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Sharon B. Jacobs

University of Colorado Law School

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Citation Information

Sharon B. Jacobs, *Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States*, 64 FOOD & DRUG L.J. 599 (2009), available at <https://scholar.law.colorado.edu/faculty-articles/251>.

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Crises, Congress, and Cognitive Biases: A Critical Examination of Food and Drug Legislation in the United States

SHARON B. JACOBS*

I. INTRODUCTION

Despite recent criticism, it is generally acknowledged that the United States has one of the world's most effective systems of food and drug regulation. Our system is of relatively recent vintage—the first comprehensive federal food and drug legislation was not passed until 1906—and was by no means born fully formed. Like most regulatory programs, it grew to accommodate new discoveries and changing priorities.

When the first pieces of federal food and drug legislation passed in the early 1900s, the most pressing concerns related to the proliferation of “filled” food products and ineffective medications. Today, some of the primary threats come from tainted overseas imports and new blockbuster medications with subtle yet dangerous side effects. Over the last century, food and drug law has evolved to encompass such concerns. But that evolution has taken the form of a series of fits and starts rather than a smooth and carefully planned expansion.

In 1992, then-Professor of Administrative Law Stephen Breyer published *Breaking the Vicious Circle*, a criticism of the way the United States regulates risk.¹ Breyer described the method by which regulatory problems are identified and addressed as a feedback loop whose ultimate result is to undermine the effectiveness of the regulatory process. The first step in this loop is public perception of risk, which Breyer argued is often irrational but nevertheless unfailingly produces a Congressional reaction. In the second step, Congress responds to public fears, often by enacting statutes that overemphasize the extent of the problem and impose overly-detailed requirements on the government agencies that must address it. The final step concerns agency regulation under these statutory mandates. Scientific uncertainty surrounding risk estimates creates an inevitable gray area in which agencies exercise discretion that is supposedly grounded in topical expertise. In reality, however, the limits of scientific knowledge mean that agencies are highly susceptible to political influence. The resulting process, Breyer concluded, produces risk determinations that are a hodgepodge of “science, fact, value, and administration” and lead to both overregulation and arbitrary and uncoordinated agenda-setting.²

Breyer focused on the third step in this process, proposing regulatory reforms to improve the evaluation and comparison of risks at the agency level. This article, by contrast, will emphasize the conjunction of the first two steps: public perception and congressional reaction. In particular, it will focus on distortions that may occur when a public outcry is triggered by a highly visible safety event. Its aim is to elaborate on the mechanism by which risk events influence the public psyche, and how that influence

* Ms. Jacobs received her J.D. in 2009 from Harvard Law School and is a first year Associate at Covington & Burling LLC. The views expressed in this article are those of the author and in no way represent the views of, and should not be attributed to, Covington & Burling LLC.

¹ STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* (1993).

² *Id.* at 51.

creates the impetus for legislation. It chronicles a pattern of such "crisis legislation" in the evolution of food and drug law, from the 1902 Biologics Control Act to the Food and Drug Administration Amendments Act of 2007 (FDAAA).

The phenomenon of crisis legislation is by no means confined to food and drug law. In 1936, John B. Andrews wrote despairingly that even meritorious labor legislation tended to "languish for years in legislative halls until some dramatic event—a factory fire, a mine catastrophe, the sinking of an ocean liner—spurred the public and their representatives to insist upon protective legislation."³ More recently, the 9/11 attacks on New York City and Washington, D.C. initiated a legislative scramble that resulted in the passage, scarcely more than a month after the planes hit the twin towers, of the USA PATRIOT Act, a voluminous piece of legislation that vastly expanded the executive branch's law enforcement capabilities.⁴ The current economic crisis also produced a rapid legislative response. In September of last year, House Speaker Nancy Pelosi called for a speedy legislative reply to the financial crisis, noting that in "a less urgent situation, we could take all the time in the world, to have an academic discussion of many possibilities. But right now, as I have said before, time is of the essence."⁵ The Emergency Economic Stabilization Act of 2008, which provided \$700 billion dollars to the federal government to purchase troubled mortgage-related assets and provide banks with cash infusions was passed, less than a month after the financial crisis became front page news.⁶

What is remarkable about the history of food and drug legislation in the United States, however, and what makes it an appropriate subject for this inquiry, is the sheer number of key statutes that have been passed in the wake of highly publicized safety crises. It therefore provides fertile ground for the study of Breyer's hypothesis about the potential pathologies of risk legislation and regulation.

The article proceeds as follows: Part I provides a historical overview of prominent food and drug laws enacted this century and posits that their passage was precipitated by highly-publicized calamities. Part II elaborates on the mechanics of Breyer's "vicious circle," while Part III proposes several additional models that might explain the Congressional behavior described in the case studies. The last Part offers some modest suggestions toward ensuring that legislative responses to crises are as thoughtful and well-tailored as possible, even while concluding that crisis legislation is here to stay.

II. CASE STUDIES

This section provides a brief history of key food and drug laws, tracing their connection to calamities in the last century. Crisis is not the sole factor motivating food and drug legislation, even in the cases examined below. Dissatisfaction with earlier legislation, interest group pressures, and personal legislative agendas, for example, also play a part. This article's findings do suggest, however, that crises can play a significant role in focusing public and congressional attention on the need for reform in the face of competing priorities. As in the passage of the Federal Food, Drug, and Cosmetic Act of 1938 and the Drug Amendments of 1962, crises

³ John B. Andrews, *The Tragedy of Silicosis*, 26 Am. Lab. Legis. Rev. 3, 3 (1936).

⁴ Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Pub. L. No. 107-56, 115 Stat. 272 (2001). Many of the Act's provisions have since been held unconstitutional.

⁵ Pelosi Remarks After White House Meeting on Crisis in Financial Markets, Sept. 25, 2008, available at <http://speaker.house.gov/newsroom/pressreleases?id=0841>.

⁶ Emergency Economic Stabilization Act of 2008, Pub. L. No. 110-374, 122 Stat. 3765 (2008).

may provide the triggers necessary to overcome legislative inertia and to move bills that languish in the halls of Congress. Or, as in the case of the 1906 Pure Food and Drug Act or the food and drug safety provisions of FDAAA, they may be the impetus for the drafting of new legislation.

A. Early Regulation

Congressman Hendrick B. Wright introduced the first comprehensive federal food purity legislation in 1879 in response to new information about the adulteration of butter, margarine, alcohol, and coffee.⁷ Due primarily to the strength of industry interests, however, no pure food bill was approved by either house of Congress during the 1800s.⁸

Shortly after the turn of the century, the deaths of children from contaminated vaccines provided the impetus for the passage of the Biologics Control Act of 1902. In one incident, several children died in St. Louis as a result of contaminated diphtheria antitoxin.⁹ In another case, nine children died in Camden, New Jersey, after being inoculated with smallpox vaccine.¹⁰ Newspapers across the nation carried the stories.¹¹ One opinion piece written shortly after the outbreak concluded that “the public ought to be as careful about where its anti-toxin comes from as about where its milk and water come from.”¹² A *New York Times* editorial went further, condemning federal legislators for failing to address vaccine safety and urging swift action to fill the breach.¹³ Congress responded with the Biologics Control Act, which required federal licensing of all biological products sold in the United States, and of all biologics manufacturing establishments. It also gave the federal government heightened inspection authority, as well as the power to punish violations of the Act by fines or imprisonment.¹⁴

It would be nearly three decades, however, before the passage of the first comprehensive federal food and drug legislation, the Food and Drugs Act of 1906. The final passage of that Act after years of debate was due to a combination of factors, including the long-time dedication of Harvey W. Wiley, chief chemist at the Department of Agriculture. However, it is often noted that the publication and popularity of *The Jungle*, by Upton Sinclair, detailing the scandalous practices of America’s meat packing industry, led to the public outrage which jolted the legislature into action.¹⁵

⁷ See PETER BARTON HUTT, RICHARD A. MERRILL, AND LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 9 (3d ed. 2007); ARTI BHATIA, *ENCYCLOPAEDIA OF HEALTH AND NUTRITION* 86 (1938).

⁸ James Harvey Young, *The Long Struggle for the 1906 Law*, in MEREDITH A. HICKMANN ED., *THE FOOD AND DRUG ADMINISTRATION (FDA)* 19 (2003).

⁹ *Held Responsible*, DALLAS MORNING NEWS, Nov. 19, 1901, at 3.

¹⁰ Later studies on rats revealed that the Camden vaccine was in fact tetanus-free, and that the infections likely occurred as a result of improper care of the inoculation site. *Camden's Lockjaw Epidemic*, N.Y. TIMES, Nov. 21, 1901, 1.

¹¹ See, e.g., *Experiments with Vaccination*, OREGONIAN (Portland), Nov. 21, 1901, at 4; *White Raft's Experiment: No Symptoms Have Developed After 72 Hours*, COLUMBUS DAILY ENQUIRER (Columbus, GA), Nov. 22, 1901, at 6; *Two More Deaths After Vaccination*, Tuscon Daily Citizen, Nov. 23, 1901, at 1; *Tetanus Claims Nine Victims in New Jersey*, IDAHO STATESMAN, Nov. 28, 1901, at 2.

¹² *Anti-Toxins for Anti-Toxins*, OMAHA WORLD HERALD, Nov. 6, 1901, at 4.

¹³ *Commercial Virus and Antitoxin*, N.Y. TIMES, Nov. 19, 1901, at 6.

¹⁴ Act of July 1, 1902 (Biologics Control Act), Pub. L. No. 57-244, 32 Stat. 728.

¹⁵ See, e.g., HUTT et al., *supra* note 7, at 10 (“Upton Sinclair . . . will forever be remembered as the person who galvanized Congress and the country to bring federal food and drug legislation to fruition after 27 years of consideration.”).

B. *The 1938 Federal Food, Drug, and Cosmetic Act*

The annual Food and Drug Administration (FDA) report in 1933, noted that the 1906 Federal Food and Drugs Act, then over a quarter of a century old, suffered from serious defects. For one thing, the Act did not cover cosmetics. Language including cosmetics was dropped from the bill in response to industry pressure, and while the absence of regulation for cosmetics did not seem unduly problematic at the time, growth in the cosmetics industry after 1906 made regulation desirable.¹⁶ Also missing from the Act was authority to define legal standards for food or to inspect warehouses. Furthermore, the definition of a "drug" was overly narrow, making it difficult to regulate medical devices and purported dietary remedies.¹⁷ For those drugs that were covered, purely misleading statements went unregulated—the Act governed only "false and fraudulent" statements about drugs found on their packaging material.¹⁸

The Secretary of Agriculture, who was originally tasked with enforcement of the 1906 Act, and the FDA, when it took over the Act's enforcement in 1927, called repeatedly for new legislation to address the law's shortcomings. It was not until 1933, however, that the Senate finally took up a bill to revise the 1906 Act.¹⁹

The Department of Agriculture drafted the first version of the bill. It was introduced on June 12, 1933 by Senator Royal S. Copeland of New York, a physician and former Health Commissioner of New York City.²⁰ The bill brought cosmetics and medical devices within the FDA's ambit. It also prohibited false advertising of food, drugs, and cosmetics, supplemented labeling requirements and imposed stricter controls on false labeling and new controls on advertising.²¹

The FDA, no doubt cognizant of the persuasive power of tragedy, cited several instances of consumer injury in support of the new legislation. These examples, including "Koremlu Cream," a depilatory containing poisonous thallium acetate that caused severe injury to users, Marmola, a risky "slenderizing" compound, and "Radithor," a radium solution that caused a high-profile death,²² were almost certainly included to communicate a sense of urgency to the legislature.

The extensive changes proposed by the first bill met with violent opposition, especially from affected industry. In January of 1934, Senator Copeland replaced it with a second draft,²³ which died in the Senate Committee on Commerce after

¹⁶ CHARLES O. JACKSON, *FOOD AND DRUG LEGISLATION IN THE NEW DEAL* 4 (1970).

¹⁷ ARTHUR PHILIP GREELEY, *THE FOOD AND DRUGS ACT, JUNE 30, 1906: A STUDY WITH TEXT OF THE ACT, ANNOTATED*, Chapter III § 23 (1907). While noting that the term "drug" is to be given "the broadest possible meaning," the Act gives as examples of a drug pharmaceutical preparations, plasters, salves, ointments, and medicinal soap, failing to list any product analogous to a medical device or dietary remedy. *Id.*

¹⁸ See James M. Best, *Significance of the Proposed Moore Amendment*, 4 *Food Drug Cosm. L.Q.* 71 (1949); see also CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 24-25 (1938) (citing a 1917 Bureau of Chemistry report).

¹⁹ See CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 25 (1938).

²⁰ See *id.* According to James Harvey Young, Senator Copeland did not even read the draft bill, which he introduced during an emergency session of Congress on June 12, 1933. JAMES HARVEY YOUNG, *THE MEDICAL MESSIAHS* 164 (1967). Rexford G. Tugwell, the Assistant Secretary of Agriculture, had urged that the hastily drafted bill be as tough as possible so that its proponents would have more provisions to concede in the inevitable negotiations with industry. JACKSON, *supra* note 17, at 27, 34 (citing an interview with Rexford Tugwell, June 7, 1968).

²¹ See CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 25-26 (1938).

²² *Id.* at 26-27.

