THE END OF AN ELUSIVE ERA: WHY THE FOOD SAFETY MODERNIZATION ACT APPROPRIATELY HOLDS IRRESPONSIBLE CORPORATE OFFICERS CRIMINALLY LIABLE

I. Introduction

More than 200 known diseases are transmitted through food. While not all foodborne illnesses are preventable, with proper care and adequate oversight, many outbreak crises may be averted. The World Health Organization (WHO) published a manual in 2006 titled 'Five Keys to Safer Food' to prevent the spread of foodborne illnesses. This manual provides detailed information on how to keep food safe, such as keeping food at the correct temperature (when storing, cooking and serving), preventing cross-contamination, and keeping the consumable item clean. The Center for Disease Control (CDC) estimates that each year, "one in six Americans (or forty-eight million people) gets sick, 128,000 are hospitalized, and 3,000 [people] die [from] foodborne diseases." Foodborne outbreaks occur when at least two people get sick from eating the same food or drink that is contaminated.

In the United States, the Federal Drug Administration (FDA) is in charge of investigating possible outbreaks to ensure that they are controlled. When a corporate officer fails to ensure the safety of products being released into the market or knowingly allows tainted items to be released to the public, they are

¹ Paul S Mead et al., Food-Related Illness and Death in the United States,

⁵ EMERGING INFECTIOUS DISEASES 607–625 (1999), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2627714/pdf/10511517.pdf.

² Food Safety Basics: Preventing Foodborne Illness Keeping Food Safe At Home, MN DEPT. OF HEALTH (2016),

http://www.health.state.mn.us/foodsafety/basics.html (last visited Nov 13, 2017).

³ FIVE KEYS TO SAFER FOOD MANUAL, WORLD HEALTH ORGANIZATION (2006), http://www.who.int/foodsafety/publications/consumer/manual_keys.pdf (last visited Nov. 13, 2017).

⁴ *Id*.

⁵ Estimates of Foodborne Illness in the United States, CENTER FOR DISEASE CONTROL AND PREVENTION (2016), https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last visited Nov 13, 2017).

⁶ *Outbreak Investigations*, U.S. FOOD & DRUG ADMINISTRATION (2017), https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272351.ht m (last visited Nov. 13, 2017).

⁷ *Id*.

seldom held personally liable for the misdeed.⁸ This is not only a grave injustice of public policy, but it also goes against the trend in tort and criminal law to hold those liable for the consequences of their actions or in the alternative inaction.⁹

On January 4, 2011, the legislature passed The Food Safety Modernization Act (FSMA or The Act). The Act is expected to be fully implemented within the next few years. The FSMA is a major overhaul to laws and policies enacted in 1938 to protect the consumer against foodborne illness. The FSMA aims to remedy the shortcomings of current regulations under the FDA and the lack of the regulations for liability by creating a framework and the necessary regulations for the enforcement of the broad public policy goals of the FDA. By imposing harsher and stricter guidelines that will hold particular corporate individuals criminally liable through authority in the FSMA, the legislature intends to create safer products and better regulation. The FSMA clarifies how these corporate individuals are liable for the harm resulting from food products.

This comment will explore the Food Safety Modernization Act and why the extension of criminal liability against corporate officers is welcome and necessary reform. Part II of this comment will explain the history of the FDA and the FSMA. Also, this part examines why there is a need for the recently enacted regulations. Part II concludes with a brief history of some significant cases of foodborne illness outbreaks in the United States and court cases that are being used to support the FDA's ability to hold corporate dignitaries criminally liable.

Part III discusses the historical trend of difference in treatment under the law for personal individuals and corporations. This part further examines corporations as they have become 'individuals' under the law.

⁸ See infra Part II. E.

⁹ See Darryl K. Brown, Criminal Law Theory and Criminal Justice Practice, 49 Am. CRIM. L. REV. 73, 73 (2012).

¹⁰ FSMA Final Rule for Preventive Controls for Human Food, U.S. FOOD & DRUG ADMINISTRATION (2017),

 $https://www.fda.gov/food/guidanceregulation/fsma/ucm334115.htm\ (last\ visited\ Nov.\ 13,\ 2017).$

¹¹ *Id*.

¹² Jordan Anderson, *Food Safety: It's The Law! 5 Key Points Of FSMA*, PARTECH (Feb. 20, 2017), https://blog.partech.com/food-safety-its-the-law-5-key-points-offsma.

¹³ FDA's Strategy for FSMA Training

Who Will Provide Training for the Food Industry? Public and Private Partners Working Together (2017),

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461513.htm (last visited Dec. 12, 2017).

¹⁴ *Id*.

¹⁵ *Id*.

Part IV of this comment analyzes the more modern cases involving foodborne illnesses to compare and distinguish the outcome of those cases. This section then shows how they apply the current guidelines set by the FDA through the FSMA. It further explores the guidelines set by the FSMA and examines whether or not they present an unfair extension of liability to individuals. This section compares the current instances with earlier case analysis for the purpose of showing the benefits of holding corporate officers responsible for the actions/inactions of the corporations they control.

Part V gives recommendations regarding the United States as a world leader in food safety. In conclusion, Part VI explains why it is not an overstep of the FSMA to hold high ranking corporate individuals accountable.

