

# Crisis and the Emergence of Economic Regulation: The Food, Drug and Cosmetic Act of 1938

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Preliminary, with tentative conclusions.  
(I wouldn't cite this if I were you.)

## **ABSTRACT**

Scholars commonly remark that new safety or environmental regulations follow a “crisis” or “tragedy” (for example, thalidomide, Bhopal, Three Mile Island). Yet these arguments are often vague and poorly established. Historians of the Food Drug and Cosmetic Act of 1938 point in particular to the elixir sulfanilamide disaster of 1937 as having generated a “public outcry” for a new law. Others invoke industry capture explanations, namely that established drug firms supported new regulation as a way of winnowing competition from patent medicine firms. In this paper we explain the 1938 Act as a combination of bureaucratic agenda-setting and the geographically conditional nature of consumer crises. We use new evidence from (1) the evolution of the dominant bills, (2) the distribution of organized pharmaceutical and patent medicine firms, and (3) the distribution of shipments and deaths from elixir sulfanilamide in 1937 to support this argument. While our conclusions are tentative, our analyses give plausible support to the argument that the concentration of sulfanilamide shipments and deaths in key Southern states induced previously reluctant but pivotal Southern Democrats to support an unprecedented expansion of bureaucratic power over a burgeoning industry. Had sulfanilamide deaths occurred outside the South, we conclude, the Act would probably not have passed. Yet had the sulfanilamide tragedy occurred at another *time*, when FDA regulation as the dominant alternative to the status quo was not advanced by bureaucratic leaders, the Act would either not have passed or would have taken a much different form. In addition, we find strong evidence against capture and rent-seeking explanations of the 1938 Act.

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It is now a commonplace assertion among scholars of regulation to say that new regulatory statutes follow “crises,” “tragedies,” or “scandals.” The content of these critical events may vary – from acts of journalism or research such as the publication of the Nader Report or Upton Sinclair’s *The Jungle*, to genuine disasters such as the Union Carbide gas leak in Bhopal, or the thousands of horrific birth defects that resulted from widespread use of the sedative thalidomide in Europe in the 1950s. As Lawrence Rothenberg (1994: 40) describes this argument, it amounts to a meta-narrative of the origins of regulation, an alternative to capture theory. In the tragedy narrative of regulation, “public opinion becomes energized by some dramatic event or condition illustrating the pitfalls of a market’s unobstructed operation; the outcry spurs elected officials to promulgate governmental regulation.” This story, as he notes, is at least as old as Bernstein (1955; see also Downs 1967).

So widely held is the claim that regulation follows from social crisis that it remains virtually unexamined in scholarly analyses. The connection between such events and the legislation that purportedly follows from them is vague, the implied causal mechanisms either poorly described or altogether evanescent.

In this paper we revisit this problem with new argumentation and new archival evidence. We re-examine one of the most important regulatory statutes in the history of the United States – the Food, Drug and Cosmetic Act of 1938. The 1938 Act gives the U.S. Food and Drug Administration (FDA) sole authority to determine the ex ante marketability of any pharmaceutical product. Along with the Durham-Humphrey Amendments of 1951, the 1938 Act also undergirds mandatory prescriptions in the United States. Taken together, these statutory declarations put pharmaceutical consumers at second remove from an ethical drug they wish to consume. In order for a patient to consume most drugs, the FDA must first approve them, and then the consumer’s doctor must prescribe them.

Historians have traditionally attributed the 1938 Food, Drug and Cosmetic Act to some combination of New Deal forces and the sulfanilamide tragedy of 1937, which occurred when the anti-infective drug, “Dr. Massengill’s Elixir Sulfanilamid,” caused 107 deaths and became the subject of national controversy (Jackson 1970, Young 1967). More recently, others (Marks 1997) have argued that the law conforms to an industry capture explanation, as the rulemaking that occurred after the Act’s passage largely conformed to the wishes of the organized pharmaceutical industry.

Our argument points to two features of the sulfanilamide tragedy that render its causal effects highly conditional. First, the tragedy occurred when leaders at the FDA had, through prodigious and entrepreneurial political action, established an FDA-strengthening measure as the dominant alternative to the status quo. By 1937, there was a relatively structured debate between those who favored the existing body of law accumulated from the 1906 Pure Food and Drugs Act (or a slightly modified version thereof that would have given the Federal Trade Commission more power), and those who favored a bill that would have given the FDA authority to determine the ex ante marketability of pharmaceutical products. In other words, the sulfanilamide tragedy did not “spur elected officials to promulgate governmental regulation.” The regulation was largely promulgated by the time the deaths occurred. The crisis rather induced a swing of attention and votes from one alternative to another, in part, we conclude, because it was concentrated among the constituencies of those who were most predisposed to abandon their opposition.

The second conditional feature of the tragedy concerns not its timing but its geographical impact. Most of the sulfanilamide deaths occurred in the South and lower Midwest, particularly in three areas: (1) upcountry states such as Tennessee, (2) rural plains areas such as Texas, Oklahoma and Arkansas, and (3) emerging new industrial cities such as Charleston and East St. Louis. These areas, as it turns out, housed two related

forces that had opposed passage of FDA-strengthening legislation: the proprietary medicine industry, and votaries of the doctrine of “self-medication.” These twin pillars of nineteenth-century health practice were mutually sustaining. The proprietary medicine industry was premised upon behavioral alternatives to professional medical practice and counsel. The doctrine of self-medication, centuries old but waning, was viable only in the presence of purchasable medications to which the consumer had relatively unimpeded access.

Our core historical argument is that the sulfanilamide tragedy induced a change in policy-specific preferences among pivotal Southern Democrats, leading them to abandon the rhetoric of self-medication, to drop their resistance to FDA-strengthening legislation and to take up and pass the core legislation comprising the 1938 Act. Since 1937-1938 coincides with the emergence of a “conservative coalition” of Southern Democrats and Republicans in Congress, the timing and geographical impact of the tragedy was particularly powerful. We use newly collected archival data on the distribution of sulfanilamide deaths to conduct some rudimentary tests of this argument. We show that shipments of sulfanilamide (and deaths resulting from its use) were more likely to occur among the constituencies of the most liberal of those legislators opposed to FDA-strengthening legislation. In other words, the crisis occurred among “pivotal” legislators most likely to change abandon their anti-regulatory positions. We also use newly collected data on the distribution of proprietary medicine manufacturers, pharmaceutical manufacturers and advertisers to show that capture and rent-seeking explanations are poorly supported by the available evidence on voting patterns over FDA-strengthening legislation. Limited data on voting over food and drug regulation bills compels us to temper our conclusions, however.

Our general argument, then, is that crises can in fact “lead to” or “cause” regulation, but the way in which they do so is highly conditional on their timing and the distribution of their impact. As such, ours is an argument by example. While our claims fall well short of a

general theory of regulation, or even a general theory of how crises lead to regulation, we believe that they offer a tighter and more testable account (both narratively and statistically) than existing scholarship does.

## I. Linking Crises and Regulation

The claim that regulation follows certain critical events (either actual events or journalistic exposes) is common to historians of numerous fields of regulation. Scholars ranging from Anderson (1958) to Young (1990) and Carpenter (2001) ascribe final passage of the Pure Food and Drugs Act of 1906 to publication of Upton Sinclair's *The Jungle*, an expose of sub-standard hygienic practices in Chicago meat packing plants that sold more than a million copies in the first year of its printing. Scholars from Quirk (1980) to Milton Friedman (*Free to Choose*) have noted that the thalidomide tragedy of the late 1950s eased the passage of the 1962 Kefauver-Harris Amendments to the 1938 Food, Drug and Cosmetic Act, which substantially tightened FDA drug approval standards. Pundits and scholars alike have noted the correspondence between events and legislation in cases ranging from Three Mile Island and nuclear facility regulation, Love Canal and toxic waste cleanup laws, and visible pollution and environmental regulation. Consider, for instance, Ringquist's assessment of the origins of environmental regulation:

Environmental regulation exploded on to the national agenda in the late 1960s. *Like most regulatory policies*, environmental regulation is profoundly affected by crises or focusing events external to the regulatory environment itself. Following a series of focusing events, from the publication of *Silent Spring* in 1962 to the outbreak of drinking water contamination in Milwaukee in 1993, federal responsibilities in environmental protection have grown to include the regulation of air and water pollution, solid wastes, hazardous wastes, noise and radiation pollution, pesticides, and most toxic chemicals traded in interstate commerce.<sup>1</sup>

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<sup>1</sup> Ringquist 1998; emphasis added. See also Ringquist's assessment of the rise of environmental concern in the late 1960s: "Beginning in the late 1960s, a series of focusing events (e.g., the Torey Canyon and Santa Barbara oil spills, Ohio's Cuyahoga River catching fire, the original Earth day celebration in 1970) radically changed the environment surrounding pollution control regulation. By

We cite Ringquist here because his argument is much clearer than those of other scholars who point to crises or tragedies as a cause of regulation. He posits a specific mechanism – the process of “focusing” – by which a certain event or publication might induce governments to pass new regulatory statutes and create new regulatory agencies. The other term used in the regulation literature is that of “outcry,” a signifier for a change in public opinion that is induced by critical events.