²³ *Id.* at 51-52.

several hearings.²⁴ When introducing a third draft in February of 1934, Senator Copeland noted that he “thought [he] had had all the troubles one could in this life,” but that he had never “had so many worries and so much trouble” as in connection with the earlier versions of the bill.²⁵ The new draft created various advisory boards made up of interest group representatives in order to disperse some of the power previously concentrated in the Secretary of Agriculture.²⁶ It also removed the requirement that manufacturers list formularies on proprietary drug labels, limited a publisher’s liability for accepting false advertisements, and eliminated the idea of establishing multiple quality grades for food products.²⁷ The bill was reported out of committee on March 15, 1934,²⁸ but the full Congress adjourned without taking further action.²⁹ In its 1934 annual report, the FDA predicted that the debate had “aroused public interest in the purity of the food and drug supply,” which would “unmistakably grow into a united demand for effective legislation which cannot be gainsaid.”³⁰ Despite the agency’s optimism, it would be another four years before the public’s interest would be sufficiently aroused to spur passage of the legislation. One author noted in late 1934 that “[a]ll is quiet on the public front”³¹

On January 3, 1935, the newest incarnation of the bill was introduced in the Senate and referred to committee.³² Again, the bill was not demonstrably different from earlier versions, although it did make concessions to industry with respect to proprietary drug labeling requirements and advertising restrictions.³³ The most contentious issues in the new legislation were provisions governing seizure of products that presented a health risk and whether the FDA or the Federal Trade Commission (FTC) should be responsible for enforcement of advertising requirements.³⁴ A conference committee reached a compromise that passed the Senate. However, as a result of the disagreement over FDA and FTC jurisdiction, as well as public apathy, the bill died in the House.³⁵

Reasons for the delay in enacting the food and drug bill were myriad. Internal congressional disagreement about the proper scope of the legislation was certainly one factor. Also, as noted above, industry lobbyists were strongly opposed to the bill. President Roosevelt, who supported the bill but gave it relatively low legislative priority, wrote in 1933 that he hoped “we can get it through in spite of the lobbies.”³⁶ But the country was in the throes of the Great Depression, and both Roosevelt and Congress had more immediate concerns.

²⁴ *Id.* at 67.

²⁵ *Congressional record, House*, Feb. 19, 1934, at 2728.

²⁶ *See DUNN, supra* note 21, at 68-69.

²⁷ JACKSON, *supra* note 16, at 51.

²⁸ DUNN, *supra* note 21, at 92.

²⁹ *Id.* at 190.

³⁰ *Id.*

³¹ JACKSON, *supra* note 16, at 55 (citing Robert Swain, *Drug Topics*, 4 FDA Scrapbooks, Dec. 10, 1934). In a 1938 article, David F. Cavers, an advisor to the USDA on food and drug administration from 1933-34, lamented the fact that the Act “never became the object of widespread public attention, much less of informed public interest.” Cavers blamed both the national press and President Roosevelt for failing to bring the Act to the public’s attention. David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 *Law and Contemporary Problems* 2, 3 (1938).

³² DUNN, *supra* note 21, at 191.

³³ JACKSON, *supra* note 16, at 76.

³⁴ DUNN, *supra* note 21, at 598.

³⁵ *Id.* at 633; *see also* JACKSON, *supra* note 16, at 84-85.

³⁶ JACKSON, *supra* note 16, at 27 (citing correspondence between Roosevelt and Harvey Cushing, April 21, 1933, at 375, Roosevelt Papers).

In an effort to counter popular apathy and industry propaganda, the FDA published a series of posters demonstrating the shortcomings of the 1906 law. These posters, dubbed the "Chamber of Horrors," depicted dangerous products such as Koremlu and Radiathor, along with information about those injured or killed as a result of their use.³⁷ The posters went on display at the Century of Progress Exposition in Chicago, were featured prominently in FDA offices around the country, and were loaned out to organizations upon request.³⁸ The posters generated widespread attention, but failed to produce the kind of organized support required to secure the bill's passage.³⁹

Then, tragedy struck in the form of Elixir Sulfanilamide. In 1937, the Massengill Company, a reputable pharmaceutical manufacturer in Tennessee, created a new liquid version of sulfanilamide, a drug used to treat streptococcal infections, by dissolving the drug in diethylene glycol. The solvent was later revealed to be a deadly poison. The existing drug laws did not require safety testing, however, and elixir sulfanilamide was not tested for toxicity before its release, even on animals.⁴⁰ The pink, raspberry-flavored drug was only screened for color, taste, and aroma.⁴¹ Even more remarkably, the company failed to perform even a cursory survey of the scientific literature, which would have revealed diethylene glycol's toxicity.⁴² One month after elixir sulfanilamide's release, the American Medical Association (AMA) began to receive reports of deaths linked to the drug's consumption, and subsequent testing established conclusively the elixir's toxicity. On October 18 the AMA released a nationwide warning via the press.⁴³

The FDA reacted relatively quickly, delegating nearly all of its 239 inspectors to discover and retrieve all remaining prescriptions of elixir sulfanilamide, but not before more than 100 people, mostly children, had died.⁴⁴ In all, fifteen states, from Virginia to California, saw fatalities.⁴⁵ Due to the inadequacies of existing federal law, all FDA seizures had to be premised on the trivial ground that the drug was misbranded as an "elixir," when it should have been called a "solution" because it contained no alcohol.⁴⁶

³⁷ *Id.* at 44.

³⁸ *Id.*

³⁹ *Id.* at 44-45. A widespread poisoning incident also failed to generate broad public support for the new legislation. This was the event known as the "Ginger Jake" incident, in which 25,000 people across the country were poisoned by bootlegged alcoholic tonic. Hundreds died, and thousands more were injured. See CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 949 (1938). Nevertheless, the floor debates on the new food and drug bill contain few references to the incident. Possibly, this mass poisoning provided only moderate legislative motivation because it involved the consumption of alcohol, and therefore those affected were seen as less sympathetic than, for example, innocent children.

⁴⁰ Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA website, <http://www.fda.gov/oc/history/elixir.html>.

⁴¹ Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 *Annals of Internal Medicine* 456 (1995).

⁴² David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 *Law and Contemporary Problems* 2, 10 (1938).

⁴³ CHARLES O. JACKSON, *FOOD AND DRUG LEGISLATION IN THE NEW DEAL* 154 (1970).

⁴⁴ Ballentine, *supra* note 40, at 1; Stephen Mihm, *A Tragic Lesson*, *BOSTON GLOBE*, Aug. 26, 2007.

⁴⁵ JACKSON, *supra* note 43, at 159.

⁴⁶ Ballentine, *supra* note 40. An interesting aside related to the elixir sulfanilamide tragedy is that the FDA used the tragedy to study variations in the doses that killed humans. This study led to the development of the 100-fold safety factor still in use today in determining safe drug dosage levels. Peter Barton Hutt, *The 1940s: Initial Implementation of the New Statute*, 45 *Food Drug Cosm. L.J.* 21, 28 (1990).

The media did its part to ensure that the incident received broad national attention. *Time Magazine* quoted an FDA agent's description of Massengill as a facility in which "they just throw drugs together, and if they don't explode they are placed on sale."⁴⁷ *Time* also noted pointedly that if the Pure Food & Drug bill had passed during the last Congressional session, Massengill would have been subject to criminal prosecution. Under existing law, Massengill was convicted solely of product misbranding and was fined \$26,000.⁴⁸

In January of 1938, the General Bulletin of Consumers' Research expressed hope that "at last the public will demand of Congress that [a new law] be passed that these more than ninety innocent victims . . . shall not have died in vain."⁴⁹ The *Chicago Daily Tribune* seized on a study by the AMA and published the following headline: "Food-Drug Laws Blamed by A.M.A. in Elixir Deaths."⁵⁰ Such reports captured the prevailing sentiment that the government was partially responsible for the elixir sulfanilamide deaths by virtue of its failure to enact new legislation that might have prevented the tragedy.

Legislators began to feel pressure from their constituents. James Harvey Young, writing in 1964, opined that the legislation finally succeeded only because of the "upsurges of public pressure felt in Congress" as a result of the elixir sulfanilamide tragedy.⁵¹ The impact may have been particularly great when such missives reached staunch opponents of new legislation, one of whom "found his mail heavy with demands for a new law 'so as to make impossible a repetition of the recent Sulfanilamide tragedy.'"⁵² New regulation would help industry, too, by helping to restore public confidence. One author put it rather poetically when he wrote that, "[t]he dramatic headlines gave politicians the impetus they needed to finally pass the Food, Drug, and Cosmetic Act of 1938" which had "flopped weakly around the Capitol for four years like a fish on the deck of a sailboat."⁵³

Senator Copeland confirmed these intuitions when, in November 16, 1937, he introduced the following resolution in the Senate:

Whereas the Nation has been startled recently by published and broadcast reports of scores of deaths of its citizens, ascribed to the administration of a drug known as elixir of sulfanilamide shipped in interstate commerce; and Whereas such reports have caused widespread editorial comment that such tragedies can be prevented by adequate revision of the Food and Drugs Act of June 30, 1906 . . . Therefore be it *Resolved*, That the [USDA] is requested to transmit to the Senate, not later than November 25, 1937, a full report of the facts concerning such deaths, together with recommendations for any needed legislation on the subject.⁵⁴

⁴⁷ *Fatal Remedy*, TIME, Nov 1, 1937, 61, available at <http://www.time.com/time/magazine/article/0,9171,882914,00.html>.

⁴⁸ JACKSON, *supra* note 43, at 161.

⁴⁹ *Id.*, at 151.

⁵⁰ *Food-Drug Laws Blamed by A.M.A. in Elixir Deaths*, CHICAGO DAILY TRIBUNE, Nov. 3, 1937, at 17.

⁵¹ JAMES HARVEY YOUNG, THE MEDICAL MESSIAHS 199 (1967).

⁵² JACKSON, *supra* note 45, at 163 (citing letter from Mecklenburg Medical Association to Bailey, March 20, 1938, Bailey Papers).

⁵³ FRAN HAWTHORNE, INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT 42 (2005).

⁵⁴ See CHARLES WESLEY DUNN, FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD 1016-1017 (1938).

The House passed a similar resolution two days later. Representative Virgil Chapman noted the "grave importance" of the matter, and pressed his colleagues not to delay in adopting the resolution.⁵⁵ Representative Edward Rees made the following appeal, which embodied the prevailing desire among members of Congress to be seen as heroes rather than delinquents so accurately that it has been reproduced with few omissions:

We talk about emergency measures. This is a measure which can well come under that classification. If there ever was need for legislation on food and drugs for this country, that time is right now. Newspapers and periodicals are crowded with information and of incidents where individuals and companies have taken advantage of people by the hundreds and the thousands, by falsification of advertising and adulteration as well as misbranding of foods and medicines.

To bring the problem closer home, we have the horrible example which occurred only a few weeks ago, when a concern in Tennessee was permitted to sell a drug known as elixir of sulfanilamide that has resulted in not only the illness of numbers of people but, according to the information received from the pure food and drug department, at least 73 innocent people have died from using this misbranded and misrepresented drug . . . During the last 4 years bills have been pending before Congress which have provided for the constructive amendment and enforcement of the pure food and drug law, but in each and every case these bills have either been killed in the committee or amended in such a way that they became ineffective. . .

It seems to me that it is high time this Congress, instead of giving consideration to the loaning of portraits to a picture gallery, or other trifling matters, should get down to business and give consideration to the problems that are of vital importance to the health, the welfare, and the happiness of the people of this country.⁵⁶

After receiving the USDA's report, Senator Copeland introduced a new piece of legislation on December 1, 1937 which became known as the "sulfanilamide bill". The bill required, for the first time, proof of safety before a drug could be distributed. It prohibited the shipment in interstate commerce of any drug composed, in whole or in part, of any substance not generally recognized as safe for use under the conditions prescribed or suggested in its labeling. Packers of these drugs would be required to submit full reports of the investigations conducted to demonstrate the drug's safety, a list of all the drug's components, a description of the manufacturing, processing, and packing of the drug, and samples of the drug and its proposed label. In a long-absent showing of expediency, the Senate Commerce Committee reported the bill without hearings, amendment, or a written report, on February 9, 1938.⁵⁷ On May 5, the Senate passed the bill unanimously, without amendment, and with almost no debate.⁵⁸

⁵⁵ *Id.* at 1024-25.

⁵⁶ Congressional record, House, Nov. 24, 1937, at 355-56 (statement of Representative Rees).

⁵⁷ *Id.* at 1019-1020.