II. FACTUAL BACKGROUND

A. The FDA

The FDA is a federal administrative agency under the United States Department of Health and Human Services. ¹⁶ "Administrative agencies [which are] created by the...Congress, ...manage contingencies, redress serious social problems, and manage complex matters of governmental concern." ¹⁷ The FDA is mainly responsible for consumer health protection. ¹⁸ The FDA's modern regulatory functions began in 1906 with the passage of the Pure Food and Drugs Act, which was "an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce." ¹⁹

The FDA officially became known as the "United States Food and Drug Administration" in 1930.²⁰ The FDA was granted power by the United States Congress in 1938 to enforce the Federal Food, Drug, and Cosmetic Act (FDCA).²¹ The FDA is part of the executive branch but is granted authority through the legislative branch.²² One of the FDA's primary responsibilities include "protecting the public health" by ensuring that the food supply of the

¹⁶ Types Of Administrative Agency Action: Rulemaking, Adjudication, Investigation, USLEGAL.COM, https://administrativelaw.uslegal.com/three-types-of-administrative-agency-action-rulemaking-adjudication-investigation/ (last visited Nov. 15, 2017).

¹⁷ *Id*.

¹⁸What We Do, FDA.GOV (2017), https://www.fda.gov/AboutFDA/WhatWeDo/ (last visited Nov. 15, 2017).

¹⁹ United States v. Dotterweich, 320 U.S. 277, 280 (1943).

²⁰ What We Do, supra note 18.

²¹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§301-399h (1938).

²² What We Do, supra note 18.

country is safe and secure.²³ The FDA is responsible for "advancing the public health" by making sure the public has help receiving the most up to date and scientific information available regarding foods that "maintain and improve their health".²⁴ Congress recognized the necessity of making laws to regulate not only food but drugs and cosmetics as there was little to no regulation of this market which resulted in serious abuses in the consumer product market.²⁵ Congress understood to ensure proper implementation of acts they needed to create independent agencies.²⁶ While not perfect, the authority for the FDA has remained consistent with public policy: the need for consumers to be protected against, or free from, dangers of consumables put on the market by, among others, corporations.²⁷

The FDA can create and enforce regulations and in turn, provide for liability when the regulations are not followed or are ignored.²⁸ The FDA is responsible for the regulation and enforcement of the Food Safety Modernization Act.²⁹ The FSMA is an example of Congress granting the FDA authority to regulate the potential dangers in the consumer product market by empowering current FDA officers to enforce the law through civil and criminal penalties and by providing funding to hire and train more enforcement officers.³⁰

B. The Food Safety Modernization Act

The Food Safety Modernization Act was the first major reform to the scope of the FDA's regulatory authority in decades. President Barack Obama signed the FSMA into law on January 4, 2011.³¹ The United States House of

 $https://www.fda.gov/AboutFDA/Transparency/Basics/ucm214403.htm\ (last\ visited\ Nov.\ 15,\ 2017).$

²³ *Id*.

²⁴ *Id*.

²⁵ When And Why Was The FDA Formed?, FDA.GOV (2017),

²⁶ See id.

²⁷United States Food and Drug Administration, *Statement of FDA Mission* (2017) https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/budgetreports/ucm298331.pdf.

²⁸Michael A Walsh, *United States: The Food Industry And No Fault Crimes - Criminal Liability For The Conduct of Others*, MONDAQ (2013), http://www.mondaq.com/unitedstates/x/278428/food drugs law/ (last visited Nov.

http://www.mondaq.com/unitedstates/x/2/8428/food drugs law/ (last visited Nov. 15, 2017).

²⁹ Background on the FDA Food Safety Modernization Act (FSMA), FDA.GOV (2015),

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm (last visited Nov. 15, 2017).

³⁰ *Id*.

³¹ Diana R.H. Winters, *Food Law At The Outset Of The Trump Administration*, 65 UCLA L. REV. DISCOURSE 28, (2017).

Representatives passed the Food Safety Modernization Act on December 21, 2010, paralleling the passage by the Senate just two days earlier on December 19, 2010.³² The vote in the Senate was not recorded, but interestingly enough it was passed unanimously.³³ Passage of FSMA gives a significant increase in power to the Food and Drug Administration.³⁴ The bill set a goal to increase FDA staff from 4000 in the fiscal year 2011, to 5000 within the fiscal year 2014.³⁵ Under the new law, the FDA will be given power to hire state officials to enforce the requirements of FSMA.³⁶

C. The Need for Updated Guidelines Provided by the Food Safety Modernization Act

In late 2008, the United States experienced one of the worst foodborne illness outbreaks of salmonella resulting in one of the largest ever food product recalls in United States history.³⁷ In *United States v. Parnell*, No. 1:13-CR-12, 2013 U.S. Dist. WL 2387714 (M.D. Ga., May 30, 2013),³⁸ The Peanut Corporation of America was found to have been responsible for a salmonella outbreak where forty-seven states reported over 700 illnesses and nine deaths that were linked to foodborne complications.³⁹ The number of total cases both reported and unreported is believed however, to total more than 220,000 illnesses.⁴⁰ The FSMA was born out of the shortcomings in food safety that

³² Meredith Shriner, *Senate Oks Food Safety Measure* Politico (2010) https://www.politico.com/story/2010/12/senate-oks-food-safety-measure-046598 (last visited Dec. 12, 2017).

³³ *Id*.

