicians have also tried to address the changing realities of medicine from within the profession. The problem of integrating the pharmaceutical laboratory into clinical practice is as key in the late 1990s as it was in the 1930s, although for different reasons. The explosion of drugs, treatments, and medical literature coming from increased research and increased access to information through computerization has created its own difficulties. The situation is compounded by the fact that patient activism and Internet access to technical information has increased as well. The American Medical Information Association reminded doctors of all of this in the announcement of its 1998 Congress. "Clinicians struggle to assimilate knowledge that accumulates at an ever-accelerating rate. Top medical stories often reach the public by the evening news well before the pertinent journal reaches most practitioners. Patients, with greater access and exposure to health information, are increasingly proactive." A new group of experts, medical informaticians, have undertaken the task of providing 'relevant information whenever and wherever clinicians may need to address patient needs."[31]

Medical schools have begun to address the issue as well; particularly those involved in training students in "Evidence-Based Medicine."[32] This new

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[31] Announcement, *Journal of the American Medical Information Association,* vol. 5, no. 1, January/February 1998.

[32] One standard textbook on the subject is D. L. Sackett, R.B. Haymes, G. H. Guyatt, and P. Tugwell's *Clinical Epidemiology: A Basic Science for Clinical Medicine,* (Boston: Little Brown, 2nd Edition, 1991).

paradigm for medical practice de-emphasizes "intuition [and] unsystematic clinical experience...as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research."[33] The emphasis in this kind of practice is on computerized searches for reports of relevant randomized controlled trials. Under the old system, physicians were told that they could lean from clinical experience by "unsystematic observations," and that all they needed was a basic understanding of the "mechanisms of disease and pathophysiological principles." Combining this training and common sense would enable them to evaluate tests and treatments; but if the physician were uncertain, he might then consult a local expert.[34] This is essentially the structure laid out in the Flexner Report.

Evidence-Based Medicine, while acknowledging that clinical experience is necessary because there are not any tests for some illnesses, stresses that observation and basic understanding of science are not enough. What is most important for a physician is that he or she knows the rules of medical evidence and the procedure or method of evaluating randomized controlled trials. This system is egalitarian in the sense that all doctors can learn to use it, thus decreasing the need for outside consultants. It means that doctors can eschew "cookbook medicine," substituting individual treatment designed specifically for

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[33] Evidence-Based Medicine Working Group, "Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine," *Journal of the American Medical Association*, vol. 268 (4 November 1992), 2420.

[34] Ibid., 2422.

each patient.[35] Again, this is another version of the argument in the Flexner era for regular medicine, as opposed to sectarian medicine.

The practical problem with this system is that physicians need to be trained in the application research to an individual patient. Though some researchers are trying to quantify risk and benefit, it is necessary for the doctor to understand the underlying statistical assumptions of each study. It is difficult, because there is always new evidence, and the evidence is always changing. Some advocates of Evidence-Based Medicine also integrate clinical experience into the system. "Clinical judgment and knowledge of people play a crucial additional role in the application of external evidence from randomized controlled trials." As if this were not enough, "patient preference is a growing variable" as well.[36]

These changes in the practice of medicine are responses to changing technology, just as surely as technology changes in response to those needs. The introduction of sulfa drugs into the United States is another illustration of how technology both shapes medical culture and is shaped by it.

The history of the impact of the introduction of sulfa drugs is also a reminder that basic health-care issues need to be addressed by more than technology. According to a 1995 study of 118 countries by Population Action

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[35] Ibid., 2425.

[36] Tom Fahey, "Applying the Results of Clinical Trials to Patients in General Practice: Perceived Problems, Strengths, Assumptions, and Challenges for the Future," *British Journal of General Practice*, 48, April 1988, 1175.

International, the United States ranked 18th in measuring the risk of death from complications of pregnancy, childbirth, and abortion.[37]

[37] *The New York Times* (24 July 1995).

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