⁵⁸ *Id.*

Finally, after five years of legislative meandering, Congress enacted what became known as the Federal Food, Drug, and Cosmetic Act (FDCA). President Roosevelt signed the Act into law on June 25, 1938.⁵⁹ The final version of the Act required that all drug companies submit a new drug application to FDA demonstrating drug safety before distributing any drug in interstate commerce.⁶⁰ Other provisions of the bill gave FDA the authority to inspect production facilities, allowed federal courts to issue injunctions to prevent violations of the Act, allowed false drug claims to be enjoined without proof of fraud, and required drug labels to include directions for use and to contain warnings of any special characteristics or hazards associated with use.⁶¹ In addition, FDA was finally given authority to regulate cosmetics.⁶²

The story of the FDCA is not atypical. A certain amount of its delay was legitimate: most agree that the first draft of the bill was far from ideal. Some of the extensive discussions in committee and on the floors of the House and Senate were fruitful, some less so (one Senator was concerned that eyelash and eyebrow dyes were being treated differently from hair dyes, for example).⁶³ The inadequacies of the bill's first draft, however, cannot fully explain why such an important piece of legislation, generally known and acknowledged to be necessary to remedy dangerous gaps in the 1906 Act, was allowed to languish in Congress for over five years, or why a national emergency was necessary to generate the political will that led to its passage. Daniel Carpenter and Gisela Sin suggest, in a paper delivered to the RJW Health Policy Workshop at Yale University in 2002, that elixir sulfanilamide's *regional* impact played a crucial role.⁶⁴ They note that deaths from the drug were concentrated in the South and the lower Midwest, areas in which political opposition to new federal legislation was strong.⁶⁵

Ultimately, the tremendous exertion required to move this legislation took its toll on the bill's champion. Four days after the bill was enacted into law, its tireless sponsor, Senator Copeland, died.

C. *The 1962 Drug Amendments*

The 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act grew out of a series of drug investigations conducted by Tennessee Senator Estes Kefauver's Antitrust and Monopoly Subcommittee of the Committee on the Judiciary.⁶⁶ The original purpose of the legislation, introduced in April of 1961 as the "Drug Industry Antitrust Act" by Senator Kefauver, was to amend the antitrust laws with respect to the manufacture and distribution of drugs in order to reduce

⁵⁹ *Id.* at 1015.

⁶⁰ Paul M. Wax, *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, 122 *Annals of Internal Medicine* 456 (1995).

⁶¹ Barry S. Robert & David Z. Bodenheimer, *Drug Amendments of 1962: The Anatomy of a Regulatory Failure*, 1982 *Ariz. St. L.J.* 581, 583 (1982).

⁶² David F. Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 *Law and Contemporary Problems* 2, 40-41 (1938).

⁶³ See CHARLES WESLEY DUNN, *FEDERAL FOOD, DRUG, AND COSMETIC ACT: A STATEMENT OF ITS LEGISLATIVE RECORD* 723 (1938).

⁶⁴ Daniel Carpenter and Gisela Sin, *Crisis and the Emergency of Economic Regulation: The Food, Drug, and Cosmetic Act of 1938* (2002) (unpublished manuscript, available at <http://people.hmdc.harvard.edu/~dcarpent/crisis1938.pdf>).

⁶⁵ *Id.* at 3.

⁶⁶ Senate Report No. 1744 on the Drug Industry Act of 1962, 87th Congress, 2d Session, Committee on the Judiciary, July 19, 1962, at 11.

the cost of patented and other prescription medication.⁶⁷ The antitrust angle had strong support from President Kennedy, as evidenced by a letter he wrote to Senator James Eastland early in 1962 emphasizing the need to protect consumer interests by ensuring competitive pricing.⁶⁸ However, many in the Senate opposed what they saw as the anti-free enterprise focus of the bill. As Senator John Carroll noted in June of 1962, the legislation was "highly controversial" and plagued by infighting.⁶⁹ In a covert meeting held in early June 1962 without the knowledge of Senator Kefauver, Judiciary Committee staff worked out a compromise measure that emasculated the licensing and antitrust provisions in the original bill.⁷⁰

On July 19, 1962, the Judiciary Committee reported out the "Drug Industry Act of 1962." The legislation's new purpose, as stated by the committee report, was to "bring about better, safer medicine and to establish a more effective system of enforcement of the drug laws."⁷¹ The bill no longer insisted, for instance, on compulsory patent licensing for all who sought it after three years of patent exclusivity. Instead, it focused nearly entirely on drug safety and effectiveness. The bill required drug manufacturing and processing facilities to register with the Department of Health, Education, and Welfare (the predecessor to today's Department of Health and Human Services).⁷² It strengthened FDA's inspection authority and required drugs that did not conform to good manufacturing practices to be labeled "adulterated." Most notably, it required that new drugs be both safe *and* effective.⁷³ The only remaining measure that impacted competition was a requirement that drugs be labeled with the generic name of their active ingredient in order to facilitate competition.⁷⁴ The impact of this last measure would be limited, however, according to Senator Kefauver, because it duplicated existing regulations.⁷⁵

As Congress pondered the new drug amendments, a crisis was unfolding in Europe. That crisis, triggered by the approval and widespread use of thalidomide in pregnant women, created shockwaves felt across the Atlantic.⁷⁶ A small German company named Greunenthal developed thalidomide while searching for a new antibiotic. While the new drug disappointed as an antibiotic, the firm remarked on its sedative properties and began to market it for a variety of purposes. The drug became a blockbuster.⁷⁷ Thalidomide-based compounds were used as sleep aids, sedatives, as well as to treat nervousness, coughs, colds, and even asthma. Crucially,

⁶⁷ Congressional Record, Senate, Apr. 12, 1961, 5368 (statement of Senator Kefauver).

⁶⁸ Letter from President John F. Kennedy to Senator James O. Eastland, April 10, 1962, as printed in Congressional Record, Senate, June 11 1962, at 10105. In this letter, the President also suggesting several amendments on ensuring drug safety. *Id.*

⁶⁹ Congressional Record, Senate, June 11, 1962, Statement of Senator Carroll, at 10110.

⁷⁰ Congressional Record, Senate, June 11, 1962, Statements of Senators Kefauver and Eastland, at 10106-07.

⁷¹ SEN. REP. NO. 87-1744 at 8. As Senator Kenneth Keating noted later in the summer, it seemed odd that the Judiciary Committee should be primarily responsible for the bill after the anti-trust provisions had been eliminated, given that food and drug administration measures were ordinarily assigned to the Senate Committee on Labor and Public Works. Congressional Record, Senate, Aug. 23, 1962, at 16317 (statement of Senator Keating).

⁷² SEN. REP. NO. 87-1744 at 9, 12.

⁷³ *Id.* at 8-10.

⁷⁴ *Id.* at 17-18.

⁷⁵ *Id.* at 34.

⁷⁶ See Julie A. Grow, *The Legislative History of the 1962 Drug Amendments: A Failure to Forget or a Lesson to Learn From?* 54 (May 1, 1997) (unpublished manuscript, available at <http://leda.law.harvard.edu/leda/data/189/jgrow.rtf>).

⁷⁷ Gina Bari Kolata, *The Thalidomide Tragedy: Was it Preventable?*, WASH. POST, Feb. 12, 1979, at D7.

thalidomide was also given to pregnant women to combat nausea.⁷⁸ Gruenenthal marketed the drug as completely safe. However, reports were made of neurological side effects, including tingling in the extremities and loss of sensation. Despite these observations, European marketing of the drug continued.⁷⁹

The discrepancy between the results of animal studies, which showed no ill effects, and the observed effects in humans caught the attention of Dr. Frances Kelsey, the FDA physician responsible for granting approval of thalidomide in the United States. Thanks to the foresight of Dr. Kelsey, thalidomide was never approved in this country. However, the Richardson-Merrell company, which partnered with Gruenenthal and attempted to secure approval to market thalidomide in the United States under the name "Kevadon," distributed the drug to physicians without engaging in any prior testing to ensure the drug's safety.⁸⁰ In all, over 2.5 million tablets were distributed to more than 1,000 physicians, and then to patients as part of the investigational program before those trials were stopped in 1962.⁸¹

In 1961, alarming reports began to circulate of a significant increase in birth defects linked to mothers' use of thalidomide in Europe. These "thalidomide babies" were born either without limbs or with flipper-like appendages as well as brain damage.⁸² Dr. Helen Taussig, a Professor of Pediatrics at Johns Hopkins University, went on a six week fact-finding trip to England and Germany to determine the magnitude of the crisis. Upon her return, she held a press conference, reporting on the widespread instances of deformities and asserting that "this compound, Thalidomide, could have passed our present drug laws."⁸³

While Dr. Taussig's speeches received limited attention at first, Senator Kefauver's secretary brought one of them to the Senator's attention in the summer of 1962. Senator Kefauver speculated that publicizing Dr. Taussig's findings would help spur passage of his legislation.⁸⁴ One member of his staff, Dr. John Blair, is reported to have remarked that "the thalidomide story, or something like it, is just what we need to ram [the legislation] through."⁸⁵ Kefauver convinced a reporter from the *Washington Post* to interview Dr. Kelsey about the near-approval of thalidomide

⁷⁸ Max Sherman & Steven Strauss, *Thalidomide: A Twenty-Five Year Perspective*, 41 Food Drug Cosm. L.J. 458, 460 (1986).

⁷⁹ See Howard B. Yeon, *Thalidomide Revisited* 7 (1998) (unpublished manuscript, available at http://leda.law.harvard.edu/leda/search/toc.php3?handle=HLS.Library.Leda/yeonhb-thalidomide_revisited).

⁸⁰ See Kristina E. Lutz, *From Tragedy to Triumph: The Approval of Thalidomide* 4 (May 1, 1999) (unpublished manuscript, available at http://leda.law.harvard.edu/leda/search/toc.php3?handle=HLS.Library.Leda/lutzke-tragedy_triumph_approval).

⁸¹ *Thalidomide*, 77 Public Health Reports 946 (1962).

⁸² See ELISABETH A. CAWTHOM, *MEDICINE ON TRIAL* 46 (2004).

⁸³ Robert K. Plumb, *Deformed Babies Traced to a Drug: 'Harmless' Tablet Given to Mothers Abroad is Cited as Infants' Crippler*, N.Y. TIMES, Apr. 11, 1962 at 37. "There is no question," Dr. Taussig continued, "that we must strengthen our food and drug regulations to include routine testing of new compounds on pregnant animals." *Id.* In retrospect, however, testing on animals alone may not have prevented the drug's approval in this case. Australian Physician William McBride, widely credited with being among the first to alert the public to the dangers of thalidomide, was unable to identify similar effects on newborns in mice and guinea pigs. See KRISTINA E. LUTZ, *FROM TRAGEDY TO TRIUMPH: THE APPROVAL OF THALIDOMIDE* 4 (May 1, 1999) (unpublished manuscript, available at http://leda.law.harvard.edu/leda/search/toc.php3?handle=HLS.Library.Leda/lutzke-tragedy_triumph_approval). But see note 92, *infra*, citing reports of abnormalities from studies performed on pregnant rabbits.

⁸⁴ Lisa A. Seidman & Noreen Warren, *Frances Kelsey & Thalidomide in the U.S.: A Case Study Relating to Pharmaceutical Regulation*, 64 The American Biology Teacher 495, 499 (2002).

⁸⁵ RICHARD HARRIS, *THE REAL VOICE* 161 (1964).

in this country.⁸⁶ The resulting front page story triggered a tidal wave of nationwide media coverage.⁸⁷ Dr. Kelsey's face appeared above the fold on newspapers across the country. She became an unlikely national hero; one newspaper article dubbed her a "quietly heroic bureaucrat."⁸⁸ Her story even piqued the interest of President Kennedy, who subsequently called for the passage of stronger food and drug legislation, noting that a possible national tragedy had been averted thanks only to the "skeptical FDA physician."⁸⁹

After the thalidomide story broke, the Judiciary Committee turned with renewed interest to the food and drug bill.⁹⁰ Senator Kefauver recognized that this momentum could carry the bill through to passage, and his rhetoric began to reflect a sense of urgency. The following is a sample of statements he made on the floor late in the summer of 1962:

"The experience with thalidomide only points up the problem in a very dramatic way. Other drugs have not been sufficiently tested . . . Unlike thalidomide, which by a series of fortuitous events, was kept off the market, these products did reach the market and then, after the American people had served as guinea pigs, had to be withdrawn . . . The tragedy involving thalidomide, horrible though it is, has served the useful purpose of dramatizing some of the abuses in the drug industry and has underscored the urgent need for laws to insure that drugs like thalidomide never get to the American public . . . if we do not write effective legislation—everyone in this country, expectant mothers included, will be courting tragedy with every trip to the medicine cabinet."⁹¹

Senator Kefauver, along with Senators John Carroll, Phillip Hart, and Thomas Dodd, proposed an amendment that would give the Secretary of Health, Education and Welfare explicit authority to require animal testing of new drugs before those drugs were approved.⁹² During meetings to consider the amendments, tempers ran high, with Jerome Sonosky, Deputy Assistant Secretary for Legislation at the Department of Health, Education, and Welfare, accusing Senator Roman

⁸⁶ Morton Mintz, *'Heroine' of FDA Keeps Bad Drug Off of Market*, WASH. POST, July 15, 1962, at A1.

⁸⁷ See, e.g., *Doctor Rejects Drug: U.S. Babies Spared*, CHICAGO TRIBUNE, July 6, 1962, at 1; Morton Mintz, *Great Tragedy Averted by Woman's Skepticism*, L.A. TIMES, July 16, 1962, at 10; *Doctor's Action Bars Birth Defects*, N.Y. TIMES, July 16, 1962, at 23.

⁸⁸ Jack Anderson, *Jury Calls for Thalidomide Files*, WASH. POST, Aug. 8, 1962, at B11.

⁸⁹ John M. Goshko, *FDA Awaits Results on Thalidomide Check*, WASH. POST, Aug. 3, 1962, at A4.