³⁴ See generally 21 U.S.C. 301 et seq. (2011).

³⁵ 21 U.S.C. 301 et seq. (2011).

³⁶ Pete Kennedy, Esq., *Congress Passes FDA Food Safety Modernization Act* (*FSMA*), FARM-TO-CONSUMER LEGAL DEFENSE FUND (Dec. 29, 2010), https://www.farmtoconsumer.org/blog/2010/12/29/congress-passes-fsma-kennedy/ ³⁷ Brian Hartman & Kate Barrett, *Timeline of the Salmonella Outbreak*, ABC NEWS (2009), http://abcnews.go.com/Health/story?id=6837291 (last visited Nov. 13, 2017). ³⁸ United States v. Parnell, No. 1:13-CR-12, 2013 U.S. Dist. WL 2387714 (M.D. Ga., May 30, 2013).

³⁹ Multistate Outbreak of Salmonella Typhimurium Infections Linked to Peanut Butter, 2008-2009 (FINAL UPDATE), CDC.GOV (2009), https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html (last visited Nov. 15, 2017).

⁴⁰ Howard Sklamberg & Michael Taylor, *Reflecting on New Food Protections in the Wake of PCA Convictions*, (Sept. 25, 2014),

https://blogs.fda.gov/fdavoice/index.php/2014/09/reflecting-on-new-food-protections-in-the-wake-of-pca-convictions/.

led to the Peanut Corporation of America salmonella outbreak.⁴¹ This outbreak highlighted the issue and brought it into the spotlight.⁴²

After this devastating event, Congress began to discuss adopting the guidelines of the FSMA which would result in harsher sanctions against corporations and individuals involved in allowing an item (specifically food item or other consumable item), that was not suitable for consumption or health, to be allowed into the stream of commerce and to be consumed by the public at large. ⁴³ Under the FSMA, the FDA now has the authority to impose criminal liability for the following violations:

- Operating a facility not in compliance with the FSMA Preventive Controls Rules (for both Human and Animal Food)
- Failure to comply with the FSMA Produce Safety Rule
- Failure to comply with FSMA food defense regulations
- Refusal or failure to comply with an FDA recall order
- Knowing and willful failure to comply with consumer recall notification requirements
- The importing or offering for importation of a food if the importer does not have a foreign supplier verification program in compliance with the FSMA Foreign Supplier Verification Program Rule
- Failure to comply with recordkeeping requirements for high-risk foods.⁴⁴

⁴¹ Thomas Jones, *Environmental Monitoring in the Age of FSMA*, SAFEFOODALLIANCE.COM, https://safefoodalliance.com/wp-content/uploads/sfc2016-Environmental_Monitoring_In_The_Age_of_FSMA.pdf (last visited Nov. 15, 2017).

⁴² Id

⁴³ Mary Clarke Jalonik, *New federal food safety rules issued after deadly outbreaks*, CHI. TRIBUNE (Sept.11, 2015),

http://www.chicagotribune.com/news/nationworld/sns-bc-us--food-safety-rules-20150910-story.html.

⁴⁴ Erik Lieberman, *Criminal Prosecutions of Corporate Officers Under FD&C Act Highlight Importance of FSMA Compliance*, LIEBERMANPLLC.COM (2014), http://www.liebermanpllc.com/criminal-prosecutions-corporate-officers-fdc-act-highlight-importance-fsma-compliance/ (last visited Nov. 15, 2017).

D. The Current Status

The FSMA was scheduled to become fully implemented in 2016, but as with any federal statute, there are specific steps that must be taken to ensure it becomes a fully enforced statute under the law. An incoming President has the authority to order that regulations enacted in a previous administration stop being implemented. This is what is known as a regulatory freeze. A regulatory freeze can be typical during the transition from one administration to another. Initially, it appeared that the new administration led by President Donald Trump would continue to allow the FDA to enforce the FSMA guidelines. However, President Trump has indefinitely suspended core protections and authorities given under the broad bipartisan supported legislation. There has been a regulatory freeze of key aspects of the FSMA, and for the remaining protections under the regulation, there have been continuous extensions given to corporations to be in compliance. The claim is that extensions are provided for the affected corporations who need more time and financial resources to be in compliance with the new regulations.

⁴⁵ Legislative Process: How a Bill Become a Law, SENATE.GOV, https://www.senate.gov/reference/resources/pdf/legprocessflowchart.pdf.

⁴⁶ Lydia Wheeler, *Trump's Regulatory Freeze in Full Force*, THE HILL (2017), http://thehill.com/regulation/administration/320014-trumps-regulatory-freeze-in-full-force (last visited Nov. 15, 2017).

⁴⁷ *Id*.

⁴⁸ *Id*.

⁴⁹ *Trump Withdraws US from Trans-Pacific Partnership, Freezes New Regulations*, CHEESE REPORTER (Jan. 27, 2017), http://npaper-wehaa.com/cheese-reporter/2017/01/s3/?g=print#?article=2870115.

⁵⁰ Dr. Peter G. Lurie, *Trump Administration Indefinitely Delays Key Food Safety Protections*, CSPINET.ORG,

https://cspinet.org/news/trump-administration-indefinitely-delays-key-food-safety-protections-20180104 (last visited Mar. 31, 2018.) While the Trump administration initially had no plans of suspending regulation, on the seventh-year anniversary of the legislation being signed into law, the announcement was made that core consumer protections would be indefinitely relaxed under the Trump FDA. *Id.*

⁵¹ The Food and Drug Administration Food Safety Modernization Act; Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules, FEDERALREGISTER.GOV (2016),

https://www.federalregister.gov/documents/2016/08/24/2016-20176/the-food-and-drug-administration-food-safety-modernization-act-extension-and-clarification-of (last visited Nov. 15, 2017).