Even so, it is not clear how the process of focusing necessarily implies any direct connection to the political processes by which regulation is produced. Do “focusing” events lead “outcrying” voters to demand new forms of regulation by exposing failures or imperfections in the marketplace? Do politicians observe these events and anticipate voter reaction, taking up and passing new forms of regulation in order to minimize the effect of these events upon their re-election outcomes? If so, which politicians – legislators or executives – are most induced to take new action?

Or consider different mechanisms. Do well-informed (and well-heeled) interest groups or agencies take up the aegis of reform after critical events or tragedies? Might they, with the help of favorable media coverage, attempt to frame the event in such a way that voters and politicians are led inexorably from the fact of the event to certain policy conclusions, from a positive fact to a normative prescription for change? Or is it the case that critical events and tragedies give cover to rent-seeking interests who can frame self-serving legislation as publicly beneficial, as a “solution” to the “crisis”?

Another puzzle is that many “tragedies” and “crises” occur, but clearly not all of them have focusing power or lead to new regulation. There were numerous deaths and widespread morbidity reported from use of patent medicines in the 1920s and 1930s, yet

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1970, public opinion polls showed that environmental protection was the most frequently cited public

none of these but the sulfanilamide tragedy led to meaningful and sustained reform.

Devastating mining accidents were a feature of the industrial landscape from the mid-nineteenth century through the twentieth, yet not until the 1950s through the 1970s did stringent mining safety regulation get enacted. Although it lies outside of the realm of “economic regulation,” neither the Columbine shooting of 1999 nor numerous other school-related shootings has, at this writing, led to broad-based reform of the nation’s gun laws.

Our criticism of existing scholarship, then, is not that it gets the account wrong. Ringquist and others are, we think, probably correct to point to the Cuyahoga fire and Carson’s *Silent Spring* as events which have some causal relationship to the emergence of more stringent environmental regulation in the late 1960s and 1970s. Our concern is not accuracy but narrative and causal specificity. What is it about “focusing events,” “tragedies,” and “crises” that induces politicians to consider and pass new legislation? Scholars lack any sort of generalizable account of the historical and political mechanisms by which such new forms of regulation are traceable to critical events.

*A Counterfactual Condition.* We believe that the traceability of legislative or regulatory change to a specific event (or set of events) requires that a particular form of counterfactual be true or at least strongly defensible. Speaking hypothetically, let us say that the historian observes an “event” and a subsequent regulatory change (a “regulation”). In order for the historian to argue cogently and persuasively that the event induced the change, *it must be the case that, in the absence of the event, the new regulation in question would not have materialized, would not have materialized **when** it materialized, or would not have materialized **in the form** that it materialized.* We seek, indeed, to go further than this statement. Since new regulations (at least new federal regulations in the United States) are the result of particular processes of institutional action, then the relationship

between the event and the eventual regulation must satisfy one or more of the following conditions:

1. In the absence of the event, the proposed regulation would not have become part of the policy agenda.<sup>2</sup>
2. In the absence of the event, certain crucial votes would have been cast against the regulatory change, or for some competitive alternative, such that the final law would not have materialized.
  - (a) In the absence of the event, public opinion regarding the proposed regulatory change would have remained in favor of the status quo or insufficiently supportive of change.
  - (b) In the absence of the event, an executive actor would have either vetoed the final law or would have refrained from lobbying in such a way as to have eased its passage.
  - (c) In the absence of the event, certain lobbying organizations (interest groups, civic organizations, or bureaucracies) would have refrained from lobbying in such a way as to have eased the law's passage.<sup>3</sup>

Note that a given event may satisfy more than one of these conditions. To the degree that more than one of the statements is satisfied, the narrative connecting the event will always be more complex. Indeed, we argue that the connection between an event and a subsequent law will always be tighter, more testable and more narratively traceable, to the extent that only one of these conditions is satisfied, or that one of them is satisfied in such a way as to identify it as a sufficient condition for passage of the new regulatory law.

*The 1938 Act as a Canonical Example.* Previous accounts of the 1938 Food, Drug and Cosmetic Act have pointed uniformly to the sulfanilamide tragedy as perhaps the principal causal factor in the passage of a new law. Charles Jackson, who has authored the most thorough monograph on the 1938 law, writes that the “Elixir Sulfanilamide disaster...for the first time really brought about a heated public demand for legislation” (1970: 218).

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<sup>2</sup> We do not intend to advance a specific concept of the policy agenda here, save that it might include the agenda of a particular committee, the president, party leaders for the congressional majority, or some other crucial actor. See Kingdon (1990) for a defensible version.

James Harvey Young, probably the most prolific historian to write on the history of food-and-drug legislation and the patent-medicine industry in the United States, writes that in response to the sulfanilamide deaths, “The public, shocked into a new awareness that the [1906] law had loopholes, urged Congress to remedy the fault” (1967: 186). Speaking more generally of the history of food and drug regulation, Young writes that “The thalidomide near-disaster, like the meat-packing scandals of 1906 and the sulfanilamide tragedy of 1937, forced the Congress to enact a major new protective law” (1967: 418). Even the FDA’s own staff historians have ratified this conventional wisdom. Along with the deaths and hundreds of cases of blindness resulting from widespread use of dinitrophenol, a weight-reduction drug, the sulfanilamide “traged[y] prompted Congress to pass the Federal Food, Drug and Cosmetic (FD&C) Act of 1938” (Grant and Olmstead 1998: 222).

This is not to deny that other interpretations of Act have been advanced. Harry Marks argues that the law conforms better to a capture account of regulation along the lines of Gabriel Kolko’s interpretation of Progressive Era regulatory laws. Marks shows that organized pharmaceutical companies extracted noteworthy concessions in the writing of the 1938 Act, and were perhaps even more successful in seeing their interests met in post-1938 administrative rulemaking by the FDA. Marks’ evidence is fresh, interesting and undoubtedly merits further exploration. Yet it is questionable whether his evidence truly supports a standard capture account. For one, businesses may be politically successful in blunting the force of a new regulatory statute, but this fact (even if well established) falls well short of evidence for capture. The essential notion behind a capture account is that existing or large producers are able to design regulation to function as an entry barrier against smaller or potential competitors. A second reason to doubt Marks’ argument is

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<sup>3</sup> This is not an exhaustive list of the counterfactual statements whose truth could be used as evidence to support a causal relationship between an event and a new law, but covers most of the

that, as Jackson points out, most business lobbying was of a defensive nature. “The support [of the 1938 law] by many segments of the affected trades was forced as a defensive reaction” (1970: 206). Patent medicine and established pharmaceutical manufacturers were alike aligned against FDA-strengthening legislation before 1935.<sup>4</sup> Resigned to the inevitability of a new regulatory statute after 1937, organized pharmaceutical manufacturers tried their best to blunt a law while supporting the general reform initiative.

Marks’ arguments notwithstanding, no historian of whom we are aware is willing to weave the narrative of food and drug regulation in the late 1930s without pointing to the sulfanilamide tragedy was a central if not historically necessary event in the reform process. Again, however, these existing accounts are lacking in narrative and causal specificity, making it difficult to trace the new law directly to the Act. Jackson’s claim that the law brought about a “heated public demand” for legislation, while plausible, remains unsupported by evidence from correspondence, media coverage, polling data and the like. Young’s similar claim that the public was “shocked” by the tragedy and subsequently pressed for a new law is similarly devoid of empirical support. Consider the possibility that politicians responded to the tragedy by anticipating public reaction or by considering the loopholes of the 1906 law themselves, *without prompting or communication from the public*. Neither Jackson nor Young offers any evidence to disprove this hypothesis. Or consider what the nefarious concepts of “public,” “public outcry” and public opinion” mean in these accounts. Was there a genuine “public outcry” for reform in the sense that it was distributed widely among citizens of all classes, all geographic sections, all ages, both

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dominant alternatives.

<sup>4</sup> Jackson provides abundant evidence that organized pharmaceutical interests were opposed to reform of the 1906 law (1970: 68, 79, 95, 104, 107, 112, 119, 123). We provide additional quantitative evidence against a capture account below.

parties, and both sexes following the sulfanilamide deaths? Jackson, Young and other authors refer to a “public outcry” and “public pressure” without specifying whence or from whom the voices came.

We investigate these questions below. In order to understand the sulfanilamide tragedy and the food-and-drug-regulation reform initiative of the 1930s, one must understand the economic and social context of the markets and commodities that politicians sought to regulate. We begin with a brief look at the early twentieth-century market for proprietary medicines.

## II. Proprietary Medicines and the “Right of Self-Medication”

Proprietary drugs (or “patent medicines”) have long been described in highly anachronistic terms, as “nostrums” marketed by “snake-oil peddlers,” or as products whose manufacture and sale are equated with “quackery.” Such language might imply that the market for such medicines was a trifling sideshow to the emergence of medically prescribed pharmaceutical products in the economic history of the West. Indeed, nothing could be further from the truth. The market for patent medicines in the United States grew from the colonial period and, by the early twentieth century, accounted for hundreds of millions of dollars in annual sales (Young, 1961, 1967). Such products accounted for millions of dollars in advertising revenue in periodicals and medical journals nationwide, including the *Journal of the American Medical Association*, which depended heavily upon patent medicine ads until 1905.