⁹⁰ Congressional Record, Senate, Aug. 23, 1962, at 16303 (statement of Senator Eastland).

⁹¹ Congressional Record, Senate, Aug. 3, 1962, at 14515 (statement of Senator Kefauver). Senator Kefauver also highlighted the story of MER/29 to persuade his fellow lawmakers that reform was necessary. In 1959, the FDA approved MER/29, manufactured by the same company that produced thalidomide in the United States. The drug was subsequently withdrawn by the manufacturer after reports of adverse side effects, and newspapers reported that the company had failed to submit sufficient data to FDA in its new drug application. PETER TEMIN, *TAKING YOUR MEDICINE: DRUG REGULATION IN THE UNITED STATES* 124 (1980). Senator Kefauver capitalized on the (admittedly minor) stir, drawing attention on the Senate Floor to "Mer-29, put out by . . . Merrell, [which] caused cataracts, and was taken off the market." Congressional Record, Senate, Aug. 3, 1962, at 14515 (statement of Senator Kefauver).

⁹² Congressional Record, Senate, Aug. 6, 1962, at 14683 (letter from Senator Kefauver to Senators Carroll, Hart, Dodd, and Long, July 31, 1962). While testing of thalidomide in rats had produced no malformations, testing on rabbits performed in Great Britain yielded conclusive results of deformity in their litters. *Id.*

Hruska of not caring about deformed babies.⁹³ Ultimately, however, neither this amendment nor several others offered by Senator Kefauver in an attempt to resuscitate the antitrust provisions of the original bill were adopted. Interestingly, during this period, FDA reacted to the thalidomide crisis by adopting regulations governing the testing of new drugs, including a regulation requiring animal testing and standards governing the distribution of new drugs for investigational use, with special care given to drugs tested for use on children or pregnant women. Many were surprised to learn that FDA possessed sufficient authority under existing law to enact these regulations.⁹⁴

Despite FDA's new rules, Congressional efforts continued. For the remainder of the debate on the bill that was to become the 1962 Drug Amendments, references to thalidomide and to the heroic efforts of Dr. Frances Kelsey were legion, and every effort was made by the bill's supporters to keep the crisis fresh. On August 23, Senator Carroll introduced into the record a news release from the FDA warning that "[t]ablets of thalidomide . . . are still at large in family medicine cabinets" as the result of a failure on the part of some doctors to contact all patients to whom they had distributed the medication.⁹⁵

The media also kept the pressure on. That month, the *Chicago Tribune* reported that, after accusations of 'dragging its feet' on drug legislation, Congress was now taking swift action "under pressure resulting from the discovery that thalidomide taken by pregnant mothers can result in deformed babies."⁹⁶ New hearings on the bill took place in what a drug industry executive cautioned was an "emotionally charged atmosphere."⁹⁷ Dr. Frances Kelsey was in attendance.⁹⁸

The bill passed unanimously in both houses of Congress and was signed into law by President Kennedy on October 10, 1962. Immediately after the bill's passage in the Senate, Senator Paul Douglas declared that Senator Kefauver had been vindicated. "[B]ecause of the many terrible tragedies which have occurred in European countries from the use of the drug thalidomide and the cases which have occurred in this country," Senator Douglas remarked, "it has been proved that" Senator Kefauver was right to take on the drug industry.⁹⁹

The true magnitude of the thalidomide tragedy's effect on the passage of the 1962 Amendments has been debated. Senator Roman Hruska of Nebraska objected to the notion that an occurrence such as the "near tragedy which threatened us in the thalidomide case" was necessary before Congress would act to strengthen the drug laws, pointing out that Senator Kefauver's bill was introduced long before news of the thalidomide tragedy reached American shores.¹⁰⁰ Other legislators disagreed. Senator Jacob Javits reflected during the summer debates on the bill that "what has . . . brought the bill to the point of passage . . . is the great concern which was sparked by the use of the drug thalidomide."¹⁰¹ That was certainly the impression

⁹³ HARRIS, *supra* note 88, at 198.

⁹⁴ *Id.* at 200.

⁹⁵ Congressional Record, Senate, Aug. 23, 1962, News Release from U.S. Dept. of Health, Education, and Welfare, Food and Drug Administration, at 16341-42.

⁹⁶ William Moore, *Senate, House Units Act on Drug Safety*, CHICAGO DAILY TRIBUNE, Aug. 21, 1962, at 22.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ Congressional Record, Senate, Aug. 23, 1962, at 16360 (statement of Senator Douglas). While Senator Kefauver no doubt appreciated the praise, he may also have been slightly amused, given that the original legislation's focus was drug pricing, not drug safety.

¹⁰⁰ Congressional Record, Senate, Aug. 23, 1962, at 16317 (statement of Senator Keating).

¹⁰¹ Congressional Record, Senate, Aug. 23, 1962, at 16335 (statement of Senator Javits).

conveyed by the media.¹⁰² The *Washington Post* described the thalidomide incident's contribution compellingly, if slightly indelicately: "Whatever its defects as a sedative," the paper proclaimed, "thalidomide has shown itself a powerful stimulant to legislative action."¹⁰³ It seems safe to conclude that, even if the bill's origins admittedly lay elsewhere, the thalidomide crisis provided the impetus for decisive Congressional action.

D. *The Infant Formula Act of 1980*

A more localized crisis unfolded in the summer of 1979. That August, the *New York Times* reported that FDA was investigating dozens of cases of babies who had become sick after consuming infant formula. The babies were diagnosed with metabolic alkalosis, a rare condition accompanied by vomiting, diarrhea, high fever, and, most worryingly, physical and mental growth retardation.¹⁰⁴ The syndrome was known to be caused by a deficiency of chloride, the less commonly-known half of sodium-chloride, or table salt.

FDA swiftly determined that the infants' syndrome was the result of long-term, exclusive use of chloride-deficient soy formulas. The illnesses could all be linked to two soy products manufactured by the Palo Alto-based Syntex Corporation, Neo-Mull-Soy and Cho-Free.¹⁰⁵ It later came to light that in 1978, Syntex had either reduced or discontinued the addition of salt to these two formulas. The company's motives were largely benevolent: it based the decision in part on studies showing that hypertension and high blood pressure later in life were linked to high salt intake.¹⁰⁶ Unfortunately, this reformulation resulted in products that contained an inadequate amount of chloride, an essential nutrient for growth and development in infants. There was no FDA regulation governing levels of either sodium or chloride in infant formula at the time, although existing regulations did list eight required nutrients.¹⁰⁷ If it had been detected earlier, the chloride deficiency might have been dealt with under the agency's existing authority to declare a product misbranded, as the labels of both soy formulas continued to represent that the product contained higher levels of chloride than many tested batches were found to contain.¹⁰⁸

Much of the credit for bringing the incident to public and Congressional attention goes to Lea Thompson, now chief consumer correspondent for *Dateline NBC*.¹⁰⁹ In 1979, Thompson was a television news reporter for WBC, an NBC affiliate. She ran a series of broadcasts chronicling the unfolding story of infants who developed brain damage from consuming the deficient formula. The controversy caught the attention of a young representative from Tennessee, Albert Gore. Gore

¹⁰² In a characteristic linkage of the thalidomide crisis to the new legislation, the *Chicago Tribune* reported on the night the Senate passed its version of the bill that the bill passed even "as the Food and Drug administration warned that a substantial percentage of 2 ½ million tablets of a drug dangerous to unborn infants may remain in medicine cabinets of American citizens." Willard Edwards, *Senate Votes Tighter Drug Control Bill*, CHICAGO TRIBUNE, Aug. 24, 1962, at 1.

¹⁰³ *Thalidomide's Potency*, WASH. POST, Aug. 25, 1962, at A8. "What a pity," the article continued, "that it took the birth of armless children in Europe and Canada to provoke the Senate into doing what it should have been doing on the merits!" *Id.*

¹⁰⁴ Judith Cummings, *FDA Checking Infant Formulas*, N.Y. TIMES, Aug. 1, 1979, at A15.

¹⁰⁵ Randal D. Shields, *Food and Drug Law: The Infant Formula of 1980*, 15 AKRON L. REV. 752, 753-54 (1982).

¹⁰⁶ *Id.* at 756.

¹⁰⁷ Gerald F. Seib, *How Two Mothers Took on Bureaucracy in Fight to Toughen Infant-Formula Rules*, WALL ST. J., Aug. 8, 1980, at 15.

¹⁰⁸ See Toby Milgrom Levin, *The Infant Formula Act of 1980: A Case Study of Congressional Delegation to the Food and Drug Administration*, 42 FOOD DRUG COSM. L.J. 101, 108 (1982).

¹⁰⁹ Msnbc.com, *Dateline NBC*, Lea Thompson, <http://www.msnbc.msn.com/id/3949442/>.

organized hearings of the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce to address the problem and hold Syntex accountable.¹¹⁰ Thompson was among those who testified. The committee report recommended that new legislation be enacted to require testing of infant formula before marketing and after any reformulation.¹¹¹

Shortly thereafter, Congress passed the Infant Formula Act of 1980 by a nearly unanimous vote, and President Jimmy Carter signed the bill into law on September 26, 1980.¹¹² This law added section 412 to the Federal Food, Drug, and Cosmetic Act. The section requires that new standards, good manufacturing practices, and quality controls be established for the production of infant formula. It establishes that any formula failing to meet these standards will be considered an adulterated food product within the meaning of the FDCA.¹¹³ FDA has implemented the Act's requirements through regulations on recall procedures, quality control practices, and labeling and nutrient requirements.¹¹⁴ Thus the controversy generated by a relatively small outbreak resulted, in one year, in new legislation governing the regulation of infant formula.¹¹⁵

E. *The Food and Drug Administration Amendments Act of 2007 (FDAAA)*

The refrain of crisis and response in food and drug legislation is not purely a thing of the past. This section will examine the history of the Food and Drug Administration Amendments Act of 2007 (FDAAA), passed unanimously in the Senate and by a vote of 405-7 in the House and signed by President George W. Bush on September 27, 2007.

The Act had five major components, the first three of which will be mentioned only briefly. First, it reauthorized the Prescription Drug User Fee Act (PDUFA).¹¹⁶ Second, it reauthorized the Best Pharmaceuticals for Children Act¹¹⁷ as well as the Pediatric Research Equity Act.¹¹⁸ It also created a new research incentives program for pediatric medical devices.¹¹⁹ Third, the Act contained new requirements for clinical

¹¹⁰ *Infant Formula Hearing Before the Subcomm. On Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 1st Sess. (1979) (cited in Shields, *supra* note 107, at 753).

¹¹¹ S. Rep. No. 96-916, 96th Cong., 2nd Sess. (Aug. 26, 1980) (cited in Shields, *supra* note 105, at 965-66).

¹¹² Pub.L. 96-359.

¹¹³ 21 USC § 350.

¹¹⁴ FDA Food Advisory Committee Meeting on Infant Formula, *available at* http://www.fda.gov/ohrms/dockets/ac/02/briefing/3852b1_01.htm.

¹¹⁵ It was not until 1982, however, in the aftermath of another crisis, that FDA finally issued rules insisting on regular nutritional testing of infant formula products. The regulations were put in place after it was reported that Wyeth Laboratories had accidentally omitted vitamin B6 from one or more batches of formula, potentially putting infants at risk of convulsions or even brain damage.

¹¹⁶ PDUFA was enacted in 1992 and requires pharmaceutical companies to pay application fees to FDA for new products as well as annual product and manufacturing fees. The Act was a response to industry frustration at the length of time it took to get a new drug to market—a median time of 29 months in the late 1980s. The original Act was set to expire on September 30, 2007. H.R. REP 110-225, 110th Congress, 1st Session; FDAAA of 2007 [version is HR 2900], July 11, 2007, at 5. The additional funds are used to expedite the review and approval of new drug applications and to improve post-market drug safety activities. Food and Drug Administration Amendments Act of 2007 (FDAAA), Pub. L. No. 110-85, § 101(c), 121 Stat. 823, 825 (codified in scattered sections of 21 U.S.C. and elsewhere).

¹¹⁷ FDAAA § 502, 121 Stat. at 876.

¹¹⁸ *Id.* at 866.