⁵² *Id*.

E. A Brief History of Major Foodborne Outbreaks in the United States

The Peanut Corporation of America salmonella outbreak, while devastating, was not the first recorded foodborne illness situation that the United States has experienced.⁵³ The history of these tragedies date back to at least 1919.⁵⁴ To understand the need for the sweeping reform that Congress is attempting to implement under the FSMA, it is important to explore cases that go back to some of the first known instances of foodborne illnesses.⁵⁵

It was widely apparent that while there was a need to protect the public from sickness and death, the government did little to enforce the industry standard of clean safe food. Early examples of foodborne illness outbreaks illustrate how criminal liability was not imposed in instances such as the 1919 Botulism Cases, the 1925-1926 Typhoid Fever Outbreak, and more recently, the Listeria Outbreak in 1985 in Los Angeles, CA. 57

In 1919, olives that were distributed to multiple locations across the United States were found to have been the perpetrator of a botulism outbreak.⁵⁸ This outbreak killed nineteen people in three different states and made many others very sick.⁵⁹ The sickness was described as being so bad that some people had wished they would have been killed by the outbreak.⁶⁰ Symptoms of botulism include nausea, vomiting, and abdominal cramps (only in foodborne botulism) and can sometimes even lead to paralysis.⁶¹ This 1919 olive botulism outbreak

http://www.foodsafetynews.com/2012/03/canned-ripe-california-olives-spread-botulism-in-1919/#.WdUvWTPMzVq (last visited Nov. 14, 2017).

http://msue.anr.msu.edu/news/history_of_food_safety_in_the_us_part_1 (last visited Nov. 14, 2017).

⁵³ See infra Part II. E.

⁵⁴ Dan Flynn, Canned Ripe California Olives Spread Botulism in 1919, FOODSAFETYNEWS.COM (2012),

⁵⁵ Michelle Jarvie, History of food safety in the U.S. – part

^{1,} MUSE.ANR.MSU.EDU (2014),

⁵⁶ See supra note 25. (Industry standard being a stated standard with no little regulation at the time. The standard was the general standard of supplying clean and safe food.).

⁵⁷ Valencia Higuera, *Worst Foodborne Illness Outbreaks in Recent U.S. History*, HEALTHLINE.COM (2017), https://www.healthline.com/health/worst-foodborne-illness-outbreaks#hepatitis-a6 (last visited Nov. 13, 2017).

⁵⁸ See supra note 54.

⁵⁹ *Id*.

⁶⁰ Chas. Armstong et al., Botulism From Eating Canned Ripe Olives, PUBLIC HEALTH REPORTS, Vol. 34, No. 51 (Dec. 19,1919)

https://www.jstor.org/stable/pdf/4575421.pdf?refreqid=excelsior%3A1de0d2fb129acbf3455364d5293123b9.

⁶¹ Danielle Moores, *Botulism -- What is Botulism?* HEALTHLINE.COM (Apr. 10, 2012), http://www.healthline.com/health/botulism#causes-and-risk-factors3.

did not result in any criminal liability for the deaths, nor the suffering of the persons who became sick because of the food mishandling.⁶²

From 1925 through 1926, it was reported that oysters kept in tainted water made 1500 sick and killed at least 150 people. The sickness caused by these mishandled oysters was typhoid fever. No criminal liability in this instance could be attributed to the oyster corporations because the technology did not exist to find the actual cause of the illness. Not one person was held liable under the law for the deaths and sicknesses that resulted from the mishandling of the oysters. The oyster companies did however, have to make changes due to the mishandling of the oysters that led to the illnesses and deaths. The individual states decided that there should be guidelines for sanitation within the oyster industry and the local governments swiftly enacted stricter regulations.

The Food Safety Modernization Act was born out of the continuing need to protect innocent citizens, paired with the authority of historic cases regarding criminal liability and corporations and those who are in control of them.⁶⁹

In *United States v. Dotterweich*, 320 U.S. 277 (1943), the United States Supreme Court first explored the idea of enforcing criminal punishment for adulteration in the food industry. In *Dotterweich*, the President of the corporation was held liable for shipping into interstate commerce misbranded and contaminated drugs. He was charged by two informations, one charging the corporation and one charging Mr. Dotterweich. Was a case of first impression and held that a corporate player could be held liable both strictly and vicariously for events that resulted in a negative effect upon public welfare. The new ruling imposes upon persons exercising authority and supervisory responsibility reposed in them by a business organization not only a positive duty to seek out and remedy violations but also primarily, a

⁶² See supra note 54.

⁶³ Dan Flynn, *Oyster-Borne Typhoid Fever Killed 150 in Winter of 1924-25* FOODSAFETYNEWS.COM (2012) http://www.foodsafetynews.com/2012/03/editors-note-in-the-winter/#.WdUwWDPMzVo.

⁶⁴ *Id*.

⁶⁵ *Id*.

⁶⁶ *Id*.

⁶⁷ *Id*.