It is difficult to demarcate patent medicines from their more legitimated “non-patent” counterparts. “Patent medicines” were just as likely *not* to have received a federal patent as to have one. Until the mid-twentieth century, patent medicines were commonly

prescribed by fully licensed and board-certified physicians, and they were frequently listed on official pharmacopoeia. The operative distinction became clearer in the late 1800s, when pharmaceutical companies began restricting their advertising to doctors and began to list the contents of their medications on the sides of the bottles. Thus proprietary medicines were usually distinguished by (1) the absence of chemical or pharmacological information on their labels and (2) their heavy reliance upon direct-to-consumer advertising (Young 1967, Chapter 2).

Over the course of the nineteenth century the market for proprietary medicines – which ranged from novel pharmacological concoctions to filling empty pharmaceutical containers with water or grain alcohol and reselling them – exploded in size.<sup>5</sup> An 1804 New York drug catalog listed some 80 or 90 names of patent medicines, but by 1858 the number of products ranged from 500 to 1,500, depending upon the estimate used. By 1905, *Druggist's Circular* listed the names of over 28,000 patent medicines, and a year later congressional testimony put the estimate at 50,000. By 1859 the proprietary medicine business was valued in census figures at \$3,500,000 in annual revenues. By 1904 that revenue estimate reached \$74,500,000, a figure which by 1912 had increased by approximately 60 percent to over \$110 million. By mid-century, congressional investigators estimated annual revenues of the proprietary medicine industry at \$1 billion to 2 billion.

The set of drugs marketed as patent medicines varied widely in their composition and therapeutic claims. They included Robert Harper's "Cuforhedake Brane-Fude," a "brain food" supplement containing a dangerous combination of alcohol and acetanilid

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<sup>5</sup> The information in the following two pages is taken from Young (1967, Chapters 2 and 3) and Jackson (1970: 127-28).

whose title subtly offered to cure headaches.<sup>6</sup> From 1888 to 1908, “Brane-Fude” sold two million bottles and returned to Harper an aggregate profit of \$2 million. Among the most popular patent medicines in the 1930s was “4-44,” a purported cure for the stomachache whose advertisements stated that “4-44 revitalizes your food with sixteen minerals without which you cannot have a sound stomach or vigorous body.” The label of 4-44 failed to list any of these magic sixteen ingredients and offered no therapeutic claims. Therapeutic claims were advanced in abundance, however, for “Triple Strength Chinese Herb Compound,” which allegedly cured indigestion, dysentery, “biliousness,” dyspepsia, gallstones, malaria, asthma, eczema, rheumatism, and bad breath.

The claims made for patent drugs ranged from the erotic to the grotesque. Anti-impotence medications and sexual stimulation drugs with names such as “Persenico” and “Revivio” were very common. Within ten days of consuming “Persenico” the patient would have success “in combating neurasthenic impotence, pre-senility, low vitality and general nervous ailments, particularly...of sexual origin.” The love-sex hormone “Revivio” offered men the chance to “improve your vigor.” Those suffering from gastrointestinal constipation or “piles” could purchase, with a money-back guarantee, “Dr. Young’s Rectal Dilators.” The dilators purportedly used “natural methods” to strengthen rectal muscles by “imitating Nature’s own process.”

These medications had far more pervasive effects of might be implied by the morbid historical curiosity that they inspire today. There were at least three deleterious outcomes of the widespread marketing of these drugs. The first was *equilibrium fraud*. Consumers were buying products with the belief that they held curing power when in fact they usually held none or were in fact harmful to health. With the possible exception of aspirin (whose

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<sup>6</sup> Compounds containing acetanilid were suspected in at least 22 deaths in 1905 (Young 1967: 6). Acetanilid mimicked opiates, inducing overdoses and lending themselves to addictive consumption.

contents were usually published) and several analgesics, no widely sold patent medicine of the late-nineteenth to early-twentieth century was later shown to have significant marginal clinical curative power for its consumers.<sup>7</sup> Perhaps worse, many patent medicines were associated with high toxicity and other safety hazards. Most “soothing tonics” for babies and children were laced with alcohol, opium, or some combination of the two. “Gouraud’s Oriental Face Cream” led to “genuine facial beauty,” but government investigators later learned that it did so by imparting significant mercury to its consumers, thereby inducing skin discoloration.

The truly severe harm associated with proprietary medicines concerned not hazards in the medicines themselves but the treatment foregone by their consumption. There were two rational or semi-rational mechanisms that engendered such an outcome. First, knowledgeable consumers would often forgo the opportunity to consume even legitimate pharmaceutical products out of awareness of the hazards associated with fraudulent varieties. Second, and most important, for every consumer trying to reduce morbidity and/or mortality by consuming a non-curative patent medicine, valuable medical treatment was forfeited (Jackson 1970: 96). In some cases, consumers would experiment with different drug products until they found something that “worked” for them. Even in cases where they eventually happened upon a remedy with true curative value, their consumption of other patent medicines in this auto-experimental process usually implied a serious delay in effective treatment. In other cases, superstitious learning led to an even worse outcome. In cases where the consumer’s ailment would have gone away on its own,

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<sup>7</sup> The most recent example was Laetrile, a highly touted cancer remedy that occasioned great controversy in the early 1980s. After the FDA relented to executive branch pressure, it approved a new form of “treatment access” to the drug and commissioned several clinical trials in order to ascertain the effectiveness of the drug. Subsequent studies showed Laetrile not to have had any effects, and its current use by cancer patients is negligible.

the consumer often wrongly reasoned that the patent medicine had in fact cured a disease, a conclusion which induced further consumption of the drug, and (via observation and informational transmission through interpersonal networks) heightened consumption by others.<sup>8</sup>

The staying power of patent medicines in the United States and other Western nations was linked to a set of beliefs about the relationship between individual agents and the curing of disease. The philosophy or ideology of “self-medication” or “auto-therapy” was centuries old and linked to organized challenges to the medical and pharmacological professions. The set of movements intertwined with these beliefs is far too diverse and complex to be discussed here, but it suffices to note that the social, economic and political authority of organized medicine came at the expense of organized homeopathy, chiropractic practice, holistic medicine and other movements (Starr 1982). The emergence of a national market for proprietary drugs was in some ways akin to, in other ways vastly different from, these movements. Patent medicine makers commonly advertised their drugs as a means of avoiding the expense and personal intrusion occasioned by a visit to the doctor. (The latter point explains why patent medicines were popular among women living under cultural norms of Victorian domesticity, and among men seeking treatment for gonorrhoea and syphilis.) Yet patent medicines competed powerfully with “alternative medicine” and indeed drove out of business many nineteenth- and twentieth-century practitioners of the (non-medical) healing arts.

The set of specific beliefs described by the “ethic of self-medication” emerged with greater cultural force during the antebellum period and continued in force through the

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<sup>8</sup> For a theoretical and empirical argument that such superstitious learning is common in consumer evaluations of doctor quality in some developing countries, see Das (2001).

early 1900s. At its core, claims for the primacy or privileged status of self-medication depended upon beliefs in consumer autonomy and judgment.<sup>9</sup> Votaries of self-medication frequently voiced their support for stronger labeling disclosure requirements for drug manufacturers, in part out of the belief that “the intelligent layman” needed maximal information to render an informed pharmaceutical purchasing decision. Yet the supporters of auto-therapy usually disdained state and federal regulatory measures. One of the most relevant political implications of their ethic was a time-honored “right of self-medication” (Jackson 1970: 79, 114). In operation, this included the absolute liberty of the consumer or patient to purchase any and all medications for the amelioration of his or her ailments. Whatever the disease, and whatever the purported cure, the “layman” should be able to exercise his own scientific judgment in drug purchasing decisions.

The proprietary medicine industry entered the twentieth century almost completely unregulated. Aside from some state-level statutes passed to regulate food in the 1880s and 1890s, no government regulation of the proprietary medicine market existed. The signal change in Progressive-Era regulation of drugs came in 1906, when Dr. Harvey Wiley of the USDA’s Bureau of Chemistry successfully completed a twenty-year campaign to pass a federal food and drug regulation bill (Young 1990, Carpenter 2001). The 1906 law gave USDA power to seize articles of manufacture deemed “fraudulent” or falsely advertised, and prodigious cooperation between Wiley and officials at the Post Office Department was successful in prosecuting hundreds of cases in the Progressive period. Yet such cases were always prosecuted *ex post*, and the associated penalties were minimal. Robert Harper’s

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<sup>9</sup> We sidestep the term “patient autonomy” here as it is a more recent concept and assumes the existence of a professional-patient relationship, a relationship which the ethic of self-medication often challenged or rejected altogether.

marketing of “Brane-Fude,” for instance, brought him a fine of \$700. Compared with the \$2 million in profits he had made on the product, it was a trifling fine.