¹¹⁹ *Id.* at 863.

trial registration. It expanded the existing clinical trial registry databank and made sure that database information was available to the public on the internet.¹²⁰

The final two components, dealing with drug safety and food safety, respectively, will be the primary subject of discussion here. FDAAA's drug safety provisions emerged in the wake of a scandal surrounding the testing and marketing of Merck's blockbuster drug Vioxx. The Act gave FDA authority to require post-approval product studies and/or labeling changes based on new safety information.¹²¹ In addition, it required that the public be given greater access to the drug information that FDA reviews prior to approval. While manufacturers were already under an obligation to report adverse events associated with their products, under the new legislation that requirement was extended to health care professionals. It was hoped that the new system would be more effective at capturing adverse events than its predecessor—FDA estimated that only one in ten adverse effects were identified under the prior system.¹²² An additional provision also related to drug safety imposed stricter conflict of interest rules for FDA advisory committees.¹²³

Finally, in response to an incident involving the widespread contamination of pet food and the deaths of companion animals, the Act contained new requirements governing food safety, including stricter ingredient and labeling standards, the creation of an adulterated food registry,¹²⁴ and improvements in public notification in the event of a recall of contaminated food.¹²⁵ A separate section dealt specifically with the safety of pet food in particular.¹²⁶

1. Drug Safety – The Story of Vioxx

In May 1999, FDA approved Merck's drug Vioxx for use in patients with arthritis and short term acute pain.¹²⁷ Vioxx is a COX-2 inhibitor, a non-steroidal anti-inflammatory drug—the second of its kind to be approved by FDA. One study indicated that Vioxx would result in fewer negative gastrointestinal effects than existing non-steroidal anti-inflammatory drugs.¹²⁸ Because it was found to represent a significant improvement over drugs currently on the market, it was granted "priority review," meaning that it was fast-tracked for approval. FDA aims to approve priority review drugs in an average of six months, compared with ten months for those drugs offering only a modest improvement over existing treatments.¹²⁹ Shortening the approval time for certain drugs has been credited by FDA with, among other things, making new cancer and AIDS treatments available to patients more quickly.¹³⁰

Even before its approval, questions were raised about Vioxx's cardiovascular risks. However, Merck declined to conduct a study of these risks, and FDA did not require one. In 2002, as part of its approval of a gastrointestinal benefit claim for Vioxx, FDA required that Merck include information about cardiovascular

¹²⁰ FDAAA § 801(a), 121 Stat. at 905.

¹²¹ FDAAA § 901, 121 Stat. at 922.

¹²² FDA Media Teleconference, Food and Drug Administration Amendments Act of 2007, Sept. 27, 2007, available at <http://www.fda.gov/bbs/transcripts/transcript092707.pdf>.

¹²³ FDAAA § 701, 121 Stat. at 900.

¹²⁴ FDAAA § 1005, 121 Stat. at 964.

¹²⁵ FDAAA § 1103, 121 Stat. at 963.

¹²⁶ FDAAA § 1002, 121 Stat. at 963.

¹²⁷ Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 Seton Hall L. Rev. 941, 945 (2006-2007).

¹²⁸ *Id.* at 945 (2006-2007).

¹²⁹ Carlos Rados, *The FDA Speeds Medical Treatments for Serious Diseases*, FDA CONSUMER MAGAZINE, Mar./Apr. 2006, available at http://www.fda.gov/fdac/features/2006/206_treatments.html#review.

¹³⁰ Gilhooley, *supra* note 127, at 945.

risks on the drug's label, but was forced to negotiate with the company about the placement and wording of the warning. The outcome of those negotiations was a warning that has been described as "tepid."¹³¹

The real Vioxx story broke on the first day of October, 2004, when the *New York Times* ran a front-page story reporting that Merck had voluntarily withdrawn Vioxx from the market after a trial to measure the drug's potential to prevent colon cancer showed a statistically significant risk of cardiovascular events in those taking the drug.¹³² Vioxx's companion drug, Celebrex, marketed by Pfizer, stayed on the market but added a prominent boxed warning on cardiovascular risks.¹³³

The media went wild. A Google news search for "Vioxx" yields almost 10,000 articles in 2004 alone. The *New York Times* has published over 100 articles on the drug since its recall. National Public Radio devoted over 50 segments to Vioxx coverage. According to a poll sponsored by the *Wall Street Journal*, nearly half of all adults in the United States followed the news coverage of Vioxx's withdrawal from the market.¹³⁴

Congress reacted. In a public statement, Senator Ted Kennedy of Massachusetts remarked that "the American public deserves to know that the prescription drugs their doctors prescribe are safe and effective," and that "the FDA gold standard has been tarnished [by the Vioxx incident]."¹³⁵ Multiple Congressional hearings were held to discuss the revelations about Vioxx and the subsequent fallout.¹³⁶ At a hearing of the Senate Finance Committee convened by Senator Charles Grassley, one of the witnesses pointed out the crisis-to-crisis evolutionary pattern of food and drug laws. David Graham, Associate Director for Science and Medicine in FDA's Office of Drug Safety, supplemented his testimony with an exhibit showing the 1938 Congressional response to elixir sulfanilamide and the 1962 response to thalidomide. He then noted, with some hyperbole, that "today in 2004, we're faced with what may be the single greatest drug safety catastrophe in the history of this country."¹³⁷ In Graham's opinion, FDA could have prevented the Vioxx incident and had "let the American people down." He proposed that his office was very much in need of structural improvement.¹³⁸

In response to Vioxx and other high-profile incidents, including allegations that FDA was delinquent in reporting studies linking the use of anti-depressants in children

¹³¹ *Id.* at 946-49.

¹³² Gina Kolata. *A Widely Used Arthritis Drug is Withdrawn*, N.Y. TIMES, Oct. 1, 2004, at A1.

¹³³ Gilhooley, *supra* note 127, at 951. The Celebrex website also carries the following message, which was probably intended to soothe consumer fears rather than provide information:

Lately, there has been confusion about some arthritis pain treatments. It is important to know that there are risks with all medicines, including the 3 most common prescription NSAIDs: CELEBREX, naproxen, and ibuprofen. In fact, the FDA requires all prescription NSAID pain relievers, including CELEBREX, to have the same cardiovascular warning.

¹³⁴ Health Care Poll: Nearly Half of U.S. Adults Closely Following News Coverage of Vioxx Withdrawal, *Wall St. J. Online*, Dec. 10, 2004, available at http://www.harrisinteractive.com/news/newsletters/wsjhealthnews/WSJOnline_HI_Health-CarePoll2004vol3_iss24.pdf (poll conducted by Harris Interactive).

¹³⁵ Sheryl Gay Stolberg, *Idea of Drug Safety Office is Already Hitting Snags*, N.Y. TIMES, Nov. 25, 2004, at A30. The article notes that the idea of a drug safety office independent from the FDA was endorsed by the AMA and had been periodically suggested in the past in the wake of high-profile drug scandals. *Id.*

¹³⁶ See, e.g., The Roles of FDA and Pharmaceutical Companies in Ensuring the Safety of Approved Drugs, Like Vioxx, Hearing Before the House Comm. on Gov. Reform, 109th Cong. (2005); FDA's Drug Approval Process: Up to the Challenge?: Hearing Before the S. Health, Educ., Labor & Pensions Comm., 109th Cong. (2005); The FDA, Merck and Vioxx: Putting Patient Safety First: Hearing Before the S. Fin. Comm., 108th Cong. (2004).

¹³⁷ The FDA, Merck and Vioxx: Putting Patient Safety First: Hearing Before the S. Fin. Comm., 108th Cong. Nov. 18, 2004 (testimony of David Graham).

¹³⁸ *Id.*

to suicidal behavior, Congress commissioned a report from its investigative arm, the Government Accountability Office (GAO).¹³⁹ The report found that the FDA suffered from acute structural problems that prevented transparency and coordination on drug safety issues, as well as a lack of authority to require post-market studies of approved prescription drugs.¹⁴⁰

According to the bill's sponsors, FDAAA's drug provisions were a direct reaction to the Vioxx scandal. Representative John Dingell attested that the legislation's postmarket surveillance provisions were inserted "with the goal of reducing the likelihood of another Vioxx situation."¹⁴¹ Similarly, during House hearings on the bill, Representative Henry Waxman asserted that "our goal here is to address tragic situations like Vioxx."¹⁴² While the Vioxx scandal may not have been solely responsible for the drug safety provisions, it was certainly no less an impetus for legislation than the thalidomide or elixir sulfanilamide scandals were in their day.

2. Food Safety – the Pet Food Crisis

Vioxx was not the only FDA scandal fueling the passage of FDAAA. Consensus was also building to strengthen the nation's food safety regulation in the wake of multiple high-profile contamination incidents. Early versions of FDAAA contained no food safety provisions—these provisions were added primarily due to national outcry over the contamination of pet food from China, which led to the deaths of over one thousand cats and dogs.

Food-borne illness is hardly a new phenomenon. Each year, one in four Americans suffers from a food-borne complaint.¹⁴³ Of these estimated 76 million instances, approximately 5,000 cases a year result in death.¹⁴⁴ Despite the pervasiveness of food-related illness, however, it took an incident like the pet food crisis to generate sufficient support for new, stronger legislation. One explanation for the tidal wave of public support in the wake of that incident is that it was the culmination of a bad media year for food safety. During 2007, significant outbreaks were traced to bagged spinach, lettuce, peanut butter, seafood, chili, and green beans.¹⁴⁵ Another reason has to do with the nature of the crisis itself. Because so many Americans are pet owners, even those who were not directly affected by the crisis may have

¹³⁹ GOVERNMENT ACCOUNTABILITY OFFICE (GAO), DRUG SAFETY: IMPROVEMENT NEEDED IN FDA'S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS (2006), available at, <http://www.gao.gov/new.items/d06402.pdf>.

¹⁴⁰ *Id.* at 4-6.

¹⁴¹ Congressional Record, House, July 11, 2007, at 7600.

¹⁴² Congressional Record, Sept. 19, 2007, at 10598. House Subcommittee on Health Chairman Frank Pallone elaborated in his opening statement for a 2007 hearing on drug safety, noting that the recent "revelations about drug safety . . . have shaken public confidence . . . [F]rom Vioxx to Paxil, tens of thousands of patients have been placed in harms [sic] way due to the failings of our current drug safety system."

¹⁴³ Bill Lambrecht, *Congress Takes Aim at the FDA*, ST. LOUIS POST-DISPATCH, May 4, 2008, at A12.

¹⁴⁴ Noam Levey, *FDA Reform Likely to Take Back Seat in Obama Plan; Despite Push for Legislation, 'Dysfunctional' Agency Overshadowed*, BALTIMORE SUN, Dec. 22, 2008 Monday, at 15A.

¹⁴⁵ See, e.g., FDA News Release, *FDA Warns About Potential for Botulism in Canned Green Beans*, Dec. 21, 2007; Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 109th Cong., 2nd Session, Food Safety: Current Challenges and New Ideas to Safeguard Consumers, Wed. Nov. 15, 2008 (statement of Robert E. Brackett, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration) (discussing e-coli outbreak in spinach and FDA's response); *Is America's Food Supply Safe? E. coli in Spinach, Salmonella in Peanut Butter – a String of Recent Contamination has Prompted Question about Food Safety*, N.Y. TIMES, Oct. 1, 2007, at 22; 628 *Sickened by Peanut Butter*, L.A. TIMES, June 3, 2007, at C3; Andrew Martin, *FDA Curbs Sale of Five Seafoods Farmed in China*, N.Y. TIMES, June 29, 2007, at A1; *FDA Warns Consumers About Risk of Botulism Poisoning from Hot Dog Chili Sauce Marketed Under a Variety of Brand Names*, FOOD AND DRUG LAW WEEKLY, Aug. 10, 2007, at 33.

experienced an increased sense of vulnerability that prompted them to seek legislative redress.

Studies suggest that the pet food's toxicity resulted from a deadly combination of melamine, added to artificially boost protein levels, and cyanuric acid, which together caused kidney damage in dogs and cats.¹⁴⁶ In all, FDA received more than 17,000 complaints about tainted pet food.¹⁴⁷ The crisis culminated in a class-action settlement involving more than 6,000 claims by pet owners whose pets became ill or died after eating the contaminated food.¹⁴⁸ Menu Foods and other pet food manufacturers and retailers implicated in the scandal agreed to pay \$24 million to compensate the class.¹⁴⁹ Two Chinese firms and an American importer have also been indicted in criminal proceedings for alleged intent to defraud and mislead American manufacturers.¹⁵⁰

In response to public furor, the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee held hearings in April 2007 entitled "Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?" Shortly thereafter, Senator Dick Durbin and Representative Rosa DeLauro introduced companion bills in the Senate and the House, both entitled "The Human and Pet Food Safety Act of 2007."¹⁵¹ The bills would have given FDA authority to take mandatory recall action in addition to improving inspections of imported food and ensuring the safety of pet food. In a shift of strategy, these efforts were abandoned and Senator Durbin instead introduced an amendment containing several food safety provisions to the drug and device bill then under consideration.¹⁵²

Media coverage operated both to amplify public attention and to pressure Congress to take action. Consider the following statement by Senator Mike Enzi (R-WY), made in the final weeks before the passage of FDAAA:

"Food safety has been making news lately. From Salmonella in peanut butter, to Chinese seafood with banned antibiotics, to contaminated pet food, we hear a constant drumbeat of food safety problems that we must address . . . When Americans purchase a snack, eat at a restaurant, or sit down to dinner with their families, they should be able to expect that the food they eat will nourish them, not make them ill. We need to restore that faith, and I am working with my colleagues to develop a comprehensive, effective strategy to enhance food safety."¹⁵³

Although the bill's original focus was not on food safety issues, Senators Enzi and Ted Kennedy, citing the concerns about melamine in pet food and the recent outbreaks of contamination in grocery products, sought to ensure that the food

¹⁴⁶ *Tainted Pet Food Likely Killed 347*, GRAND RAPIDS PRESS (Michigan), Nov. 30, 2007, at A6.

¹⁴⁷ Julie Schmit, *Pet-food Recall Leads to 6,000 Claims and Counting*, USA TODAY, Aug. 26, 2008, at 9A.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Louise Story, *Indictments in Pet Food Poisoning*, N.Y. TIMES, Feb. 7, 2008, at C1.

