Encouraging a Broader Narrative of American Pure Food Legislation: Understanding the Federal Food, Drug and Cosmetic Act of 1938

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As the trend of 'conscious consumption' has grown throughout the 21st century, Americans are paying more attention to the purity and quality of their food. One of the key ways that purity and safety can be guaranteed is through government regulation. In the historiography of American pure food legislation, and broader interdisciplinary discussions by food studies scholars, their analysis has largely focused on the Pure Food and Drug Act of 1906 (PFDA). This paper argues that the historiography of this topic should be broadened to include the Food, Drug and Cosmetic Act of 1938 (FDCA). The FDCA replaced the PFDA, and brought more comprehensive regulatory power to the Food and Drug Administration. This study outlines the shortcomings of the PFDA, along with the passage of the FDCA and the function of the new law. This work offers a preliminary outline of the significance of the FDCA, and a call to other scholars to examine this landmark legislation. Without a complete historiography of American pure food legislation, understanding the history of the American consumer marketplace, and current regulatory challenges is greatly hampered.

In February 1906, Upton Sinclair's account of the Chicago stockyards, *The Jungle*, was published. While Sinclair had written the book with the intent of exposing the deplorable working conditions of the stockyards, his account instead captured the nation's attention due to his graphic descriptions of the unsanitary meat processing conditions of Chicago's commercial butchers. President Theodore Roosevelt responded with his own investigation of

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Sinclair's claims, and, after confirming the allegations, Roosevelt signed the Pure Food and Drug Act (PFDA) into law on 30 June 1906. This story of America's first federal pure food and drug law is a familiar one in American popular consciousness, however the narrative does not end there. In 1938, the PFDA was replaced by the Federal Food, Drug and Cosmetic Act (FDCA). A product of Franklin Delano Roosevelt's New Deal, the FDCA was enacted to strengthen the limited regulatory scope of the PFDA. In the historiography of American pure food legislation, numerous articles and books have examined the widespread food adulteration that existed throughout the country prior to *The Jungle's* publication as well as the fight to secure the passage of the PFDA, while a smaller number of works have analysed how the law functioned in practice.[2] Surprisingly, few historians have investigated the FDCA's influence on the safety and purity of the American food supply.[3] While the PFDA was immensely important in establishing federal oversight in the American marketplace, it was ultimately repealed, and represents just one part of American food regulatory history.

This work will examine the limitations of the PFDA and outline the passage and early implementation of the FDCA with a view to assessing the place of the FDCA within larger narratives of American pure food legislation. This paper will begin by oulining the shortcomings of the PFDA, then discuss the passage of the FDCA, and finally outline the new regulatory power and scope that the FDCA brought to federal oversight of consumer goods. The paper argues that the FDCA not only strengthened the Food and Drug Administration's regulatory scope, but also brought many innovations, most notably the food identity standards provision. By highlighting the significance of the FDCA, this work ultimately aims to encourage the development of a more comprehensive historiography of American pure food

[2] Works on the passage of the PFDA include:
Marc T. Law, 'The Origins of State Pure Food Regulations', *The Journal of Economic History* 63 (2003).
Ilyse D. Barkan, 'Industry Invites Regulation: The Passage of the Pure Food and Drug Act of 1906' *American Journal of Public Health* 75 (1985).
James Harvey Young, *Pure Food: Securing the Federal Food and Drugs Act of 1906* (Princeton: Princeton University Press, 1989).
Lorine Swainston Goodwin, *The Pure Food, Drink, and Drug Crusaders, 1879-1914* (Jefferson: McFarland & Company, Inc., 1999).
Works on the function of the law:
James Harvey Young, 'From Oysters to After-Dinner Mints: The Role of the Early Food and Drug Inspector', *The Journal of the History of Medicine and Allied Sciences* 42 (1987).
Philip J. Hilts, 'Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation', (New York: Alfred A. Knopf, 2003) pp. 56-71.
[3] The historiography of the drug regulations of the FDCA is more complete than the historiography of food regulations.