⁶⁸ Flynn, supra note 54.

⁶⁹ What is the Food Safety Modernization Act?, NATIONAL SUSTAINABLE AGRICULTURE COALITION, http://sustainableagriculture.net/fsma/overview-and-background/ (Last visited Jan. 29, 2017).

⁷⁰ United States v. Dotterweich, 320 U.S. 277 (1943).

⁷¹ *Id.* at 285.

⁷² *Dotterweich*, 320 U.S. at 278.

⁷³ Dotterweich, 320 U.S. at 284.

duty to implement measures that will ensure that violations will not occur.⁷⁴ While the jury did not find the corporation itself guilty, they did find its president as an individual liable.⁷⁵ Mr. Dotterweich was fined \$500 for each count with most counts being suspended, was given no time in custody, and only sixty days of probation for each count, run concurrently.⁷⁶ Although the Second Circuit Court of Appeals found that Mr. Dotterweich should not be held responsible because the 'person' responsible in this case was the company, the Supreme Court found that Mr. Dotterweich was responsible for his inaction as the president and general manager of the company.⁷⁷ The Supreme Court disagreed with the appellate court ruling noting that the only way a corporation 'person' could commit any act is through persons who could "act on its behalf."⁷⁸

The next time that the court recognized criminal liability for corporate individuals was in *United States v. Park*, 421 U.S. 658 (1975).⁷⁹ This case revolved around John Park, the president of food store chain Acme Markets.⁸⁰ Mr. Park was informed by the FDA over the span of two years that at least one of the chain's warehouses had a rodent infestation.⁸¹ Mr. Park spoke with Acme counsel and was informed that the employee in charge of the location was taking all remedial action to remedy the situation.⁸² Upon continued inspection, the officers of the FDA found Acme noncompliant and the corporation was charged under the law.⁸³ This case created a doctrine know today as the Responsible Corporate Officer (RCO) Doctrine.⁸⁴

"Under the RCO Doctrine, the CEO of a company can be held personally liable for these and other violations of the Food, Drug & Cosmetic Act for violations committed by their employees." The *Park* court expanded on *Dotterweich* by including in the majority opinion that "first, 'any person – including a corporation [charged]—' within the meaning of 21 U.S.C. §333

⁷⁴ *Id*.

⁷⁵ *Dotterweich*, 320 U.S. at 278.

⁷⁶ U.S. v. Dotterweich, UNODC.ORG, https://www.unodc.org/cld/case-law-doc/fraudulentmedicinecrimetype/usa/1943/usa_v._dotterweich.html (last visited Nov. 15, 2017); Suspended Sentence: the defendant has no penalty to pay. However, the defendant's criminal conviction will remain part of the public record.

⁷⁷ *Dotterweich*, 320 U.S. at 281.

⁷⁸ United States v. Dotterweich, 320 U.S. 277, 281 (1943).

⁷⁹ United States v. Park, 421 U.S. 658 (1975).

⁸⁰ Park, 421 U.S. at 658.

⁸¹ Park, 421 U.S. at 658.

⁸² Park, 421 U.S. at 658.

⁸³ Park, 421 U.S. at 659.

⁸⁴ This is also known as the Park Doctrine.

⁸⁵ Erik Lieberman, *Criminal Liability Exposure Under the Food Safety Modernization Act: What Every CEO Should Know*, RETAILLEADER.COM (2014), https://retailleader.com/criminal-liability-exposure-under-food-safety-modernization-act-what-every-ceo-should-know (last visited Nov 15, 2017).

may include any corporate officer or employee 'standing in responsible relation' to a condition or transaction forbidden by [an act]". 86 Second, a person may be convicted of a criminal offense under the Act even in the absence of "the conventional requirement for criminal conduct-awareness of some wrongdoing." First, *Park* affirmed that corporate individuals could be held liable for criminal misconduct. 88 Next, the court expanded that liability to include corporate officers. 99 And lastly, the court provided that the standard for convicting such persons may be lower than the traditional standard used in criminal convictions. 90

Park's interpretation of the legislation was fairly narrow in scope by limiting corporate officer's liability to misdemeanors. ⁹¹ John Park was only charged \$50 per count for five counts and served no jail or prison time. ⁹² While this case did better define and strengthen the rule from *Dotterweich*, the author maintains it should have gone further in defining the scope of criminal liability. ⁹³

Even after the Responsible Corporate Officer Doctrine was enacted, another notable outbreak occurred in 1985, when consumption of Mexican-style cheeses was linked to an outbreak of listeriosis that killed over twenty-five people in Los Angeles County. 4 The deaths included newborn babies, new mothers, and unborn fetuses. 5 In the civil case against the Alta-Dena Dairy, that never went to trial, the court granted injunctive relief to consumers for the mislabeling of potentially dangerous products. 6 The corporation's lower management team pleaded no contest to criminal misdemeanor charges. 7 The

⁸⁶ Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321(e) (1938).

⁸⁷ United States v. Park, 421 U.S. 658 (1975).

⁸⁸ *Id*.

⁸⁹ Park, 421 U.S. at 683.

⁹⁰ Park, 421 U.S. at 676.

⁹¹ United States v. Park, 421 U.S. 658 (1975).

⁹² John R. Fleder, et al., *FDA and the Park Doctrine*, FDALAWBLOG.NET (2010), http://www.fdalawblog.net/wp-content/uploads/archives/docs/fda-and-the-park-doctrine.pdf.