¹⁵¹ DONNA V. PORTER, CONGRESSIONAL RESEARCH SERVICE, FOOD SAFETY: PROVISIONS IN THE FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT OF 2007 at 2 (Jan. 8, 2007).

¹⁵² *Id.* at 2.

¹⁵³ Enzi: Report on Import Safety a Good Start to Improve, Enhance Safety of Imported Food Products, Congressional Documents and Publications, Sept. 10, 2007 (U.S. Senate Docs).

safety amendments were included in the version of the bill that ultimately passed.¹⁵⁴ The final version passed the House on September 19 with overwhelming bipartisan support. Only seven members voted against it. In the Senate, the vote was unanimous.

The language of FDAAA explicitly acknowledges the significance of the previous year's outbreaks. Section X, which deals with food safety, begins with a Congressional finding that:

(2) illnesses and deaths of individuals and companion animals caused by contaminated food—

(A) have contributed to a loss of public confidence in food safety; and

(B) have caused significant economic losses to manufacturers and producers not responsible for contaminated food items.¹⁵⁵

The Act requires that the Secretary improve information-gathering and public communication in the event of a recall.¹⁵⁶ The Secretary must also establish, within one year of the Act's passage, a Reportable Food Registry for the aggregation of information about tainted food products. Food manufacturers, processors, packers, and holders must generally report such food products within twenty-four hours of discovering the problem.¹⁵⁷

With respect to pet food, the new law requires that, within two years of its passage, the Secretary of Health and Human Services must provide ingredient standards and definitions as well as processing standards. The agency must also ensure that pet food labeling includes nutritional and ingredient information.¹⁵⁸ Within a year, the Secretary must establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of pet food-related illness.¹⁵⁹

The language of the legislation acknowledges that further measures are needed. A nonbinding "Sense of the Congress" section concluded that Congress must provide FDA with "additional resources, authorities, and direction with respect to ensuring the safety of the food supply," that FDA needed additional inspectors, and that additional agreements with trading partners were required due to the increasing volume of international trade in food products.¹⁶⁰ The legislation also underscores the importance of working toward the development of a comprehensive legislative response to the issue of food safety.¹⁶¹ Given the public response to the pet food crisis, however, there appeared to be a pervasive conviction on Capitol Hill that an interim solution was essential. As of the writing of this article, there have been no

¹⁵⁴ Zachary Richardson, Senate Passes FDA Revitalization Act, FDA Food Chemical News, May 14, 2007, at 15. In response to the Senate's approval of his 2007 amendment on food safety, Senator Durbin described the amendment as responding to the food safety concerns "in the wake of nationwide recalls and quarantines of tainted pork, spinach, peanut butter and pet food."

¹⁵⁵ FDAAA, 21 U.S.C. 2101(2)(A), (B) (2007).

¹⁵⁶ FDAAA, 21 U.S.C. 2103. The section requires that all information regarding pet food and human food recalls be posted in a single location on the FDA website, which must include a searchable index of recalled foods "that is easily accessed and understood by the public."

¹⁵⁷ FDAAA, 21 U.S.C. 350f. Public health officials must also submit reports about food incidents.

Id.

¹⁵⁸ FDAAA, 21 U.S.C. 2102(a).

¹⁵⁹ FDAAA, 21 U.S.C. 2102(b).

¹⁶⁰ FDAAA, 21 U.S.C. 2107(a), (b), and (c).

¹⁶¹ FDAAA, 21 U.S.C. 2107(d).

food contamination crises to rival the magnitude of those that triggered FDAAA's food safety provisions, and no further legislation has been passed.

* * *

The food and drug safety provisions of FDAAA may therefore be seen as Congressional responses to a series of highly-publicized crises. The legislation fits neatly into the pattern of food and drug laws chronicled in this Part, all of which were at least partially motivated, by public outcry following a food or drug crisis. Given the prevalence of this phenomenon, its mechanics deserve further study.

III. THE CRISIS RESPONSE MECHANISM

The above Part charted a brief history of the role crises have played in food and drug legislation. This section will examine the chain of events connecting safety scandals to legislative reform. It will suggest a pattern consistent with the first two steps in Breyer's "vicious circle," public overreaction and Congressional response, as well as the sociological literature examining the social amplification of risk. It posits that, whether the triggering event be contaminated vaccines, a reported rash of birth defects, or the death of companion animals from adulterated pet food, public perceptions of risk are colored by cognitive limitations, magnified by media coverage, and reinforced by peer responses. In the cases of the crises chronicled above, the furor eventually built to a point where rent-seeking members of Congress could only ignore its effects at their peril.

A. *Public Perceptions and Cognitive Biases*

A growing body of work acknowledges that human beings often fail to make rational decisions in their everyday lives.¹⁶² As individuals, we lack comprehensive information about the increasingly complex world around us. When presented with situations about which we have imperfect knowledge, we evaluate them using an array of heuristics, or rules of thumb. These heuristics simplify the task at hand, but may result in decisional errors, which can be magnified by inherent biases. Reliance on intuition is essential because we simply do not have the time or resources to become universal experts. The problem is particularly acute when laypeople attempt to estimate the magnitude of risk. Breyer, emphasizing this failing in describing the "vicious circle," writes that people "simplify radically" in estimating risk, which "may help cut a swath through the modern information jungle," but "oversimplifies dramatically and thereby inhibits an understanding of risks"¹⁶³

Estimating risk in the face of a crisis, whether that crisis takes the form of food contamination or the unwitting approval of a dangerous drug, is complicated by several well-known heuristics and biases, including the "availability heuristic" as well as our natural predisposition to become more fearful of risks with certain characteristics.

In a seminal article published in 1987, Paul Slovic sought to explain why people are unable to evaluate relative risk correctly.¹⁶⁴ He concluded that certain risk char-

¹⁶² For a good introduction to the literature from a lawmaking perspective, see CASS SUNSTEIN, ED., *BEHAVIORAL LAW AND ECONOMICS* (2000). See also William N. Eskridge & John Ferejohn, *Structuring Lawmaking to Reduce Cognitive Bias: A Critical View*, 87 Cornell L. Rev. 616 (2002).

¹⁶³ STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 35 (1993).

¹⁶⁴ Paul Slovic, *Perception of Risk*, 236 Science 280 (1987).

acteristics produce a disproportionate public reaction leading to a greater desire for regulation. Fears about drug side effects and food contamination may be more pronounced than warranted because they possess many of these attributes. Slovic discovered, for instance, that people may overestimate the magnitude of risks that are unobservable and whose exact natures are unknown.¹⁶⁵ Food and drug risks fall into these categories because, unlike risks from reckless driving, for instance, the potential harm from adulterated substances or drugs with dangerous side effects is not readily apparent. Similarly, establishing the extent and nature of the risk is often a time consuming process fraught with uncertainties.

In addition to filtering our perceptions through inherent biases, we are often guided by what has become known as the "availability heuristic" in estimating risk magnitude. According to this heuristic, risks that are more prominent, or available, will appear to be of greater consequence. Selective media coverage plays a key role in determining risk "availability".

B. *Media Amplification*

There is a low correlation between the attention hazards receive in the press and the magnitude of the risk associated with those hazards, as measured by the number of annual deaths with which they are associated.¹⁶⁶ Consider the common fear of air travel. In a 1989 study, Massachusetts Institute of Technology Professor Arnold Barnett examined the *New York Times*' selection of stories for its front page. Barnett found that, per 1000 deaths in each category, the newspaper ran 1.7 front page murder stories, 2.3 front page HIV/AIDS stories, and only .02 front page cancer stories. In striking contrast, there were 138.2 front page plane crash stories per 1,000 deaths.¹⁶⁷ These results yield important clues about why the fear of flying is so widespread, as well as the effect of the media on popular perception.

Disproportionate coverage of sensational events like plane crashes dramatically increases their salience for the general public and leads readers to form an erroneously high estimate of how likely such disasters are to occur. A mechanism that has been termed the "availability cascade" magnifies the effect. Timur Kuran and Cass Sunstein define availability cascades as "social cascades . . . through which expressed perceptions trigger chains of individual responses that make these perceptions appear increasingly plausible through their rising availability in public discourse."¹⁶⁸ Thus, impressions from a front page news story about a plane crash accompanied by graphic photos are likely to be passed along from person to person, becoming more and more "available" as the news spreads.

In their article on availability cascades, Kuran and Sunstein cite the case of Alar, a pesticide used primarily on apples from the 1960s through 1980s. In 1989, Uniroyal, which manufactured Alar, concluded that exposure to Alar resulted in higher incidences of tumors in rodents. The National Resources Defense Council (NRDC) translated this finding into the statement that one in 4,200 preschool children would develop cancer by age six if exposed to Alar. A media

¹⁶⁵ *Id.* at 282 fig. 1.

¹⁶⁶ See, e.g., Barbara Combs and Paul Slovic, *Newspaper Coverage of Causes of Death*, 56 *Journalism Q.* 837 (1979) (observing that the number of deaths caused by various hazards had little to do with the likelihood of their coverage in two daily newspapers).

¹⁶⁷ Catherine Trevison, *Safety Statistics Fail to Settle Fliers' Nerves*, *THE OREGONIAN*, Feb. 6, 2000, at A01.

¹⁶⁸ Timur Kuran and Cass R. Sunstein, *Controlling Availability Cascades*, in SUNSTEIN, ED., *BEHAVIORAL LAW AND ECONOMICS* 374-375 (2000).

flurry ensued, including a “60 Minutes” segment depicting an apple covered by a skull and crossbones. Apple consumption plummeted. Subsequent analyses by the EPA and the United Nations, among others, revealed that the earlier results were flawed and that Alar posed no danger to humans. But the new information failed to displace the already ingrained social perception that apples posed a risk to children’s health. The damage to the apple industry was done.¹⁶⁹

The media contributes to these effects in two ways: by devoting disproportionate space to reporting selected events, and by framing those events as catastrophic in order to capture the public interest. The latter tactic feeds the cognitive bias dubbed the “framing effect.” Amos Tversky and Daniel Kahneman have shown that people react differently to logically identical scenarios producing exactly the same result, depending on how the scenario is presented.¹⁷⁰ While Tversky and Kahneman focused their research on risk preferences, this effect is present in any situation in which people are called upon to evaluate information and choose between alternatives.¹⁷¹ For instance, framing a news story about a case of food contamination by emphasizing the speed of the FDA’s response and effective containment of the problem would be expected to cause much less public anxiety than a story focusing on the fact that a baby was seriously sickened by the incident. The latter story, however, makes better news.

The unfortunate reality is that stories about danger and suffering capture the human imagination more effectively than stories about bureaucratic response. Reporting on accidents sells papers, while reporting on risk in the absence of a negative event is typically not considered “newsworthy.” As an example, consider news stories covering the space shuttle program. Eleanor Singer and Phyllis Endreny found that no newspaper articles covering the space shuttle made any mention of the potential risks to astronauts until the *Challenger* exploded shortly after launch on January 28, 1986.¹⁷² After the accident, however, a wave of media coverage focused in great detail on those risks.¹⁷³

Similarly, journalistic prizes are handed out for exposing government failure, not for presenting a nuanced view of the bureaucracy. Upton Sinclair’s *The Jungle*, with its graphic portrayal of the meat-packing industry in turn of the century Chicago, became an instant bestseller. The *Los Angeles Times* won a Pulitzer Prize in 2001 for investigating drugs with dangerous side effects that the FDA approved and later had to recall in the late 1990s and early 2000s.¹⁷⁴ Less egregious problems also become front page news. Ironically, as our society becomes safer, any hint of risk of disease or death has become newsworthy.¹⁷⁵ In today’s

¹⁶⁹ *Id.* at 378-79.

¹⁷⁰ See Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 *Econometrica* 263 (1979).

¹⁷¹ For a survey of work on frames and framing in the social and cognitive sciences, see James N. Druckman, *The Implications of Framing Effects for Citizen Competence*, 23 *Political Behavior* 225, 226-31 (2001).

¹⁷² ELEANOR SINGER AND PHYLLIS M. ENDRENY, *REPORTING ON RISK: HOW THE MASS MEDIA PORTRAY ACCIDENTS, DISEASES, DISASTERS, AND OTHER HAZARDS* 22 (1993).

¹⁷³ *Id.* Singer and Endreny identify a pattern of concentrated media coverage in the immediate aftermath of a hazardous event that soon dies down, not because the problems that led to the event have necessarily been resolved, but because in the absence of new developments the public imagination moves on.

¹⁷⁴ HAWTHORNE, *supra* note 53, at 140.