The Need for New Federal Food, Drug & Cosmetic Oversight

While meta-narratives of the Progressive era suggest that securing the passage of the PFDA solved the issue of food and drug safety and purity in America, I will argue that the PFDA was poorly written, and did not allow for comprehensive regulation. Even Harvey W. Wiley, America's first Chief Chemist for the Bureau of Chemistry (which would later become the Food and Drug Administration) and driving force behind the passage of the PFDA felt that industry pressure had led Congress to weaken the final version of the PFDA.[4] Major shortcomings included limited resources for federal inspectors, which led to improper inspections, lenient penalties for dishonest food and drug manufacturers, and ineffectual definitions for adulterated food.[5] Wiley, who was often referred to by the media during this period as "the father of the pure food law", resigned from his role in the Bureau of Chemistry in March of 1912, just six years after the passage of the PFDA. Though Wiley had spent over two decades advocating for a federal pure food law, he ultimately felt that the law was too weak to allow for effective regulation.[6]

The flaws in the PFDA became especially apparent as the century progressed. New technologies in adulterants and additives led companies to engage in unfair and unsafe practices that were legal under the existing legislation. These loopholes allowed for the selling of products such as conventional noodles packaged in yellow cellophane to give the appearance of egg noodles and chicken packaged to look like it was white meat, when it was actually dark meat.[7] While these deceptive practices were technically harmless, they represent a marketplace in which consumers were consistently misled or cheated. The PFDA was especially weak in regulating patent medicines, which were often much more dangerous than some adulterated foods. Products such as Ban Bar, a diabetes 'cure' made from horsetail weed, Radithor, an energy tonic which caused radium poisoning, and the Wilhide Exhaler, a product which falsely promised to cure tuberculosis, were all legal under the existing law.[8] Furthermore, cosmetics were completely unregulated at this time. Products like Lash Lure, an eyelash tint, which contained coal-tar dyes that caused serious eye injuries, blindness, and sometimes death, had no government oversight.[9]

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[4] Barkan, p. 18. Junod, 'Food Standards'., p. 166-169. Young, 'From Oysters to After-Dinner Mints' pp. 32- 35.
[5] Young, 'From Oysters to After-Dinner Mints' pp. 32- 35.
[6] Ibid.
[7] Michelle Meadows, 'A Century of Ensuring Safe Foods and Cosmetics', *The FDA Consumer* 9 (2006) p. 8.
[8] 'FDA History Part II: The 1938 Food Drug and Cosmetic Act', *US Food and Drug Administration*
<http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> [accessed 10 April 2013].
[9] Meadows, p. 8.

As technological advancements outpaced regulators, some activists and organisations worked to educate the public about the perils of many popular consumer products. In the spirit of Upton Sinclair and other whistleblowing journalists of the Progressive era, the 1927 book,Your Money's Worth: A Study in the Waste of the Consumer's Dollar exposed the deceptive nature of contemporary advertising. The authors, Stuart Chase and F.J. Schlink, aimed to educate consumers in the value of 'buying goods according to impartial scientific test, rather than according to the fanfare and trumpets of the higher salesmanship'.[10] Chase and Schlink were aware, however, of the scientific limits to ascertaining the value of a product, and likened the public's confusing and frustrating quest to Alice's Adventures in Wonderland. In order to fight for greater transparency in advertising, and overall consumer rights, the authors founded Consumers' Research, an advocacy group which would later prove instrumental in the campaign for increased government regulation of foods, drugs and cosmetics.

F.J. Schlink, along with co-author Arthur Kallet, later published 100,000,000 Guinea Pigs: Dangers in Everyday Foods, Drugs and Cosmetics. The authors alleged that the public was serving as 'guinea pigs' because existing legislation did not require any safety testing before putting a product on the market. Additionally, Kallet and Schlink warned that these unregulated practices posed both short and long-term health risks. Ultimately the authors advised consumers to avoid all products marketed as proprietary, especially patent medicines and cosmetics, and instead suggested that readers visit medical professionals for an informed diagnosis.[11] The research and advice of Kallet and Schlink proved to be very popular, as the book was reprinted thirteen times within the first six months of publication. The popularity of these guides to smart consumption indicate that the public did not trust government regulators, nor companies to provide a safe marketplace, despite the existence of the PFDA.

By 1933 the shortcomings and loopholes of the PFDA had become so apparent that the FDA, the organisation responsible for enforcing federal food purity standards, began campaigning for revisions of the existing legislation. The FDA put together an exhibition of many of the adulterated, deleterious and deceptive practices that were then legal under the PFDA, due to the many loopholes and regulatory gaps in the law. The exhibition exposed discrepancies in manufacturing standards, labelling inconsistencies, and

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'FDA History Part II' <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm>.