Whether due to the unevenness of state regulation or the greater staying power of self-medication ideologies in the South, Southern states provided, by the 1930s, a truly comfortable home for many firms in the proprietary medicine industry. Indeed, the proprietary medicine industry was characterized by some exclusively regional markets. Some nostrums sold in California were virtually unheard of on the East Coast, and many more drugs marketed in Southern states were generally unavailable or not widely purchased in states outside the former Confederacy.

### III. The Emergence of New Regulatory Alternatives: Bureaucratic Agenda-Setting and the Power of Organized Women

Calls for a revision of the 1906 Pure Food and Drugs Act were largely unrelated to changes in the proprietary medicine industry or to consumer tragedies of the 1920s and early 1930s. Two forces – the FDA (backed by Roosevelt Administration USDA officials) and organized women’s groups – exercised strong leverage in pressing for changes to the 1906 law. Their principal success was finding able legislative sponsors, principally New York Senator Royal Copeland and Tennessee Representative Virgil Chapman. From 1934 to 1937, Copeland authored a succession of bills that would have substantially strengthened the FDA.

FDA officials had long been disappointed with the operation of the 1906 Act, repeatedly lamenting that manufacturers were able to exploit loopholes in the statute, that successfully prosecuted proprietary manufacturers quickly relabeled their products and entered the market again, and that dangerous and worthless medications were entering the market. Patent medicine manufacturers circumvented the labeling and fraud restrictions

of the 1906 Act by veiling their therapeutic claims (hence “Cuforhedake”) or by removing information from the label altogether.

The first bill addressing these problems was authored by FDA personnel, was sponsored by Copeland, and was titled “S. 2800.” Along with its successors “S. 5” and “S. 1944,” S. 2800 attempted to rein in the patent medicine industry. S. 2800 required disclosure of ingredients on labels, removed the 1906 Act’s requirement that the FDA had to prove intent to defraud in order to seize shipments of a good, gave the FDA power to seize multiple shipments of “misbranded” goods, and rendered advertisers and manufacturers alike legally liable for fraudulent claims. The bill also gave to the FDA power over pharmaceutical advertising. S. 5 relaxed many of these provisions, in particular by introducing judicial constraints on seizures and by relaxing the formula disclosure provisions of earlier bills. As the legislation progressed through congress, debates over labeling, seizure and advertising regulation would attract the greatest energy and debate.

Administrative leaders at the FDA, most notably Walter Campbell and Paul Dunbar – careerists who had trained under USDA Chief Chemist Harvey Wiley before 1910 – made use of three strategies in advancing the case for strengthening the 1906 Act. First, they allied with friendly forces in the Roosevelt Administration, most notably Rexford Tugwell. Tugwell was FDR’s assistant secretary of agriculture and perhaps the most powerful liberal voice in the administration in the early 1930s. He desired for the pharmaceutical industry a system of industrial oversight not unlike that envisioned in the National Recovery Administration or antitrust law, where “fair and responsible competition” would be a primary policy goal. His continued support of FDA-strengthening legislation was crucial in light of a salient fact about the food and drug regulatory struggle: *FDR was not supportive of the FDA’s or of Copeland’s efforts.* At a general level, the president was generally uninterested in regulatory measures and more interested in laws specifically aimed at

economic recovery and national infrastructure. More specifically, Royal Copeland was a New Deal dissident, and New Dealers in Congress and the Administration resented his sponsorship of the bill.<sup>10</sup>

The FDA's second stratagem was a skilled and indirect publicity campaign aimed at demonstrating the hazards of adulterated food and medicines to the nation's press. The FDA had been prevented from direct lobbying and publicity efforts in the Deficiency Appropriations Act of 1919, yet the FDA found creative ways to circumvent this rule, distributing pamphlets such as the one entitled *Why We Need a New Pure Food Law* and making radio talks on S. 2800. FDA Information Officer Ruth Lamb successfully invited press outlets to give fresh attention to Copeland's first Senate bill (S. 1944), and she used her own time and money to author a popular book on the hazards of patent medicines entitled *The American Chamber of Horrors* (1936).

The FDA's third strategy was one that required coordination but not persuasion. FDA officials drew upon their decades-old alliances with women's groups and organized consumer unions. Two women's groups – the General Federation of Women's Clubs (GFWC) and the Women's Christian Temperance Union (WCTU) – were instrumental in lobbying for the 1906 Act (Carpenter 2001). As Theda Skocpol (1992) and Elizabeth Clemens (1998) have argued, the GFWC and the WCTU were some of the most powerful lobbies of their time, almost single-handedly waging successful campaigns for mothers' pensions and child-labor laws. Joining the women's groups, moreover, was the increasingly assertive and powerful Consumers' Research (CR). CR was founded in 1929 with 1,000 members and by 1933 had ballooned to 45,000 members. As Jackson (1970: 20-21) describes the union, "CR's influence and significance far exceeded its actual membership. The organization served as a coordinating body for Congressional and other sympathizers of consumer

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<sup>10</sup> See Jackson (1970: 63-65, 84, 118).

legislation.” Rexford Tugwell found “astounding” the “receptive attitude of the general public” towards CR.

Despite the seemingly favorable circumstances – an overwhelming Democratic majority in Congress with pro-regulation impulses, a Democratic president, supportive women’s groups and a well-coordinated rhetorical campaign – several factors combined to blunt the FDA’s initiative for food and drug law reform in the mid-1930s. The first was well-organized and well-represented opposition from the affected industries. As Jackson (1970: 38-39) describes the rise of opposition, “Many existing trade bodies were turned almost immediately into vehicles of resistance. Especially militant were the Proprietary Association [PA] and the United Medicine Manufacturers of America [UMMA].” The PA and UMMA sponsored protest gatherings, radio advertisements, and coordinated petition campaigns against FDA-strengthening bills. The manufacturers found able legislative defenders such as Senators Josiah Bailey of Tennessee and Arthur Vandenberg of Michigan.

Two other difficulties were related less to the opponents of reform than to its supporters. Rexford Tugwell was the lightning rod of the early Roosevelt Administration, was disliked by rural Democrats and conservatives, and his visible association with the Copeland bill soon became a serious liability for the FDA. Opponents of “S. 2800” and “S. 1944” sounded alarms of “Tugwellmania” and called the Copeland measure “the Tugwell bill.” Yet Copeland himself was perhaps a more serious liability, at least early on. Copeland was a New Deal dissident whom Administration Democrats resented. FDR withheld endorsement for his home state’s senator in the 1934 midterm elections and made no secret of the fact. Roosevelt loyalists in the Democratic Party, including Alben Barkley and other Southerners, were determined to keep Copeland an arm’s length away from political or moral victories on food and drug regulation.

Opponents of reform landed an apparent deathblow in 1935, when the Senate passed Copeland's S.5, but only after attaching the infamous "Bailey Amendment" which vitiated the measure. The Bailey amendment prohibited the FDA from regulating any aspect of pharmaceutical advertising and would give all such control to the Federal Trade Commission (FTC). From the vantage of the 1906 law, this was a step backwards for the FDA. Even under the Progressive Era statute, the FDA had at least ex post control over fraudulent advertising. Once the Bailey Amendment was approved, S. 5 passed the Senate but was doomed from criticisms from the left and the right. S. 5 then died in the House by an overwhelming 190-70 vote.

Roll call votes are available for three crucial votes on the Senate measure in the 74<sup>th</sup> Congress (1935-1936), and we analyze these votes here to test for the impact of observed ideology, party, region and organized interests. The first two votes were on procedural measures to reconsider an amendment that had been attached to S.5 during committee. Those who favored a stronger FDA wanted to revisit the committee's decisions and voted "yes" on this measure. The third vote was a vote on the Bailey amendment prohibiting the FDA from regulating pharmaceutical advertising. Proponents of reform voted "no" on this measure, while most opponents of reform voted to pass it.<sup>11</sup>

We conduct probit regressions of these three votes in the 74<sup>th</sup> Congress. Our regressors are chosen to unearth patterns of support for FDA-strengthening regulation before the sulfanilamide disaster. We first include two general measures of ideology or voting propensity, namely first and second-dimension D-NOMINATE scores (Poole and

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<sup>11</sup> Some friends of reform who were also favorable to increased FTC jurisdiction of the economy voted for the Bailey amendment as well. The FTC had powerful friends in the House, not least among Brandeisian liberals who saw the commission as the best hope for a Progressive policy of economy wide central management and antitrust. This was the wisdom of Bailey's measure, to have split economic liberals from the FDA by sending them headlong into an embrace with the Commission.

Rosenthal 1998). We also include the senator's party (1 if Democrat) and the underlying Democratic strength of his constituency, measured by the percentage of vote for FDR in the 1932 election. To this we add a variable measuring the shift in voter support for FDR from 1932 to 1936 as a way of measuring political trends within each state. We also include demographic and economic variables measuring the state's rate of unemployment in 1930, the percentage of its residents aged 18-20 in school, the percentage of its residents who were illiterate as defined by the Census, the percentage of its residents who were African-American. To these we add a "South" dummy variable indicating the states of former Confederacy.