¹⁷⁵ Mark Neal, *Risk Aversion: The Rise of an Ideology*, in LAURA JONES, ED., *SAFE ENOUGH? MEASURING RISK AND REGULATION* 13 (2000). Neal identifies a dozen devices by which the media can exaggerate the nature of a risk, including conflating coincidence and causality, using imagery, sentimentalizing the victims, and omitting the costs and dangers of regulation. *Id.* at 23-28.

relatively risk-free environment, stories about food and drug safety often make front page news.¹⁷⁶

The media can be a powerful tool for influencing behavior. For instance, Pfizer withdrew its diabetes drug Rezulin from the market voluntarily after the *Los Angeles Times* published an article called "The Rise and Fall of the Killer Drug Rezulin."¹⁷⁷ But the headlines do not convey the whole story. According to one recent article, a series of "deadly food-borne disease outbreaks . . . called public attention to gaping holes in the FDA's capacity to stay on top of a rapidly expanding market."¹⁷⁸ While neither the seriousness of each of these occurrences nor the suffering of the affected families should be minimized, the annual number of food-borne illnesses has remained relatively constant.¹⁷⁹

Because the public lacks the ability to estimate the relative seriousness of many risks, media sensationalization creates pressure on government to address even minor risks. The public often desires that risks be *eliminated*, not simply managed. Some have attributed this preference to the fact that, at least in much of the Western world, we are confronted with many fewer risks today than past societies.¹⁸⁰ This creates a false sense of entitlement to a risk-free existence, and the idea that the government can and should be providing an ultimately unrealistic level of safety. Thus legislative priorities, which should ideally be rationally determined, are influenced instead by media and flawed public perceptions.

C. Congressional Response

Breyer argues that government regulation is distorted by sensational media reports of disasters that affect relatively few citizens.¹⁸¹ The above section discussed how cognitive error may lead to public overreaction after food and drug crises. This section attempts to explain how that overreaction can trigger a Congressional response.

Public choice theory teaches us that lawmakers, no less than ordinary citizens, are utility maximizing rational actors. Most legislators desire to stay in office—a perfectly natural ambition. To do so, they must continue to satisfy the expressed preferences of their constituents.¹⁸² Public attitudes about risk therefore affect the

¹⁷⁶ The following is a sample of headlines from the front page of the *Chicago Tribune* dealing with food and drug investigations: "U.S. Orders Probe of Saccharin Safety," CHICAGO DAILY TRIBUNE, Oct. 21, 1969 at 1; *Poison-Laced Tylenol Found in California*, Jerry Crimmins and Jove Brown, CHICAGO TRIBUNE, Oct. 6, 1982 at A1; Michael L. Millenson, *FDA: America's Watchdog in Distress* (three-part series), CHICAGO TRIBUNE, Sept. 18, 1983, at 1 (opening with stories of a man who died in an Arizona restaurant after an allergic reaction to a food preservative, a woman collapsing from shock after taking a prescription pain killer, and a nurse discovering that the amount of medication being administered to an infant through an intravenous pump was incorrect); Ronald Kotulak, *Food Irradiation: Consumers' Boon or Safety Threat?*, CHICAGO TRIBUNE, Feb. 26, 1984 at E1; *FDA Erred on Drug Tied to Deaths*, May 15, 1984, at 1 (chronicling story of vitamin E drug given to premature infants).

¹⁷⁷ David Willman, *The Rise and Fall of the Killer Drug Rezulin*, L.A. TIMES, June 4, 2000, at A1 (cited in Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs*, 5 Yale J. Health Pol'y & Ethics 741, 744 (2005)).

¹⁷⁸ Noam Levey, *FDA Reform Likely to Take Back Seat in Obama Plan; Despite Push for Legislation, 'Dysfunctional' Agency Overshadowed*, BALTIMORE SUN, Dec. 22, 2008 Monday, at 15A.

¹⁷⁹ Centers for Disease Control and Prevention, FoodNet Facts and Figures, Percent Change in the Incidence of Laboratory-Confirmed Bacterial Infections in 2007 Compared With the Previous 3 Years (2004-2006), available at <http://www.cdc.gov/foodnet/factsandfigures/10.pdf>.

¹⁸⁰ See Neal, *supra* note 28, at 23-28.

¹⁸¹ Jeffrey Rosen, *Supreme Court Inc.*, N.Y. TIMES, Mar. 16, 2008.

¹⁸² See Bender & Lott, *Legislator Voting and Shirking: A Critical Review of the Literature*, 87 Pub. Choice 67, 89 (1996) (surveying empirical studies and finding that legislative voting behavior is highly correlated to the interests of constituents).

likelihood that legislation to address those risks will be enacted.¹⁸³ Most of the time, public preferences are diverse and no one interest predominates. James Madison, in defending a stronger federal government in the Federalist Papers, argued that in larger societies the dangers of factionalism will be reduced because it becomes more difficult to secure a majority for any given proposition.¹⁸⁴ A national crisis upsets that balance. Vanderbilt University economist Kip Viscusi cautions that while “responding to citizen fears may be a ‘rational’ political act that maximizes popular support,” it may not lead to rational risk decisions at the societal level.¹⁸⁵

Congressional attention to public priorities, even in the face of other, seemingly more pressing responsibilities, is unquestioned. Despite the ongoing financial crisis and our continued embroilment in two wars, for example, the House of Representatives found the time this spring to consider and pass the Captive Primate Safety Act, which prohibits the interstate sale and transport of monkeys and apes. The motivation for this bill was the highly-publicized mauling of a Connecticut woman by a neighbor’s pet chimpanzee.¹⁸⁶ In a statement, House Natural Resources Committee Chairman Nick Rahall cautioned that, while “[i]mages of ‘Curious George’ . . . may lead us to believe that these creatures are cuddly and harmless . . . last week’s tragedy and other similar attacks stand as evidence that this is not the case—that they are in fact wild animals and they simply must not be kept as pets.”¹⁸⁷ The move was popular, but some may question whether, given the finite resources available to legislators, their time and effort could have been better spent.

Members of Congress have openly acknowledged the pressure this phenomenon puts on their ability to prioritize in a rational manner. In a 2005 hearing on FDA’s drug approval process, Senator Kennedy remarked that he had discerned a “rule of legislating” over the years “that if it is worth reacting to, it is worth overreacting to, and part of our job is to make sure that we don’t overreact but that we appropriately react.”¹⁸⁸ Unfortunately, as Senator Kennedy implied, that check does not always operate. Thus Congress may, as Breyer suggested, contribute to the cycle of overreaction by devoting too many resources to a legislative response in a never-ending quest for constituent approbation.

IV. COMPETING PARADIGMS

If we accept that crises have played a role in the passage of food and drug legislation, the question remains as to whether that influence is harmful. The previous Part builds on Breyer’s view, as embodied by the “vicious circle” metaphor, that public reaction to risk can be a pernicious influence on the legislative process. But Breyer’s model is not the only possible lens through which this phenomenon may be viewed. Accordingly, this Part will describe three competing paradigms: the “Knee-Jerk” paradigm, the “Crisis as Catalyst” paradigm, and the “Necessary Evil” paradigm.

¹⁸³ Roger G. Noll and James E. Krier, *Some Implications of Cognitive Psychology for Risk Regulation*, in CASS SUNSTEIN ED., *BEHAVIORAL LAW AND ECONOMICS* (2007), at 326.

¹⁸⁴ James Madison, “Federalist No. 10,” in CLINTON ROSSITER (ED.), *THE FEDERALIST PAPERS* 81, (1961).

¹⁸⁵ KIP VISCUSI, *RATIONAL RISK POLICY* 104 (1998).

¹⁸⁶ Richard Cowan, *U.S. House Votes to Stop Interstate Chimp Trade*, REUTERS, Feb. 24, 2009.

¹⁸⁷ *Id.*

¹⁸⁸ Hearing of the Senate Committee on Health, Education, Labor, and Pensions, 109th Congress, 1st Session, FDA’s Drug Approval Process: Up to the Challenge? Mar. 1, 2005 (statement of Senator Kennedy).

A. *The "Knee-Jerk" Paradigm*

One description of the pattern of crises and response in the history of food and drug legislation may be termed the "Knee-Jerk" paradigm. According to this view, which most closely tracks Breyer's "vicious circle" metaphor, post-crisis legislation is an irrational and often ineffective reaction to widely publicized events by vote-seeking members of congress.

Legislation enacted subsequent to a disaster, according to this paradigm, is largely symbolic with respect to the problem legislators are ostensibly seeking to remedy. The actual text of the 1962 Drug Amendments, for example, had little to do with preventing a drug like thalidomide from being approved in this country. The 1938 Act's safety provisions, it should be recalled, were sufficient to keep thalidomide from the market in the United States. Furthermore, the 1962 Amendments focused primarily on efficacy, not safety.¹⁸⁹

Even if the legislation does address the events that led to the crisis, according to the "Knee-Jerk" paradigm it is likely that its provisions will not reflect the best thinking about how to remedy weaknesses in existing law. The need for expediency is high in these circumstances because legislators desire to be seen as responding to public outcry. These conditions make it doubtful that resulting legislation will be the product of careful, reasoned problem-solving.

Legislators may also fail to fund new agency mandates, because they receive the political benefits of having enacted new legislation in the face of crisis regardless of whether FDA's current budget will enable it to fulfill additional responsibilities. Thus, "Knee-Jerk" responses to crises may be ineffective and/or may draw resources away from existing agency programs. At a hearing of the House Energy and Commerce Committee last January, Catherine Woteki, a member of FDA's Science Board, testified that crisis management in the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine had sapped attention and resources, preventing FDA from developing the science and infrastructure base necessary to support industry innovation and provide adequate surveillance.¹⁹⁰ At the same hearing, former FDA General Counsel Peter Barton Hutt went further, asserting that FDA was dangerously underfunded and was "barely hanging on by its fingertips."¹⁹¹

Another problem with crisis legislation, according to the "Knee-Jerk" paradigm, is that legislators may fail to consider the opportunity costs of focusing on this particular societal ill as opposed to less highly publicized problems. The danger is that a myopic focus on issues of public concern will cause legislators to neglect other risks that in fact pose greater dangers. The chimpanzee legislation, discussed above, represents just such a dilemma.

¹⁸⁹ It would be hyperbole to argue, however, that legislation enacted in the wake of the crises described in Part II was *purely* symbolic. A counterpoint may be seen in China's reaction to international condemnation for its role in the pet food scandal, as well as scandals surrounding contaminated toothpaste and other household goods. To prove its commitment to improving the safety of its exports, China executed its former top food and drug regulator. Joseph Kahn, *China Executes Former Drug Regulator*, N.Y. TIMES, Jul. 10, 2007.

¹⁹⁰ House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, Science and Mission at Risk: FDA's Self-Assessment (Jan. 29, 2008) (statement of Catherine E. Woteki), available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.012908.FDASelfAssessment.shtml.

¹⁹¹ *Id.* (statement of Peter Barton Hutt, Senior Partner, Covington & Burling LLP), available at http://energycommerce.house.gov/cmte_mtgs/110-oi-hrg.012908.Hutt-Testimony.pdf.

Crisis legislation may even be counterproductive. While the 1962 Amendments may have generated political capital for its sponsors, it put in place a complex and time consuming approval process that has delayed a significant number of beneficial drugs from reaching the marketplace. Some critics argue that these costs outweighed any benefits produced by the new legislation.¹⁹² Others go even further, describing the 1962 Amendments as having caused more actual deaths than they prevented.¹⁹³ According to the literature on cognitive biases, both legislators and members of the public may favor errors of omission over errors of commission.¹⁹⁴ In other words, the public is less likely to condemn FDA for a failure to approve a drug that could have saved or extended lives than it is to punish the agency for approving a drug that later causes injury or death in even a small number of people. Even if the absolute number of lives saved may decrease if expensive and time consuming hurdles are added to the drug approval process, the public may favor the legislation.

The “Knee-Jerk” paradigm thus suggests that, consistent with Breyer’s concerns, a system in which legislators are motivated to create new laws only in the wake of a crisis will produce legislation that fails to consider the bigger picture. Food and drug laws, by this account, may give a disproportionate amount of attention to infant formula and pet food, for example, while leaving less sensational risks unaddressed.

B. The “Crisis as Catalyst” Paradigm

A second possible description of the mechanics at work may be termed the “Crisis as Catalyst” paradigm. This paradigm posits that crises demonstrate significant flaws in existing legislative and regulatory regimes that may not have been apparent before the event. It suggests that post-crisis legislation is a rational reaction to new, especially pointed evidence of systemic problems that demand attention but have not been addressed due to informational deficit or regulatory failure.

According to this view, crises are an organic part of regulatory evolution. This idea has its roots in the social science literature, where it goes by the name of “Incrementalism.” Charles E. Lindblom, a Professor of Economics at Yale University,

¹⁹² See, e.g., Barry S. Roberts & David Z. Bodenheimer, *The Drug Amendments of 1962: The Anatomy of a Regulatory Failure*, 1982 Ariz. St. L.J. 581 (1982) (finding that the delays in getting a drug to market and the increased costs of regulatory compliance under the Act decreased incentives for research and innovation); Sam Peltzman, *An Evaluation of Consumer Protection Legislation: the 1962 Drug Amendments*, 81 J. Political Econ. 1049 (1973) (concluding that the 1962 amendments resulted in substantial increases in costs for consumers); see also Sam Peltzman, *An Evaluation of Consumer Protection Legislation: the 1962 Drug Amendments*, 83 J. Political Econ. 663 (1975) (responding to critics and asserting that the 1962 amendments produced net costs to consumers, even when the benefits of the law are taken into account). The costs and delays described in these articles have to some extent been alleviated by the passage of the Prescription Drug User Fee Act (PDUFA), enacted in 1992 and most recently reauthorized in FDAAA. See FDA White Paper, Prescription Drug User Fee Act (PDUFA): Adding Resources and Improving Performance in FDA Review of New Drug Applications, available at <http://www.fda.gov/oc/pdufa/whitepaper11-10/whitepaper11-10.html>.