[10] Stuart Chase and F.J. Schlink, *Your Money's Worth: A Study in the Waste of the Consumer's Dollar* (London: Jonathan Cape, 1927) p. 4.

[11] 'One Hundred Million Guinea Pigs: And Ten Million More', *Canadian Medical Association Journal* 30 (1934) pp. 310- 311.

deceptive packaging.[12] While the FDA had initially intended to only display the exhibit for members of Congress, the popular success of Your Money's Worth and 100,000,000 Guinea Pigs led the agency to organize a tour of the exhibition, with the goal of educating consumers and building support for their cause. The exhibition travelled the country, stopping at the 1933 World's Fair in Chicago and the White House, where it was visited by new First Lady Eleanor Roosevelt and dubbed by a journalist as the 'Chamber of Horrors'.[13] Ultimately the exhibit succeeded in building consumer support for comprehensive federal food regulation, and even compelled some manufacturers featured in the exhibit to change their practices in order to be removed from the display.[14]

This section has outlined the consumer goods marketplace in the years following the passage of the PFDA and considered public and industry reaction to regulation. While the PFDA made important strides in establishing federal food and drug regulation, the law quickly became outdated and ineffectual. The work of consumer advocates and the FDA indicates that the law was not succeeding in protecting the safety and value of goods.

Securing Passage of New Legislation

In the spring of 1933, just as President Franklin Roosevelt was begining his first term in ofice, calls to fill the regulatory gaps in the PFDA began to gain momentum. Though the nation was in the midst of the Great Depression, Roosevelt's prioritisation of the issue reflects the urgency of the matter. Rexford G. Tugwell, Roosevelt's Assistant Secretary of Agriculture was aware of the work of Chase, Kallet and Schlink, and, after verifying their allegations with the FDA, Tugwell received presidential sanction to revise the PFDA.[15] He assembled a team consisting of members of staff from the FDA and Department of Agriculture, as well as several lawyers to begin working on drafting recommended revisions to the PFDA. Tugwell's group soon found that the flaws of the old law ran so deeply throughout the document that it would be necessary to draft an entirely new bill.[16] After nearly a year of work the first draft of the 'Tugwell Bill' was proposed in December of 1933. At the hearing, industry representatives made vocal criticisms of the language of the law, and its stricter scope. Despite opposition from the affected industries,

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12 'The American Chamber of Horrors', *The U.S. Food and Drug Administration,* <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132791.htm> [accessed 8 April 2013].
13 Andrea T. Borchers and others,'The History and Contemporary Challenges of the US Food and Drug Administration' *Chemical Therapeutics* 29 (2007) p. 7.
14 'The American Chamber of Horrors', <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132791.htm>.
15 David F. Canvers, 'The Food, Drug and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions', *Law and Contemporary Problems* 6 (1939) p. 6.
16 Canvers, p. 7.

most consumer groups and public health agencies were in favour of the bill, although Chase and Schlick's Consumer Research felt that the the proposed legislation could have offered even further protection to consumers.[17]

Because of the criticisms the bill received from both corporate and consumer representatives, Tugwell's team began revising their proposal. Over the next two years, Tugwell's committee submitted three revisions of the bill, but criticism from industry and consumer organisations persisted, and in January 1935 an entirely new bill was proposed.[18] Two months later, President Roosevelt declared his support for stricter food, drug and cosmetic regulation in a message to Congress:

> In such a situation as has grown up through our rising level of living and our multiplication of goods, consumers are prevented from choosing intelligently and producers are handicapped in any attempt to maintain higher standards. Only the scientific and disinterested activity of Government can protect this honour of our producers and provide the possibility of discriminating choice to our consumers.[19]

Despite Roosevelt's message urging legislators to pass the bill, the bill spent another two years stalled in Congress due to disagreements over phrasing within law.