To test industry capture and rent-seeking hypotheses, we employ two variables measuring the presence of organized patent-medicine and pharmaceutical manufacturers in a state. The first measures the number of industry members of the Proprietary Association whose headquarters were in a state. The second measures the number of primary (above associate) members of the United Medicine Manufacturers' Association whose headquarters were in a state. Table 1 gives the summary statistics for these and other variables used in our analyses.

[Tables 1 and 2 about here.]

The vote regressions in Table 2 suggest several factors. First, the first dimension D-NOMINATE score has a negative coefficient estimate in the first two regressions and a positive estimate in the third. Since higher scores indicate more conservative members, this result implies that more liberal senators were more likely to vote for the first two measures and less likely to vote for the third. Conditioning on this effect, Democrats appear to be slightly more likely to vote against FDA-strengthening legislation, but these coefficient estimates are statistically indistinguishable from zero. The variables measuring

support for FDR are also insignificant, suggesting that underlying Democratic support in one's constituency did not, net of other factors, induce more or less support for reform.

A key result from the Table 2 regressions is that rent-seeking hypotheses are strongly rejected. The variable measuring UMMA firms headquartered in a state is negatively associated with “yes” votes for the first two reconsideration measures and positively associated with votes for the Bailey amendment. In other words, much as Jackson (1970) has argued, pharmaceutical interests aligned themselves against the legislation, and their legislative representatives followed suit. The variable measuring state-level presence of proprietary manufacturers is insignificant at the  $p < 0.05$  level in all regressions.<sup>12</sup> In addition, senators from states with higher unemployment rates were more likely to support the reconsideration measure, which may reflect anticipated effects of tighter regulation upon proprietary manufacturers in the state. This result is not, however, predicted by a rent-seeking perspective.

Rent-seeking and industry capture explanations are not, then, supported by our probit regressions. Indeed, a hypothesis which runs counter to the capture perspective receives strong support. Affected industries, particularly the organized pharmaceutical firms that would have benefited from removed proprietary competition, nonetheless agitated against the legislation, and their representatives were more likely to vote against FDA-strengthening measures.

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<sup>12</sup> The coefficient estimate for the PA measure does achieve significance at the  $p < 0.10$  level in the model for the first reconsideration vote, but this is due to the fact that this measure is highly correlated ( $\rho = 0.5598$ ) with the UMMA measure. Once the UMMA measure is removed, the coefficient estimate for the PA measure in this model switches sign and becomes insignificant ( $b = -0.00029$ ;  $z = -0.019$ ). This is not true for the UMMA measure, which remains negative and statistically significant in the first two models and positive and statistically significant in the third model when the PA measure is removed.

Indeed, pharmaceutical and proprietary opponents of the Copeland bill won the early battles. While the 1936 election confirmed FDR's popularity, strengthened the hand of liberals in the Democratic Party, and solidified Democratic congressional majorities, it did not generate added momentum for passage of new pharmaceutical regulation. Perhaps the most important reason was the rise of the Conservative Coalition in Congress, a cross-party alliance of Southern Democrats and Republicans that frustrated many of Roosevelt's legislative initiatives through voting and through control of the House Rules Committee (Patterson 1967; Schickler 2001). For this reason, the challenge for Copeland and FDA officials was all the greater. Some of the most steadfast opponents of regulatory reform had just become more institutionally formidable.

#### IV. The Sulfanilamide Tragedy of 1937

In the summer of 1937, Royal Copeland confided to friends and colleagues that S.5, along with other hopes for strengthening the Food and Drug Administration's power over the pharmaceutical market, was dying. Months later, the FDA began to hear reports of several deaths in Tulsa, Oklahoma, associated with a proprietary drug called "Elixir Sulfanilamide," an anti-infective drug manufactured by the patent medicine concern Dr. Massengill, of Bristol, Tennessee. FDA officials began investigating the Tulsa deaths, but as they did so, a number of other reports of mortality and morbidity, many of them among children, were making rounds in medical and regulatory networks.

Dr. Massengill's Elixir Sulfanilamide was manufactured as part of a larger trend toward the use of sulfanilamides in the 1930s. Popular in Europe for the treatment of common colds, pneumonia and other infections, sulfanilamide was now making its way into many medicines manufactured in the U.S. FDA officials therefore suspected that the

problem lay not in the sulfanilamide itself but rather in the elixir solution in which it was suspended for pharmacological delivery. Dr. Massengill's solvent, as it turned out, was diethylene glycol, which remains an essential ingredient in antifreeze and is highly toxic even in small doses.

Dr. Massengill's Elixir Sulfanilamide began to ship to localities from three distribution points – New York City, Bristol, and San Francisco – in September 1937. By late October, seventy-three persons had perished in ways that doctors could directly attribute to having consumed the elixir. Another twenty deaths were suspected to be related to the drug, but the FDA and doctors lacked sufficient autopsy evidence to make a direct link in these cases. In the fall of 1937, an emergency session of the Congress called upon the Department of Agriculture to make a report regarding the tragedy, and the Secretary published a highly detailed report of the deaths that was cited repeatedly in the press and in congressional testimony. At the end of this document, the USDA published a map showing all of the shipment points to which the elixir had been distributed, as well as all localities in which any deaths occurred, as well the number of deaths occurring in a locality. A photocopy of this map appears in Figure 1.

[Figure 1 about here.]

As it turns out, the deaths from sulfanilamide were not as widely distributed, and the public outcry was not as broad, as blunt scholarly descriptions would have us believe. Jackson (1970: 159) reports that "Fatalities took place in fifteen states, as far east as Virginia and as far west as California." Yet he fails to mention that most of the deaths occurred in Southern and "border" states, and that some states of the former Confederacy were spared relative to others. There were six deaths in East St. Louis, Illinois, and another eight in Charleston, South Carolina. Louisiana experienced no fatalities, while Oklahoma experienced 11 and Mississippi 21. Part of the problem is that the map, which is

in the legislative archives of the House of Representatives, was not published with the Secretary's report. As a result, USDA officials and members of Congress saw the map, but the public (as far as we can tell) did not. Yet the concentration of deaths (and shipments) suggests something about the mechanisms by which the drug was propagated through a large population of consumers. The prescription and consumption of elixir sulfanilamide was probably dependent upon local referral networks and the idiosyncratic practices of individual physicians.

[Table 3 about here.]

In order to get a richer understanding of the sulfanilamide tragedy, we conducted maximum likelihood count regressions of the number of deaths and the number of towns receiving shipments of elixir sulfanilamide, using two different levels of geographic aggregation (state and county). These analyses appear in Table 3, which reports the results of four negative binomial regression analyses. In each analysis, one of two variables – (a) the number of towns receiving shipment in a county/state or (b) the number of deaths in a county/state – is regressed upon several economic and demographic variables. These include all of the measures used earlier to proxy for education, literacy, racial composition of the population, unemployment, and retail/wholesale composition of the local economy. To these, plus the south dummy used earlier, we add the percent of the population that is in a classified “rural” area (farm and non-farm) and the log of value-added in manufacturing (a measure of aggregate wealth). The rural measure in particular is one that we hope will help to characterize some of the information networks that may have influenced prescription and consumption of elixir sulfanilamide.

The count regression analyses show that the Massengill Company was more likely to ship elixir sulfanilamide to the South, to areas where the population was less educated, and both (1) to areas that were characterized by greater manufacturing value-added and (2)

areas with more population in rural residence. The percentage population rural variable is insignificantly related to shipments and deaths in the county-level analyses, but significantly related in the state analyses. The reason probably has to do with the large number of rural counties in Southern and middle Western states, which have many more counties per state than do eastern and Pacific Coast states. Conditioned on the number of towns receiving shipment, deaths were unassociated with all of the variables in our analyses except the Southern dummy, a result which may simply imply that consumption conditional on shipment was higher in Southern states than in non-Southern states.

For several reasons, the sulfanilamide tragedy was a highly evocative and memorable drama. First, USDA officials and news reports connected the deaths together in a way that wove the entire affair into a single narrative, making it ready for consumption by news hungry reporters and editors. Many of the deaths were, moreover, among young children who had taken the drug to combat an infection. The most widely known story was prompted by a letter from Mrs. Maise Nidiffer of Tulsa – whose six-year-old daughter Joan died from taking the drug – to President Roosevelt. Nidiffer wrote of her daughter’s harrowing death, “her little body tossing to & fro...& that little voice screaming with pain and it seems as tho it drive me insane [sic].” She pleaded with the president that he would “take steps to prevent such sales of drugs that will take little lives & leave such suffering behind and such a bleak outlook on the future as I have to-night.” Along with the letter she enclosed a photograph of her smiling but now deceased child, a print that made its way into several newspaper report and into the USDA report on the tragedy.<sup>13</sup>

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<sup>13</sup> Maise Nidiffer to President Roosevelt, November 8, 1937; copy in typescript “Report to the Secretary of Agriculture on Deaths due to Elixir Sulfanilamide Massengill,” National Archives I, RG 46, SEN75A-F674.