⁹³ An Examination of Strict Criminal Liability Under the Food, Drug and Cosmetic Act of 1938: Is It Time For Change?, DASH.HARVARD.EDU (1999),

https://dash.harvard.edu/bitstream/handle/1/8889485/Holt,_Breanna_-

Paper.pdf?sequence=1 (last visited Nov 15, 2017).

⁹⁴ Robert Lindsey, *62 Deaths From Cheese Traced To Single Source*, N.Y. TIMES, (Jul. 14, 1985) http://www.nytimes.com/1985/07/14/us/62-deaths-from-cheese-traced-to-single-source.html.

⁹⁵ *Id*.

⁹⁶ Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy, 4 Cal.App.4th 963, 966 (Cal.App.1992).

⁹⁷ Dan Flynn, *Remembering the Sad 1985 Listeriosis Outbreak*, FOODSAFETYNEWS.COM (2011),

employee manager served the longest sentence: sixty days in jail and received fines totaling \$48,000, while the owner only served half the time. The company caused over one hundred million dollars in damages but only maintained an insurance policy with approximately ten million dollars in coverage. Later, in *Consumers Union of U.S., Inc. v. Alta-Dena Certified Dairy*, 4 Cal. App. 4th 963, 970 (Cal. App, 1992), the company was found guilty for the inclusion of the harmful ingredient in the cheeses and was mandated to label their items with harsh labels that included warnings that the products were known to cause deaths. 100

With the exception of the 1985 case, ¹⁰¹ in all of these prior cases there was little to no criminal liability charged or imposed against anyone. ¹⁰² With more than twenty-five people losing their lives, the person held the most responsible for the outbreak only served a de minimis sixty days in jail. ¹⁰³ This appears to go against the basic public policy to protect against preventable harm and to protect human life. ¹⁰⁴

The FSMA provides for criminal liability under the authority of the RCO Doctrine. In the *Park* case in 1975, the Supreme Court of the United States held that before a person can be convicted of a criminal violation of this Act, a jury must find--and must be clearly instructed that it must find--evidence beyond a reasonable doubt that he engaged in wrongful conduct amounting at least to common-law negligence. Stated differently, if a person could prevent a foodborne illness from occurring, or prevent a tainted product from entering into the stream of commerce, and the individual failed to do so, there could be criminal sanctions, albeit minor. The RCO Doctrine put corporations on notice that there could be consequences, criminally, for misdeeds or inaction to correct misdeeds, for persons responsible for oversight within the corporation.

http://www.foodsafetynews.com/2011/11/remembering-the-sad-1985-listeriosis-outbreak/#.WW18STOZPVo.

⁹⁸ *Id*.

⁹⁹ *Id*.

¹⁰⁰ Alta-Dena Certified Dairy, 4 Cal.App.4th at 976.

¹⁰¹ Flynn, *supra* note 97.

¹⁰² See supra Part II. E.

¹⁰³ Louis Sahagun, *Dairy Cleared of Liability in 1985 Listeriosis Cases*, L.A. TIMES (Jul. 15, 1989), http://articles.latimes.com/1989-07-15/local/me-3053_1_listeriosis-cases.

¹⁰⁴ Thomas R. Frieden, *Government's Role in Protecting Health and Safety*, NEJM.ORG (2013),

http://www.nejm.org/doi/full/10.1056/NEJMp1303819#t=article (last visited Nov. 15, 2017).

¹⁰⁵ See Fleder, note 92.

¹⁰⁶ Park, 421 U.S. at 683.

¹⁰⁷ See supra note 104.

¹⁰⁸ *Id*.

III. LEGAL AUTHORITY

A. The Trend of Different Treatment Under the Law Between Corporations and Corporate Officers

The Food and Drug Administration (FDA), the United States' leader in regulating food safety, has toughened up on threatening criminal liability to individual players within the chain of command in a corporation. While a corporation is considered an 'individual' under the law, a corporate officer has seldom been held liable criminally for food illness related suits. Even on the rare occasion of corporate dignitaries being held liable, the punishment does not appear to rise to the level that punishment for other crimes resulting in death or injury often do. 111

Generally, persons affected by foodborne illnesses are informed by public health centers on how to settle the matter through civil court. Extreme illness and death, if caused by a private individual's wrongful behavior, often results in criminal punishment. Whereas the same injury if caused by a corporate dignitary acting for a corporation, ordinarily goes unpunished. When a private individual commits any action with intent or reckless disregard of consequence, the individual is held liable, either civilly or criminally. This includes liability regarding something one had no immediate control over, for example vicarious liability or something "referred to as strict, or no-fault, liability because the employer itself is not actually or personally at fault." These are examples showing that under the law, a person may have liability for something that they were unaware of or had no control over, similar to the liability a corporate officer would face under the FSMA/RCO Doctrine.

¹⁰⁹ See Fleder note 92.

¹¹⁰ Citizens United v. Federal Election Commission, 558 U.S. 310 (2010).

¹¹¹ See generally supra Part III. A.

¹¹² Determining Legal Responsibility for Foodborne Illness & Injury, publichealthlawcenter.org (2016),

http://www.publichealthlawcenter.org/sites/default/files/resources/phlc-fs-Det-Legal-Resp-Foodborne-Illness-2016.pdf (last visited Nov 15, 2017).