After four years of continued failure to agree on any legislation, the nation experienced a crisis that exposed the urgency with which this regulation was needed. In the fall of the 1937, a new liquid preparation of the drug Sulfanilamide was marketed as Elixir of Sulfanilamide. Because drug manufacturers were not required to test their products for safety under the PFDA, the manufacturer of this elixir found that an ideal appearance, flavour and texture could be achieved if the Sulfanilamide was dissolved in diethylene glycol, known commonly today as antifreeze.[20] As a result of this oversight, over 100 people, predominantly children, were killed across fifteen states.[21] Doctors from affected areas notified the FDA of the lethal effects of the elixir, and the FDA responded by dedicating all their resources to retrieving what remained of the product on the market. The agency was only able to seize the

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[17] Canvers, p. 9.
[18] Canvers, pp. 11- 12.
[19] Kenneth F. Davis, *FDR: The New Deal Years 1933-1937* (New York: Random House, 1986) pp. 485- 486.
[20] J.C. Geiger, 'Concerning Elixir of Sulfanilamide', *Cal Med West* 47 (1937) p. 353.
[21] Carol Ballentine, 'Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident', *The US Food and Drug Administration* <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SulfanilamideDisaster/default.htm> [accessed 15 April, 2013].

remaining Elixir of Sulfanilamide through a technicality in the PFDA. Under the existing legislation, the only charge the FDA could levy against the manufacturer was misbranding, as 'elixirs' were required to contain alcohol. Because diethylene glycol was not alcoholic, the product should have been labelled as a 'solution.'[22] Ultimately, the FDA was able to retrieve 234 of the 240 gallons manufactured, indicating that the death toll could have been much higher.[23] This tragic event was instrumental in garnering support for improved regulation, as it confirmed the claims the FDA, journalists and consumer groups had been making for years.

The Federal Food, Drug and Cosmetic Act of 1938: On Paper and In Practice

Following the Sulfanilamide incident, Congress came under increasing pressure from the public, the FDA, women's groups, and consumer organisations to pass regulatory legislation based, at least partly, on the Tugwell bill. Just as the The Jungle provided the impetus necessary to secure the passage of the PFDA, once again shock and tragedy were the catalysts required to compell lawmakers to take action. Throughout the five year struggle to pass new food, drug and cosmetic legislation, the conflicts that had stalled its passage were largely semantical and related to issues with enforcement jurisdiction. In the face of Sulfanilamide tragedy these issues appeared increasingly trivial, and on 25 June 1938 President Roosevelt signed the Federal Food, Drug and Cosmetic Act of 1938 into law. The fight to pass this legislation had been a struggle between the interests of industry and of consumers, and, while industry had powerful resources and influence, the FDCA ultimately strengthened the weak regulation of the PFDA in favour of protecting consumers.

In regulating food, the FDCA required manufacturers to follow stricter processing and labelling standards that would allow consumers to make more informed choices about the food they were purchasing. While the new law improved commercial food production in many ways, it was provisions affecting labelling, packaging and quality standards that brought some of the most far-reaching changes and innovations. The FDCA improved and standardised labelling requirements by mandating that products bear the common name of the food in addition to the brand name, and that producers disclose any artificial colourings or flavourings present, though exceptions were made for some dairy products such as butter, cheese and ice cream.[24] The

[22] Ballentine, 'Taste of Raspberries'.
[23] Ibid.
[24] Rayburn D. Tousley, 'The Federal Food, Drug and Cosmetic Act of 1938', *The Journal of Marketing* 5 (1941) p. 261.

law also addressed the packaging discrepancies displayed in the 'Chamber of Horrors' exhibit by establishing filling standards for containers.[25]

Of the new provisions introduced by the law, numerous scholars have argued that the food identity standards clause was the most significant regulatory innovation in the law.[26] Contemporary journalists wrote that the food identity standards provision was one of the strongest positive changes to the law, and ranked its significance on par with the new federal oversight of cosmetics, and the mandatory safety testing of new drugs.[27] The favourable public reception to the provision is notable because there were separate provisions in the law that regulated food adulteration (section 402), misbranding (section 403), and the use of poisonous ingredients and colouring agents in foods (section 406), yet the food standards provision seemed to bring consumers the greatest assurance that their foodstuffs would change for the better.[28] Overall, consumers at the time considered the law a 'great advance'.[29]

The food identity provision is part of a three-part power found in section 401 of the Act which states:

> *'Whenever in the judgement of the Secretary such action will promote honesty and fair dealing in the interest of consumers he shall promulgate regulations fixing and establishing for any food under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality and/or reasonable standards or fill of container.'*[30]

While this provision allows the Secretary of Agriculture to create three separate types of standards, Junod states that all three were intended to ensure consumers received the value they expected from their food.[31] This power applied to any food, except those that already had a standard or foods that