The reaction to the disaster was not simply confined to deaths but also to fear of numerous medications marketed under the title of “Elixir,” as well as fear of other sulfanilamide drugs that were not suspended in a diethylene glycol solution. Worried consumers flooded FDA investigators and county and state medication societies with questions about whether they had taken a deadly medication, or whether anything in their medicine cabinet was safe (Jackson 1970: 159-160). For this reason, the pattern of *shipments* of Elixir Sulfanilamide Massengill was just as important politically as the pattern of deaths it caused. Virtually every town that received at least one shipment of the Elixir later hosted several or more FDA investigators, state food and drug regulators, members of state and local presses, and visitors from local and state medical societies.

The success of the FDA in quickly ridding the country of the elixir shipments was notable and noted. By December 1937, FDA officials had removed 99.2 percent of the 240 gallons of the elixir that were originally sent out in September. Fred B. Linton published a pamphlet entitled *Federal Food and Drug Laws – Leaders Who Achieved their Enactment and Enforcement* (Jackson 1970: 160). Linton’s pamphlet offered a horrifying counterfactual: had the entire shipment of Dr. Massengill’s Elixir Sulfanilamide been consumed, and had deaths occurred in the same proportion as they had to earlier levels of consumption, over 4,500 persons would have died from the elixir.

Despite the success of the FDA in cleaning up Massengill’s mess, observers keenly noted one other detail of the affair. Technically nothing in the elixir sulfanilamide disaster implied that the Massengill Company had broken a single law. There was little basis in federal statute for prosecuting Bristol. The only charge against Massengill that stuck was an arcane mislabeling charge, namely that “elixir” implied alcoholic content yet “Elixir Sulfanilamide” contained no alcohol. Numerous commentators noted that this discrepancy

pointed to obvious faults in the 1906 statute and the need for reform (Jackson 1970: 156-57).

## V. The Sulfanilamide Tragedy and the Passage of the Food, Drug and Cosmetic Act of 1938

Congress acted quickly in the wake of the sulfanilamide tragedy.<sup>14</sup> On December 1, 1937, less than two months after the first sulfanilamide deaths became known, Copeland introduced a new measure to replace S. 5. S. 3073 had many of the provisions of S. 5, but added a crucial pre-market stage of regulatory review. The bill required manufacturers to supply the USDA with records of their clinical and non-clinical experiments, a list of the drug's ingredients, a plan for manufacturing practices, and examples of labels. The Secretary of Agriculture would then certify the drug for sale or give reason why the drug was refused marketability. Although a proprietary trade journal warned that under S. 3073, "the Food and Drug Administration would become absolute dictator, the overlord of the drug industry." After referral to the Committee on Commerce, Copeland brought S. 3073 to the Senate floor for a vote in May 1938, where it passed unanimously. After an extended discussion in the House, and inter-chamber bargaining in the Conference Committee, Roosevelt signed the bill into law on June 25, 1938.

For historical purposes, the essential puzzle is this: Why did Congress move from a highly fractious treatment of the bill in one session (the 74<sup>th</sup> Congress in 1935) to a generally unanimous approval in the next session (the 75<sup>th</sup> Congress in 1937-1938)? There are several possible explanations other than the thalidomide tragedy, not least a host of possible narratives connected to the 1936 general election. We discuss these below.

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<sup>14</sup> We direct readers to more detailed accounts, namely Jackson (1970) for more specifics than we can provide here.

For now, before examining this transition, we note that the data with which we can do so is rather limited. We have none of the House votes at our disposal, and all we know about the final outcome of the Senate is that it was unanimous. As a result, our puzzle at this juncture is a puzzle about why Senate opponents of FDA-strengthening legislation voted unanimously for a more liberal bill (S. 3073) than the one they voted against in 1935 (S. 5). Several possibilities related to the 1936 election are evident. It might be that most of the opponents were replaced by more liberal, pro-regulatory members. Another possibility is that increased competition from liberal Democrats in the home states and districts of conservative opponents may have led otherwise recalcitrant conservatives who remained in the 75<sup>th</sup> Congress to adopt a more pro-regulatory stance, as a way of making peace with FDR or to demonstrate to concerned voters that they could be friendly to some kind of consumer protection regulation.

[Figure 2 here.]

All available evidence casts severe doubt upon these possibilities. Before considering quantitative evidence, we note that the 75<sup>th</sup> Congress was famous not for its liberalism but for its conservatism, namely the institutional emergence of the Conservative Coalition and its hostile takeover of the House Rules Committee. This coalition effectively frustrated many of Roosevelt's New Deal initiatives. Figure 2 sheds some light upon the possibility of change in the composition of the Senate. Using DW-NOMINATE medians that are directly comparable over time, we observe that the Senate did in fact become more "liberal" in its voting propensity from the 74<sup>th</sup> Congress to the 75<sup>th</sup> Congress. Yet the Democratic party was less liberal in its voting behavior in the 75<sup>th</sup> Congress than it was in the 73<sup>rd</sup> (and the 72<sup>nd</sup>), during which Copeland's bill was under consideration. Nor is there appreciable change in the Republican median. The chamber median shift, then, must have been driven by the replacement of conservative Democrats and Republicans with liberal

Democrats. At the aggregate level, this in fact occurred. The Democratic majority in the Senate went from 69-25 in the 74<sup>th</sup> Congress to 76-16 in the 75<sup>th</sup> Congress. In order for this shift to help explain the movement in regulation voting, however, it must have been the case that opponents of S. 5 were more likely to be replaced than those Senators voting for it. We create a "replacement" variable scored 1 if a Senator voting on FDA-related legislation in the 74<sup>th</sup> Senate was replaced and 0 if not, and then we regress this variable on the votes for the three bills analyzed in Table 2. The *t*-statistics are -1.45 and -2.16 for the recommitment measures and -0.09 for the Bailey amendment. Only in the case of the second recommitment measure is there a significant relationship. There is indeed nothing resembling a systematic pattern here, and the votes on the Bailey amendment, which killed S. 5 in the 74<sup>th</sup> Congress, are entirely unrelated to

Whether or not the chamber medians were shifting, the reason that replacement and ideological shifts cannot explain the shift in voting is that, before the sulfanilamide deaths became known, the 75<sup>th</sup> Congress took several strong steps to weaken the reform initiative. Copeland's measure had indeed been taken up in the 75<sup>th</sup> Congress early in 1937. Yet FDR had lashed out at the measure in a press conference on February 23. The Commerce Committee had dramatically weakened S.5 and, while it then passed the Senate, it did so over the objections of Copeland, the FDA, and consumers' and women's groups. To make matters worse, the Senate in March 1937 passed the Wheeler-Lea Act giving control over all advertising regulation to the Federal Trade Commission. In the House, meanwhile, Copeland's much-weakened Senate measure was pigeonholed in the Commerce Committee there. The upshot of these developments is that the 75<sup>th</sup> Congress was acting more conservatively on matters related to pharmaceuticals than was the 74<sup>th</sup>.

Shifts in Senate partisanship cannot, then, explain why Congress moved from tightly divided votes over FDA regulation in the 74<sup>th</sup> Congress to unanimous support of a

*more liberal bill* in the 75<sup>th</sup> Congress. (Note that none of these explanations can explain the voting shift in the House either, since the House medians did not change from the 74<sup>th</sup> to the 75<sup>th</sup> Congresses. Since we lack House roll-call votes on the Copeland measure, of course, neither can we explain this shift.) FDR's broadsides against the Copeland measure in February 1937 -- Copeland was the most vigorous Senate opponent of the President's court-packing plan -- suggest one other thing. The shift in legislative fortunes for FDA-strengthening legislation was not one induced by FDR's warming to the Copeland bill. suddenly got on board. If FDR did warm to stronger FDA regulation of patent medicines and pharmaceuticals, this was a shift directly related to the fall 1937 tragedy.

[Tables 4 and 5 about here.]

Our explanation for the shift in Senate support of FDA-strengthening legislation points to the geographically conditional nature of the sulfanilamide tragedy. The deaths -- and just as important, the shipments that caused so much fear and triggered highly publicized visits by FDA inspectors -- were concentrated in areas where opponents of reform in 1935 were more likely to be liberal and less likely, we think, to have adopted an anti-regulatory posture in the first place. Our analysis from this point forward isolates all those Senators who voted no on the first two recommitment measures and "yea" on the Bailey amendment. In numerous bivariate analyses reported in Table 4 and 5, we ask whether sulfanilamide shipments and deaths were more likely to occur among those opponents of reform who were least committed to the anti-regulatory clause in the sense of ideological purity. Table 4 shows the first set of these correlations. It turns out that shipments of Massengill's Elixir Sulfanilamide were more likely to be dispatched to liberal areas than to conservative ones. Yet this relationship is considerably stronger for the South than for the rest of the country. In other words, sulfanilamide shipments and deaths occurred among

the states of those Senators who were least ideologically committed to the conservative coalition.