¹⁹³ Dale H. Gieringer, *The Safety and Efficacy of New Drug Approval*, 5 Cato J. 177, 188 (1985).

¹⁹⁴ See, e.g. Christine Jolls, Cass R. Sunstein, and Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 Stan. L. Rev. 1471 (1998); Henry G. Grabowski & John M. Vernon, *THE REGULATION OF PHARMACEUTICALS* 46 (1983) (classifying errors of commission as “type 1” and errors of omission as “type 2,” and noting the existence of “strong incentives in our system for FDA to err on the side of too much delay and to be overrestrictive in approvals”). A 1990 study applied this concept to parents’ reluctance to vaccinate their children, concluding that the parents favor the much greater risk of avoiding the inoculation to the comparatively minimal risk that their child will suffer side effects from the vaccine. Ilana Ritov & Jonathan Baron, *Reluctance to Vaccinate: Omission Bias and Ambiguity*, 3 J. Behav. Decision Making 263 (1990).

is generally credited with originating this concept in his 1959 article entitled *The Science of Muddling Through*.¹⁹⁵ In complex areas of policymaking, Lindblom argued, humans are incapable of designing perfect systems because human rationality is inherently limited.¹⁹⁶ Instead of striving to apply a universal theory to the task and hope that first efforts will yield a fully-formed, all-inclusive scheme, Lindblom advises, policy-makers should accept that incremental alterations will be required as the policy is tested, with each test yielding useful information about its utility.¹⁹⁷

A proponent of the "Crisis as Catalyst" theory would argue that the history of food and drug legislation has been one of trial and error, in which the strength and coverage of our laws and regulations gradually improves in response to events highlighting the system's weaknesses. For instance, the Vioxx scandal and pet food contamination incident revealed flaws in FDA's structure and operations, including inadequate resources and a lack of coordination.¹⁹⁸ FDAAA, according to this theory, was a logical and timely response to these revealed systemic weaknesses.

The "Crisis as Catalyst" theory is agnostic on whether systemic flaws that lead to crises are susceptible to advance detection. Even if systemic shortcomings are apparent to regulatory insiders, it may not be possible to achieve a legislative fix in the absence of high-profile crises because of a lack of political will. The "Crisis as Catalyst" theory posits that legislation enacted in response to crises often includes important but unrelated measures that would have been difficult to pass had the crisis not spurred legislative action. Proponents might point to the 1938 Federal Food, Drug, and Cosmetic Act, which languished in Congress for four years before the elixir sulfanilamide tragedy. That Act contained much-needed improvements to the 1906 law that had little to do with drug safety, including an expansion of the government's regulatory authority to cosmetics. These improvements might not have been possible, or might have taken much longer to implement, had there been no such thing as elixir sulfanilamide.

C. *The "Necessary Evil" Paradigm*

The final paradigm, the "Necessary Evil" paradigm, concludes that irrespective of the actual substance of the legislation, most post-crisis laws are a necessary response to public outcry, consistent with the specific mandate of the FDA, democratic governance, and economic principles. According to this paradigm, Congress should respond to food and drug crises even when legislation will fail to address the immediate problem that triggered the crisis or will shift legislative and agency resources away from equally pressing but less visible concerns.

In support of this view, consider that FDA could not achieve its mission without public confidence in the products it regulates. There is thus an argument to be made that even a purely symbolic response to a crisis is worthwhile if it succeeds in deterring irrational public behavior that might undermine effective regulation.

An examination of the literature on the social amplification of risks serves to strengthen this hypothesis. This literature argues that risk perception does not take place in a vacuum. Rather, it is highly influenced by social norms, institutions, and values. The media can serve as a proxy for such norms and values, acting as "stations of amplification" that increase the salience of risk events for the general

¹⁹⁵ Charles Lindblom, *The Science of Muddling Through*, 19 Public Admin. Rev. 79 (1959).

¹⁹⁶ MICHAEL T. HAYES, INCREMENTALISM AND PUBLIC POLICY 15 (2006).

¹⁹⁷ *Id.* at 86.

¹⁹⁸ See *Why We Can't Trust Our Food*, BOSTON GLOBE, Dec. 6, 2007, at A10.

population.¹⁹⁹ Interestingly, the social impact of a risk event may be colored more by social processes than by the actual characteristics of the event itself, such as how many people are affected.²⁰⁰

Much of the literature on the social amplification of risk focuses on ways in which knowledge about risk perception can increase the effectiveness of risk communication.²⁰¹ If the government can “manage” societal risk communication, it may be able to prevent irrational reactions on the part of consumers. One way to do this is to be seen as responding to public concern, even if the scope of the “crisis” is a product of media amplification and public misperception.

The “pill scare” of 1995 in Great Britain is a lesson in the importance of a government response to public perceptions of increased risk. On October 18, 1995, the Medicines Control Agency in Great Britain sent out nearly 200,000 letters to general practitioners warning of possible increased risks of blood clotting for women taking the latest generation of oral contraceptive pills.²⁰² The mailing was followed by a press conference on the national news.²⁰³ There was no indication of the absolute risk associated with taking this medication, and in fact it was recommended that women continue to take their current cycle of pills. But the “scare” itself generated negative outcomes: many women failed to continue taking their birth control pills, and the abortion rate in 1996 was 8% higher than in 1995, reversing a downward trend.²⁰⁴ Taking legislative action after such a public scare, even if that action does little to decrease actual risk levels, may serve the important purpose of calming public fears and helping to restore public confidence.

In addition, while symbolic or minimally effective legislation may not prevent another tragedy in the future, it may serve to counter some of the indirect harm produced by events. According to Paul Slovic, like a stone dropped in a pond, an adverse event may create a “ripple effect” that touches persons and institutions with only tangential connections to the immediate victims.²⁰⁵ This is especially true in the case of low-probability events that carry a risk of serious harm. Cass Sunstein gives an example of this phenomenon in his recent book, *Worst Case Scenarios*. He points out that the harm from the 9/11 terrorist attacks was not limited to the death and destruction caused by the attacks themselves.²⁰⁶ People changed their behaviors in reaction to the attacks, for instance by switching from flying to driving, an inherently more dangerous activity, which put them at greater risk. This behavioral change alone may have caused as many as 1500 avoidable deaths,²⁰⁷ as well as contributing to the decline of the airlines. New York City’s tourist industry suffered as well. Job loss in the wake of the attacks is estimated to have reduced

¹⁹⁹ Julie Barnett & Glynis M. Breakwell, *The Social Amplification of Risk and the Hazard Sequence: the October 1995 Oral Contraceptive Pill Scare*, 5 *Health, Risk & Society* 301, 302 (2003).

²⁰⁰ *Id.*

²⁰¹ See, e.g., Barnett & Breakwell, *supra* note 204; C. ALLISON, J. ROIZEN, AND P. OLIVIER, *The 1995 Pill Scare: Women's Perceptions of Risk and Sources of Information*, 23 *British Journal Of Family Planning*, 79, 79-82 (1997); P. BENNETT, *Understanding Responses to Risk: Some Basic Findings*, in: P. BENNETT AND K. CALMAN (EDS.), *RISK COMMUNICATION AND PUBLIC HEALTH* (1999).

²⁰² Barnett & Breakwell, *supra* note 201; at 306.

²⁰³ *Id.*

²⁰⁴ *Id.* at 306-07.

²⁰⁵ Slovic, *supra* note 164, at 283.

²⁰⁶ CASS SUNSTEIN, *WORST CASE SCENARIOS* 139 (2007).

²⁰⁷ See Gerr Gigerenzer, *Out of the Frying Pan Into the Fire: Behavioral Reactions to Terrorist Attacks*, 26 *Risk Analysis* 347, 350 (2006).

income by between \$3.5 and \$6.4 billion, with the hotel and restaurant industries among the hardest hit.²⁰⁸

According to some estimates, the total cost of the terrorist attacks to New York City, including lost property values, lost jobs, and lost income, may have been as high as \$8 billion.²⁰⁹ Mark Zandi, chief economist at Economist.com, predicted that "the more quickly and effectively President Bush's promised reprisals against the terrorist network restore public confidence . . . the more quickly the rebuilding of Lower Manhattan will begin."²¹⁰ The lesson to be gleaned from this example is that even a symbolic legislative response to a crisis may restore sufficient public confidence to mitigate psychological and economic impacts, especially those that are the product of irrational fears.

V. IMPLICATIONS AND CONCLUSION

There appears to be ample evidence, at least in the arena of food and drug legislation, to support Breyer's hypothesis that the way this country regulates risk is closely tied to public perception and attendant Congressional reactions. The public may respond irrationally to adverse events linked to unsafe food and drugs, especially where the victims are children or other innocents, and especially where the media undertakes to enhance the story and broadcasts it nationwide, thereby magnifying its impact.

Lawmaking may inevitably be dominated by a crisis mentality. Certainly the political mechanisms that facilitate this mode of operation are natural and well-ensconced in our system of governance. It is as yet unclear whether this process results in obligatory if imperfect public confidence building, as described by the "Necessary Evil" paradigm, irrational risk regulation, as the "Knee-Jerk" paradigm suggests, or rational gap-filling, as the "Crisis as Catalyst" paradigm posits. In all likelihood, some combination of the three is at work. While the normative implications of "crisis legislation" must be resolved elsewhere, the framework set forth above lays the groundwork for such an analysis.

Regardless of which of the above paradigms best represents the mechanics of crisis and response in United States food and drug legislation, two proposals may help improve the quality of that response. First, where possible, the legislature should engage in continuous maintenance rather than crisis response. The continuous maintenance approach suggests that the legislature's task should be seen as more analogous to "police patrols" than responding to "fire alarms" (emergency situations in which constituent interests are at stake).²¹¹ Continuous maintenance will increase the likelihood that, if a crisis points out flaws in existing legislative schemes, those gaps will be narrower and more easily addressed.

It will also be important for interest groups and the media to find ways to make the possibility of future catastrophes relevant to the public and to lawmakers before they occur. In their book on how to prevent the disappearance of species, Paul and Anne Ehrlich suggest that changing the nature of the debate will be crucial. They propose analogizing the perils of extinction to watching worker pry rivets out of

²⁰⁸ Jason Bram, James Orr, and Carol Rapaport, *Measuring the Effects of the September 11 Attack on New York City*, 8 FRBNY Economic Policy Review 5, 15 (Nov. 2002).

²⁰⁹ Timothy Williams, *New York City Economy Struggles After 9/11*, U.S. MAYOR NEWSPAPER, Sept. 9, 2002.

²¹⁰ Mary Williams-Walsh, *Urban Pain, From Sea to Sea*, N.Y. TIMES, Sept. 30, 2001.

²¹¹ See Matthew D. McCubbins and Thomas Schwartz, *Congressional Oversight Overlooked: Police Patrols Versus Fire Alarms*, 28 AMERICAN J. OF POLITICAL SCIENCE 165 (1984).

a plane's wing while in flight.²¹² This kind of image, it is hoped, by making future harms more salient in the present, will help to generate the necessary political will to confront problems before they occur.

Second, assuming that it is inevitable that there will be greater political will to pass legislation in the wake of a food or drug crisis, the best way to ensure intelligent legislation may be to have carefully considered bills written and in reserve so that when the crisis hits, responsive legislation is not the result of hurried drafting. During the Senate debates on the 1962 Drug Amendments, when asked whether disaster was a predicate to action on domestic policy issues, Senator Philip Hart replied that "disaster helps, provided there have been at work concerned men and women who have developed a position on which the legislative body can quickly take a stand when disaster confronts it."²¹³ Unfortunately, Senator Hart may have been too sanguine in assuming that preexisting legislation is a prerequisite to action in the wake of highly publicized negative events. The foregoing discussion shows that while some crises, including the 1962 Amendments, serve as the catalyst for the passage of legislation already working its way through Congress, others produce legislation crafted from whole cloth in a short time frame.

There is no better way to sum up the questions posed by this article than by quoting the response of Senator Douglas to the passage of the 1962 Amendments. "Can we learn from this lesson," Senator Douglas wondered aloud, "or can mankind educate itself only by disaster and tragedy?"²¹⁴ Irrespective of the ultimate answer to Senator Douglas' query, food and drug legislation continues to embody a rich field for study, providing valuable data about the nature of public responses to risk and about the legislative process.

²¹² PAUL R. ERLICH & ANNE ERLICH, *EXTINCTION: THE CAUSES AND CONSEQUENCES OF THE DISAPPEARANCE OF SPECIES* (1981).

²¹³ 108 Cong. Rec. 22,043 (1962) (statement of Sen. Hart), *reprinted in* 23 FDA, A LEGISLATIVE HISTORY OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND ITS AMENDMENTS, at 194 (1979). I am grateful to Harvard Law Student Julie A. Grow for locating this quotation in her 1997 paper, *The Legislative History of the 1962 Drug Amendments: A Failure to Forget or a Lesson to Learn From?* (May 1, 1997) (unpublished manuscript, available at <http://leda.law.harvard.edu/leda/data/189/jgrow.rtf>).

²¹⁴ RICHARD HARRIS, *THE REAL VOICE* 215 (1964) (citing HARVEY TEFF & COLIN R. MUNRO, *THALIDOMIDE: THE LEGAL AFTERMATH* 111 (1976)).