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25 David F. Canvers, 'The Food, Drug and Cosmetic Act of 1938: Its Legislative History and its Substantive Provisions', *Law and Contemporary Problems* 6 (1939) p. 25.
26 Richard A. Merrill and Earl M. Collier Jr., '"Like Mother Used to Make": An Analysis of FDA Food Standards of Identity', Columbia Law Review 74 (1974) p. 566.
Robert W. Austin, 'The Federal Food Legislation of 1938 and the Food Industry', *Law and Contemporary Problems* 6 (1939) p. 131.
27 'New Food and Drug Bill Given to House', *Los Angeles Times,* 16 April 1938.
'President Breaks Deadlock on Food and Drug Bill', *Los Angeles Times,* 12 June 1938.
28 'The Federal Food Drug and Cosmetic Act', *United States Statutes at Large*, 34 Stat. 768 (1938).
29 Louise G. Baldwin and Florence Kirlin, 'Consumers Appraise the Food, Drug and Cosmetic Act', Law and Contemporary Problems 6 (1939) p. 144.
30 'The Federal Food Drug and Cosmetic Act'(1938).
31 Suzanne Junod, 'Food Standards in the United States: The Case of the Peanut Butter and Jelly Sandwich', in *Food, Science, Policy and Regulation in the Twentieth Century: International and Comparative Perspectives*, ed. David F. Smith and Jim Phillips (London: Routledge, 2000) p. 180.

were sold in their natural, or nearly natural, state such as fresh or dried fruits or vegetables.[32] Of the three types of standards, creating and enforcing standards of identity posed a more complicated regulatory task. Enacting a standard of identity required (and continues to require, as the provision is still in effect) careful consideration because a single identity standard can dictate exactly what ingredients are permitted in a particular food, how it is prepared, how it is named, and how it is labelled. If all of these variables are properly considered, the provision can give the FDA improved control over the entire manufacturing process, therefore offering comprehensive oversight regarding both the safety of food and the sincerity of manufacturers.[33]

The FDCA also introduced various necessary changes pertaining to the drug and cosmetic industries. Overall, the new law corrected many of the PFDA's inherent problems, extending, among other things, the regulatory power of the FDA, and ensuring the safety and purity of drugs.[34] Specifically, as a result of the Elixir of Sulfanilamide incident, the law mandated that all drugs must be tested for safety before being sold to the public.[35] Furthermore, the law required that labelling standards for drugs be very clear in informing the user of the directions required for safe use, and warning of any potential for abuse.[36] The new legislation also regulated the use of habit-forming substances in drugs, most notably alcohol and narcotics such as opium and heroin, and also required that any use of such ingredients be disclosed on the label with a statement warning of the product's addictive nature.[37] The provisions affecting the cosmetic industry were significant because the FDCA was the first federal legislation regulating this industry in any way. Overall, the FDCA regulated cosmetics by making it illegal for manufacturers to use any harmful or unsanitary ingredients, and also prohibiting the misbranding of any cosmetics.[38]

Following the ratification of the FDCA, the FDA mandated that all provisions requiring safety testing be effective immediately, but allowed manufactures one year to establish compliance with all other requirements. The FDA also began drafting their federal food identity standards, as national 'recipes' needed to be established for all commonly purchased foods. The first round of identity standards were released in 1939, and created standard recipes

[32] At the time a standard of identity for butter was regulated by Congress.
Joseph M. Vallowe, 'Informing Consumers of the Existence and Significance of Food and Drug Administration Standards of Identity', *Food Drug and Cosmetic Law Journal* 38 (1983) p. 257.
[33] Vallowe, p.257.
[34] Canvers, p. 31.
[35] Tousley, p. 262.
[36] Canvers, p. 36.
[37] Canvers, p. 37.
[38] Canvers, p. 41.

for all popular tomato products.[39] Despite the slow process of writing each individual food identity standard and implementing the new manufacturing and labelling requirements, the effectiveness of the FDCA was apparent soon after ratification. In the first year the law was in effect the FDA prosecuted 79 companies in violation of the law and seized 187 products.[40] Furthermore, of the 1,107 drug applications the FDA received in the first year, 683 were approved, 376 were found to require further investigation and 48 were withdrawn.[41]Overall, despite the lengthy passage of the bill, the resulting legislation asserted bold protections for consumers that not only addressed the problems that had plagued the consumer goods marketplace, but aligned with the broader goal of promoting the wellbeing of all Americans that underpinned much of Roosevelt's New Deal. The FDCA remains in effect today, including hundreds of food identity standards. Over the past 77 years the FDCA has adapted to the changing consumer marketplace, which included a shift from simple pantry foods to prepared, convenience items. While the challenge of industry lobbying has remained persistent (see the standard hearings for bread and peanut butter), standards of identity continue to affect America's food industry.[42] In 2008 an entirely new food standard was created for white chocolate, and in 2014 Unilever sued Hampton Creek (and later withdrew their suit) for infringing upon the food identity standard for mayonnaise with their eggless spread called 'Just Mayo.'[43] This dialogue indicates that standards of identity, and the FDCA overall continue to be relevant in the consumer marketplace.