¹¹³ *Homicide Definition*, FIND LAW (2017), http://criminal.findlaw.com/criminal-charges/homicide-definition.html (Last visited Jan. 26, 2018).

¹¹⁴ See generally JOSEPH J. ROGERS, CHARTERED,

https://www.rodgerscriminallaw.com/Articles/Criminal-Intent.shtml (last visited Feb. 19, 2018).

¹¹⁵ See Homicide Definition, supra note 113.

¹¹⁶ § 2338. Responsibility for agent's negligence or omission Cal. Civ. Code, § 2338.

¹¹⁷ United States v. Park, 421 U.S. 658 (1975).

There are also instances of liability with a lack of specific intent in both civil and criminal courts. 118 An example of such criminal liability is involuntary manslaughter, 'the unlawful killing of a human being without malice aforethought and without an intent to kill.'119 Under tort, in the realm of civil liability, there is recompense for what is referred to as intentional infliction of emotional distress (IIED). 120 IIED has elements that must be met in order to bring a successful tort action. 121 "[T]o state a [claim] ... for intentional infliction of emotional distress[,] a plaintiff must show...(2) the defendant's intention of causing or reckless disregard of the possibility of causing emotional distress. 122 These are examples where someone could have intended a harm, but even go so far as to find liability even where there was no intent for harm to occur. 123 Harm caused does not have to be intentional but merely foreseeable. 124 The standard of "reckless disregard" has led to civil and criminal liability for individuals. 125 Yet until recently, individuals acting on behalf of corporations have not faced the same consequences. ¹²⁶ Corporations have tended to get the rights afforded to individuals, but not the responsibilities by being permitted to escape criminal liability by the corporate cloak. 127

B. Corporations as Individuals

If corporations are legally people under the law, they should be held liable for criminal misconduct under the law as would their individual personhood counterparts. ¹²⁸ In order to come to this conclusion, it is important to examine

¹¹⁸ Liability Without Fault, LECTLAW.COM, https://www.lectlaw.com/mjl/cl046.htm (last visited Feb. 20, 2018).

¹¹⁹ People v. McGeHee, 246 Cal.App.4th 1190, 1208 (Cal.App. 2016); University of Minnesota Libraries, *Criminal Law – 7.2 Vicarious Liability*,

http://open.lib.umn.edu/criminallaw/chapter/7-2-vicarious-liability/ (Last visited Feb. 15, 2018).

¹²⁰ Avlana K. Eisenberg, Note, *Criminal Infliction of Emotional Distress*, Mich. L. Rev. 622 (2015),

https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1195&context=mlr.

¹²¹ Gregory v. City of Vallejo, 63 F.Supp.3d 1171, 1181 (E.D. Cal 2014).

¹²² *Id*.

¹²³ *Id*.

¹²⁴ *Id*.

¹²⁵ *Id*.

¹²⁶ *Id*.

¹²⁷ Kate Cox, *How Corporations Got The Same Rights As People (But Don't Ever Go To Jail)* consumerist.com (2014), https://consumerist.com/2014/09/12/how-corporations-got-the-same-rights-as-people-but-dont-ever-go-to-jail/.

¹²⁸ Corporate Criminal Liability, EA-ATTY.COM, http://www.ea-atty.com/business-newsletters/business-law/corporate-criminal-liability/ (last visited June 30, 2018).

its history.¹²⁹ The idea of corporations as individuals was apparent in the early history of our country, beginning with *Santa Clara County v. So. Pacific R.R. Co.*, 118 U.S. 394, (1886).¹³⁰ This case involved challenging the State of California taxing certain railroads.¹³¹ Before the trial even took place the unanimous court was of the opinion that corporations were clearly intended to be protected by the Fourteenth Amendment.¹³² Chief Justice Waite stated that the issue was moot because the entire court was of the opinion that the Fourteenth Amendment protections did extend to corporations.¹³³ Another early example dates back to language in the Fair Labor Standards Act of 1938, where a 'person' was defined as an individual, partnership, association, corporation, business trust, legal representative, or any organized group of persons.¹³⁴

Further, in 1977, the United States Supreme Court heard arguments in *United States v. Martin Linen Supply Company*, 430 U.S. 564 (1977).¹³⁵ This case was centered around Martin Linens and Texas Sanitary Towel Supply, two corporations alleged to have violated antitrust/consent decrees that prohibited the corporations from "threatening, coercing, inducing or attempting to induce any linen rental supplier to refrain from furnishing linen supplies to any customer."¹³⁶ The jury in the civil action was hung and the judge granted an acquittal as to the defendants.¹³⁷ The case was appealed by the state, however the defendant claimed that this would violate the Double Jeopardy rule.¹³⁸ The Supreme Court granted certiorari and found that double jeopardy not only applied to humans but also to corporations and that the double jeopardy rule applied to Martin Linen Supply Co., meaning it could not be tried twice for the same offense.¹³⁹

In Citizens United v. Federal Election Commission, 558 U.S. 310 (2010), a political action committee organization sued the Federal Election Commission arguing that people's campaign donations are a protected form of speech, and the fact that corporations and people enjoy the same legal rights, the

¹²⁹ See infra Part III. B.

¹³⁰ Santa Clara County v. Southern Pac. R.R. Co., 118 U.S. 394, 397 (1886).