Whether these legislators were in fact less ideologically committed to anti-regulatory voting is another question that we address in Table 5. The first portion of Table 5 displays bivariate correlations between the sulfanilamide variables and first-dimension D-NOMINATE scores among those who voted against FDA-strengthening legislation in the 74<sup>th</sup> Congress. For those Senators voting against the first recommitment measure or for the Bailey amendment, sulfanilamide shipments and deaths were more likely to occur where these legislators were more liberal on a "left-right" ideology dimension. The second portion of the table conducts a similar analysis, but this time replaces the D-NOMINATE measure with the predicted probability of a vote on the measure in question. These predictions are culled from the models reported in Table 2. Again, the shipments and deaths of sulfanilamide were more likely to occur among those more likely to vote for the reconsideration measures. There is no such relationship for predicted probabilities of favoring the Bailey amendment. Yet this result is likely driven by the fact that the model in Table 2 performs quite poorly for in predicting votes on the Bailey amendment, except for the D-NOMINATE measure, which of course is negatively related to sulfanilamide variables among those voting for the Bailey measure. In other words, sulfanilamide deaths were concentrated among the most ideologically liberal opponents of stronger FDA regulation, and among those who were more likely to vote for stronger FDA regulation, except for that model (for the Bailey amendment) where only ideology itself seem to do the predictive work.

There is some narrative evidence to support our hypothesis that the sulfanilamide deaths peeled liberal members of the anti-regulatory coalition from its ranks and sent them into an embrace of FDA control. In the last, very brief Senate debate on S. 3073 in May

1938, Arthur Vandenburg still expressed his reservations about the measure, but Josiah Bailey, who was the most vociferous and public opponent of earlier reform bills, did not (even though he was apparently on the floor). Bailey's home state of Tennessee suffered an above-average share of sulfanilamide deaths and, it is worth pointing out, was the point of manufacture and principal point of shipment of the deadly product. Bailey was, moreover, hardly the conservative ideologue that Vandenburg was.

At this writing, however, our narrative evidence remains (like our statistical evidence), weak and incomplete. We would like to observe a series of endorsements, announced vote intentions, observable acts of participation (Hall 1997), or some similar measurable index of support for a new law in such a way that individual support for a new measure could be gauged during the fall of 1937. If those who broke from the ranks of the opposition, and those who broke ranks earlier, were more likely to have sulfanilamide shipments and deaths in their constituencies, then our story would receive additional support. Of course, had there been a non-unanimous vote on the final bill in the Senate or the House, we could have regressed changes in votes on the distribution of the deaths and shipments themselves.

We note, moreover, a significant problem with our explanation. It plausibly accounts for the shift in votes from a divisive battle over a weak bill to stronger support for a vigorous law. It does, moreover, perform better than the available alternatives, which are irreconcilable with anti-regulatory posture struck by the early 75<sup>th</sup> Congress. Yet our explanation does *not* explain the convergence of Senators to uniformity, to unanimous support. We cannot at present rule out the hypothesis that the tragedy convinced everybody – whether their constituency was affected or not – that additional regulation was needed. We cannot dismiss the possibility that the symbolic character of the tragedy made regulation more palatable to all those who had previously opposed strengthening the FDA.

There is some evidence against this alternative hypothesis, however. Hardcore opponents of FDA authority continued to speak out against the Copeland legislation, imply that the unanimity observed in the vote was not indicative of a full embrace of the 1938 Act by all those who voted for it. Although the final House margin of passage was "overwhelming" (but also unreported), FDA opponents there continued a vigorous defense of the right of self-medication and loudly voiced their worries about the continued accretion of bureaucratic power to federal agencies.

One possibility is that the sulfanilamide tragedy pushed the Senate over the tipping point by splitting the nascent conservative coalition. In this scenario, the distribution of deaths and shipments removed more liberal members of the opposition from the coalition and converted them into issue-specific supporters of FDA-strengthening legislation.

## Conclusion

We conclude by returning to the counterfactual conditions that guided us in this study. Had sulfanilamide deaths occurred outside the South, we conclude, the act may not have passed. The sulfanilamide tragedy struck at the heart of the patent medicine industry and the Southern roots of self-medication. It struck the states and constituencies of those legislators who were least committed to the increasingly conservative path of Southern politicians.

Yet it is also worth reflecting on the historical context. The sulfanilamide tragedy occurred when the Senate and House were already well informed about alternative regulatory measures facing them. In both chambers of Congress, the FDA had found able and energetic sponsors for FDA reform (Copeland and Tennessee Rep. Virgil Chapman). Much of the costly work of building coalitions behind legislation had already been

accomplished. Had the sulfanilamide tragedy occurred at another *time*, when FDA regulation as the dominant alternative to the status quo was not advanced by bureaucratic leaders, the Act would either not have passed or would have taken a much different form. In this respect, we can with some confidence reject the counterfactual that, had the sulfanilamide tragedy *not* occurred, regulatory reform in food and drugs would not have been on the agenda in the 75<sup>th</sup> Congress. It indeed was on the agenda of the 75<sup>th</sup> Congress in the spring of 1937. This is not to say that pharmaceutical regulation was warmly embraced by that legislature. Our account is in fact stronger to the extent that FDA-strengthening measures were on the agenda but unlikely to be passed.

Our strongest conclusion is a negative one. Rent-seeking and capture explanations of the 1938 Food, Drug and Cosmetic Act fare poorly in explaining either the process of agenda-setting or the votes on regulatory legislation. Indeed, our analyses support not merely the null hypothesis that affected industries were uninvolved in buying protection from the legislative process, but the opposite conclusion that affected industries, including and especially those who stood to profit from entry barriers that would be created in the 1938 Act, were opposed to new regulation.

VARIABLE	Valid N	Mean (Std Error)	Min	Max
Towns to which <i>Massengill's Elixir Sulfanilamide</i> was shipped, 1937	48 states	8.10 (14.10)	0	61
Confirmed Deaths from <i>Elixir Sulfanilamide</i> , 1937	48 states	1.89 (4.24)	0	21
Percentage of State Population African-American, 1930 Census	48 states	9.51 (13.63)	0.06	50.23
Percentage of Population Illiterate (Census Definition), 1930 Census	48 states	4.65 (3.94)	0.79	14.92
Percentage of State Population 18-20 in School, 1930 Census	48 states	22.89 (5.11)	14.31	33.62
Percentage of State Employable Workers Unemployed, 1930 Census	48 states	4.33 (1.71)	1.27	8.19
Retail Value-Added as a Percentage of Whole Value-Added, 1930 Census	48 states	118.42 (71.41)	40.16	373.73
Number of Proprietary Association Firms Headquartered in State, 1935	48 states	4.06 (10.33)	0	67
Number of UMMA Firms Headquartered in State, 1935	48 states	2.35 (4.08)	0	17
Percentage of Two-Party Presidential Vote for FDR, 1932	48 states	59.74 (17.76)	23.76	100
First-Dimension D-NOMINATE SCORE, 74 <sup>th</sup> Senate	106 Senators	-0.15 (0.34)	-0.717	0.763
Vote on First S. 5 Reconsideration Measure, 1935	75 votes	0.54 (0.50)	0	1
Vote on Second S. 5 Reconsideration Measure, 1935	67 votes	0.58 (0.50)	0	1
Vote on Bailey Amendment, 1935	73 votes	0.52 (0.50)	0	1

**Table 2: Probit Analyses of Three Votes on S.5.**  
[Senate Votes, 74<sup>th</sup> Congress]

Variable	S. 5 Amendment Reconsideration [4/1/1935]	S. 5 Amendment Reconsideration [4/2/1935]	Bailey Amendment [4/8/1935]
Constant	1.8371 (1.5636)	<b>3.8839</b> (1.8262)	-1.7690 (1.4917)
D-NOMINATE 1-D	<b>-2.0944</b> (0.8531)	<b>-2.6960</b> (1.0643)	<b>1.8166</b> (0.8019)
D-NOMINATE 2-D	-1.3916 (0.8194)	0.3583 (1.1096)	0.3844 (0.8613)
Party (Democrat = 1)	-0.7572 (0.6857)	-1.3627 (0.8369)	1.0947 (0.6750)
Percentage of State Vote for FDR, 1932	-0.0041 (0.0206)	0.0169 (0.0250)	0.0081 (0.0185)
Change in % of State for FDR, 1932-1936	-0.0103 (0.0321)	-0.0471 (0.0386)	-0.0177 (0.0250)
% of State Population African-American	-0.0445 (0.0396)	-0.0429 (0.0492)	0.0153 (0.0377)
% of State Population Illiterate	-0.1166 (0.0790)	<b>-0.2109</b> (0.0924)	0.1061 (0.0818)
% of State Population Educated	-0.0879 (0.0494)	<b>-0.2119</b> (0.0683)	0.0370 (0.0469)
% of State “Gainful Workers” Unemployed	<b>0.4181</b> (0.1327)	<b>0.5893</b> (0.1736)	-0.0815 (0.1134)
Retail Sales as % of Wholesale	-0.0010 (0.0026)	-0.0009 (0.0028)	-0.0007 (0.0025)
South	<b>2.1259</b> (0.9639)	1.1556 (1.5649)	-0.8767 (0.8770)
Number of Proprietary Association firms in state	0.0375 (0.0215)	0.0311 (0.0245)	-0.0179 (0.0178)
Number of UMMA firms in state	<b>-0.2596</b> (0.0829)	<b>-0.2888</b> (0.0929)	0.0882 (0.0541)
N (df)	83 (69)	75 (61)	81 (67)
LLF	-43.512	-33.796	-49.307
Pseudo-R <sup>2</sup>	0.2417	0.3396	0.1139

Notes: Asymptotic standard errors in parentheses. Bold coefficient estimate implies statistical significance at  $p < 0.05$  (two-tailed test). UMMA firms and Par firms variables correlated at 0.5598. Removal of UMMA firms variable results in negative but insignificant estimate on PA firms variable.