For Future Study

In 1929, Wiley self-published the text The History of a Crime Against the Food Law. Though he had devoted his life to consumer advocacy, Wiley felt compelled to publish his account of the failures of the PFDA one year before his death. In the text, he described what he believed were the two major shortcomings of the law: industry scientists who engineered loopholes and

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[39] 'Food Standards Under the 1938 Food, Drug, and Cosmetic Act: Bread and Jam', *The US Food and Drug Administration* <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/ucm132892.htm> [accessed 19 April, 2013].

[40] Tousley, p. 267.

[41] Ibid.

[42] Junod, pp. 46-47.
M. Markel, 'Baking Industry Progress,' Food, Drug, and Cosmetic Law Journal, 1951, vol. 6, p. 782.

[43] 'Guidance for Industry: Standard of Identity for White Chocolate,' *US Food and Drug Administration* <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059076.htm> [accessed 29 April, 2015].
David Pierson, 'Unilever drops lawsuit against vegan mayonnaise maker,' *Los Angeles Times,* <http://www.latimes.com/business/la-fi-mayo-lawsuit-20141218-story.html> [accessed 29 April, 2015].

government officials who 'permitted and encouraged' food manufacturers to do so.[44] While these issues affected the success of the PFDA in particular, Wiley's account ultimately detailed challenges that existed and continue to exist for most types of government regulation in the United States. In framing consumer protection regulation specifically, it is impossible to know what types of technological advancements will arise, thus challenging the regulatory scope of the law. As the FDCA approaches its 80th anniversary, Wiley's observations outline a common challenge to creating effective regulation, and also suggest that the FDCA's longevity could be attributed, in part, to its success in managing the ever-evolving challenges of consumer demands, industry lobbying, and technological change.

This paper has summarised the history of federal pure food and drug regulation in the United States from 1906 to 1939. Though the legislation of 1906 and 1938 are both crucial aspects of the expansion of government regulatory practice in the United States, they mark the beginning of the story, not its end. This research reveals that the implementation of the FDCA made an important contribution to the health and safety of Americans in the twentieth century. It also indicates that while the PFDA receives much historical notoriety, the FDCA brought more comprehensive oversight. Further research on the continuing effects of the legislation, including amendments, industry involvement and consumer perception of the law is required to create a more comprehensive historiography of the FDCA. At the time of writing, no comprehensive historical accounts of the FDCA exist, with most sources written by FDA professionals and lawyers, intended for use within these fields.[45] As the FDCA has now been in effect for over three times as long as the PFDA, this legislation offers a wealth of opportunities for historical investigation.

This research, and further in-depth research on the FDCA, are essential to understanding how food purity and safety for American consumers emerged in the twentieth century. Furthermore, this research contributes not only to the historiography of American pure food legislation, but also interdisciplinary discussions on food policy and food safety. Without considering the origins of American's current regulation, and the amendments and changes that have led to the current climate, it is impossible to address present issues. As Wiley wrote of loopholes and corruption relating to the PFDA, these challenges have

[44] Harvey Washington Wiley, *The History of a Crime Against the Food Law: The Amazing Story of the National Food and Drugs Law Intended to Protect the Health of the People, Perverted to Protect Adulteration of Foods and Drugs* (Washington DC: the author, 1929 repr. Milwaukee: Lee Foundation for Nutritional Research, 1955) p. 402.

[45] The most comprehensive sources on the FDCA available are from legal journals and the FDA, including the journals *The FDA Consumer* and *The Food Drug and Cosmetic Law Journal.*

the potential to affect any type of legislation.[46] Thus, continued investigation of key regulations like the FDCA is crucial to not only to build the historiography, but also contextualise contemporary issues and create adaptable, effective legislation.

[46] Wiley, p. 403.