**Table 3: Negative Binomial Regression Analyses  
Of Shipments and Deaths from Elixir Sulfanilamide, 1937**

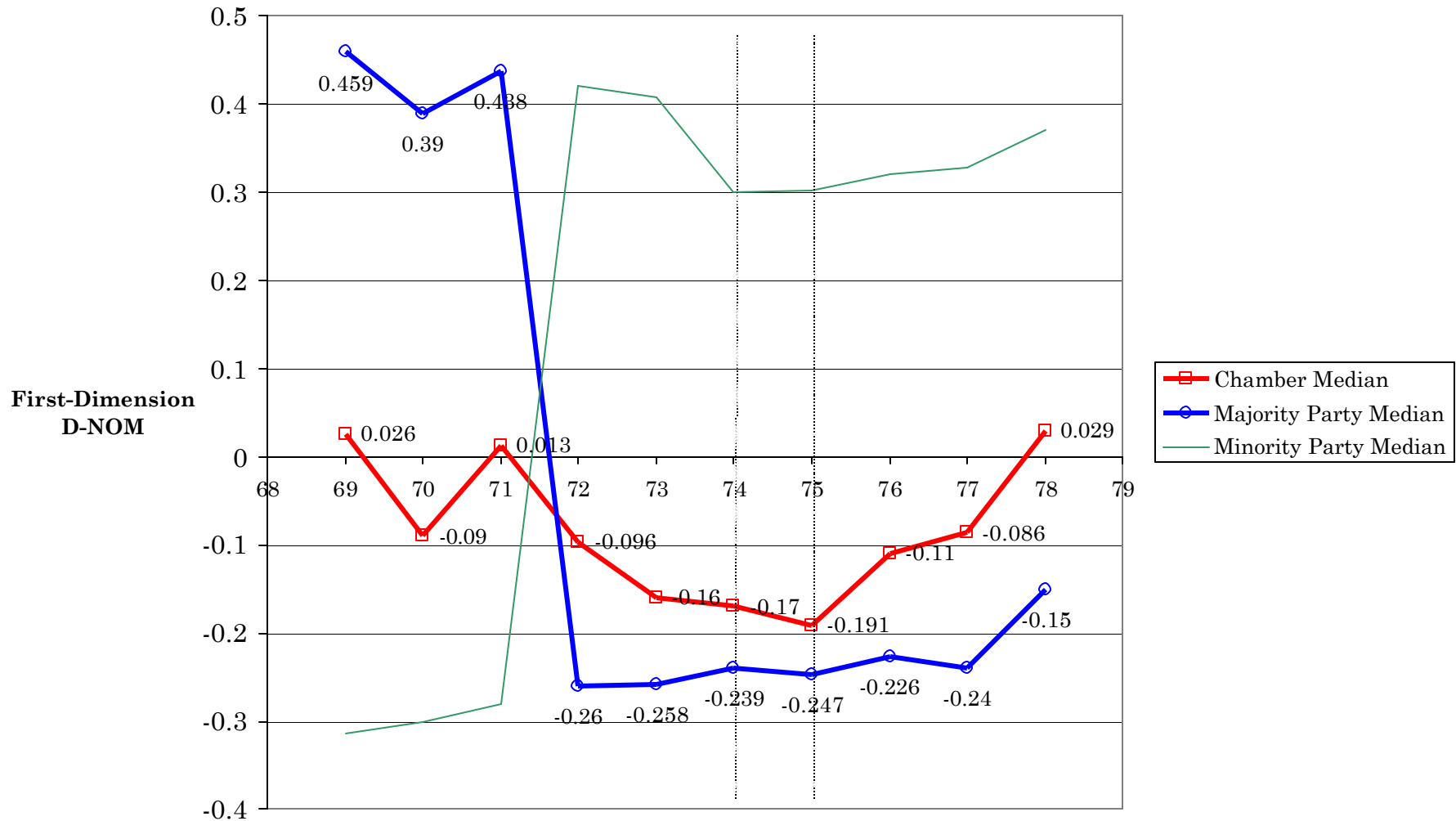
VARIABLE	Shipments [State]	Shipments [County]	Deaths [State]	Deaths [County]
Constant	<b>-22.1858</b> (5.2501)	<b>3.1175</b> (0.7132)	<b>-24.7381</b> (13.4956)	<b>-8.8145</b> (3.1772)
% of State Population African-American	0.0437 (0.0347)	0.0008 (0.0048)	0.1523 (0.0864)	0.0226 (0.0182)
% of State Population Illiterate	-0.1239 (0.1308)	0.0122 (0.0165)	-0.2928 (0.3153)	-0.0180 (0.0703)
% of State Population Educated	-0.0148 (0.0440)	<b>-0.0240</b> (0.0116)	0.0812 (0.1072)	0.0581 (0.0357)
% of State “Gainful Workers” Unemployed	0.4039 (0.2483)	0.0563 (0.0405)	<b>1.6160</b> (0.6824)	0.0090 (0.1910)
Retail Value-Added as % of Wholesale Value-Added	-0.0096 (0.0058)	0.0000 (0.0000)	<b>-0.0498</b> (0.0229)	0.00001 (0.00004)
South	1.0747 (0.7243)	<b>1.3139</b> (0.1801)	0.5197 (1.3894)	<b>2.5361</b> (0.8599)
ln(Value-Added Manufacturing)	<b>1.3668</b> (0.2731)	<b>0.1326</b> (0.0463)	0.6521 (0.6214)	0.0717 (0.2082)
% of County Population Rural (farm & non-farm)	<b>0.1056</b> (0.0278)	-0.0040 (0.0041)	<b>0.1936</b> (0.0816)	-0.0143 (0.0179)
Number of towns receiving sulfanilamide shipments	-----	-----	<b>0.0450</b> (0.0225)	<b>3.2789</b> (0.4907)
ln(dispersion) [se]	<b>-0.1738</b> (0.2973)	<b>0.6520</b> (0.1962)	<b>0.3268</b> (0.4598)	<b>2.4090</b> (0.2354)
N	48	2563	48	2563
LLF	-109.488	-976.328	-50.799	-167.010

Note: “Shipments” is not actual number of shipments but number of towns in the county/state that received at least one shipment of the elixir.

Table 4: Bivariate Correlation between Shipments of Elixir Sulfanilamide and D-NOMINATE 1-D	
Correlation for Total Sample [n = 106]	<b>-0.3156</b>
Correlation for South Only [n = 27]	<b>-0.5169</b>

Table 5: The Relationship between Sulfanilamide Shipment Incidence and Anti-Regulatory Propensity, 1937 [Senate Votes, 74 <sup>th</sup> Congress]			
Variable	S. 5 Amendment Reconsideration [4/1/1935]	S. 5 Amendment Reconsideration [4/2/1935]	Bailey Amendment [4/8/1935]
<b>Sample vote on bill</b>	“Nay” voters	“Nay” voters	“Yea” voters
<b>Bivariate Correlations</b>			
Correlation btw Shipments and D-NOMINATE 1-D	<b>-0.3366</b>	-0.2474	<b>-0.3485</b>
Correlation btw Deaths and D-NOMINATE 1-D	<b>-0.3234</b>	-0.1937	<b>-0.2825</b>
Correlation btw Shipments and Predicted Yes Vote	<b>0.2173</b>	<b>0.3742</b>	0.0443
Correlation btw Deaths and Predicted Yes Vote	0.1038	<b>0.2554</b>	0.1511
<b>Univariate Regressions</b>			
Regression of D-NOMINATE 1-D on Shipments	<b>-0.0118</b> (0.0054)	-0.0195 (0.0140)	<b>-0.0082</b> (0.0034)
Regression of D-NOMINATE 1-D on Deaths	<b>-0.0373</b> (0.0179)	-0.0249 (0.0230)	-0.0282* (0.0146)
Regression of “Yea” Probability on Shipments	0.0035 (0.0026)	<b>0.0112</b> (0.0050)	0.0004 (0.0013)
Notes: Asymptotic standard errors in parentheses. Bold estimate implies statistical significance at $p < 0.05$ (two-tailed test). * implies statistical significance at $p < 0.10$ . “Univariate regressions” always include a constant term. “Predicted Yea Votes” and “Predicted Nay Votes” based on Table 2 models.			

Figure 2:  
Changes in DW-NOMINATE Medians, 69th-78th Congresses



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