¹³¹ Santa Clara County, U.S. 118 at 394.

¹³² Santa Clara County v. Southern Pac. R.R. Co., 118 U.S. 394 (1886); Cox *supra* note 116.

¹³³ See Santa Clara County v. Southern Pac. R.R. Co., 118 U.S. 394, 397 (1886)., note 117 at "before argument.".

¹³⁴ Fair Labor Standards Act, 29 U.S.C. § 203.

¹³⁵ United States v. Martin Linen Supply Company, 430 U.S. 564 (1977).

¹³⁶ Martin Linen Supply, 430 U.S. at 564.

¹³⁷ Martin Linen Supply, 430 U.S. at 564.

¹³⁸ Id.

¹³⁹ *Id.* at 575.

government can't limit a corporation's independent political donations. ¹⁴⁰ The Supreme Court agreed, reasoning that "[g]overnment may not suppress political speech on the basis of the speaker's corporate identity." ¹⁴¹ The *Citizens United* ruling might just be the most sweeping expansion of corporate personhood to date. ¹⁴²

More recently in 2014, *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), a private, for-profit corporation challenged the constitutionality of the Affordable Care Act's mandate to provide certain services, including contraceptives, for its employees. ¹⁴³ The United States Supreme Court held that "[a]s applied to closely held corporations, the regulations promulgated by the Department of Health and Human Services requiring employers to provide their female employees with no-cost access to contraception violate the Religious Freedom Restoration Act." ¹⁴⁴ In other words, the court ruled that the corporation had the right for the enjoyment of the protection of the Religious Freedom Restoration. ¹⁴⁵

The FDA through the FSMA has now been granted the resources and an increase in personnel to be able to extend criminal liability to the officers of the corporations. ¹⁴⁶ Corporations should answer to the same criminal justice system as individual persons do because they enjoy the benefits and protections of being a "person" under the law. ¹⁴⁷

¹⁴⁰ Buckley v. Valeo, 424 U.S. 1 (1976) (ruling that limitations on political contributions were unconstitutional and a violation of an individual's and corporation's right to associate); *see also* Citizens United v. Federal Election Com'n, 558 U.S. 310, 365, (2010).

¹⁴¹ Citizens United v. Federal Election Com'n 558 U.S. 310, 365 (2010) (Overturning *Austin v. Michigan Chamber of Commerce*, 494 U.S. 652, (1990). The *Austin* court found that state laws could deny corporations constitutional violation.

¹⁴² Citizens United 558 U.S. at 365.

¹⁴³ Juliane De Vogue, *Hobby Lobby Wins Contraceptive Ruling in Supreme Court* ABC NEWS (2014), http://abcnews.go.com/Politics/hobby-lobby-wins-contraceptive-ruling-supreme-court/story?id=24364311 (last visited Nov. 15, 2017).

¹⁴⁴ Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014).

¹⁴⁵ Burwell v. Hobby Lobby Stores, Inc., scotusblog.com (2014), http://www.scotusblog.com/case-files/cases/sebelius-v-hobby-lobby-stores-inc/ (last visited Nov. 15, 2017).

¹⁴⁶ See supra note 44.

¹⁴⁷ See supra Part III. B.

IV. LEGAL ANALYSIS

A. The Food Safety Modernization Act is Welcomed Reform

The FSMA, enforced under the authority of the FDA, is a welcomed reform regarding how the drug and food administration is ran and enforced. Historically, there has been minimal to no criminal liability for the individuals who oversee the corporations that are introducing the consumables/food products into the stream of commerce. He

More recently, since the passage of the FSMA in 2011, there has been a greater push for criminal liability for corporate individual players. ¹⁵⁰ For instance, the grandfather of cases that sparked the outrage and the action by the Obama administration to update and modernize the FDA guidelines specifically criminal liability, is the Peanut Corporation of America case, supra Part II. C. 151 In this case the Parnell brothers, among others, were found to have placed misbranded or adulterated food products into the stream of commerce. 152 The prosecution showed evidence that the defendants, the Parnell brothers deceived their customers by not being transparent with the fact that at least some of their products had tested positive for salmonella. 153 The brothers were charged with many counts, including a violation of introduction of adulterated food with the intent to mislead the public or to defraud.¹⁵⁴ Prosecutors said Mr. Parnell's company, Peanut Corporation of America, repeatedly sold contaminated peanut products and misled customers about test results. 155 They also said the company, which was "headquartered in Virginia but also had facilities in Texas and Georgia, sometimes shipped

¹⁴⁸ Caroline Smith DeWaal, *Proposed Food Safety Regulations a Welcome Sign of Progress, Says CSPI*, CSPINET.ORG (2013), https://cspinet.org/news/proposed-food-safety-regulations-welcome-sign-progress-says-cspi-20130104 (last visited Nov. 15, 2017).

¹⁴⁹ See Dotterweich, 320 U.S. at 284; Tove Danovich, When Farmers Get Arrested for Foodborne Illnesses, MODERNFARMER.com (2014),

https://modernfarmer.com/2014/04/foodborne-illness-case-farmers-rarely-made/ (last visited Nov. 15, 2017).

¹⁵⁰ Shawn Stevens, *The Food Police Are Coming: DOJ And FDA Say Criminal Prosecution Of Food Companies Is A*

Priority, FOODINDUSTRYCOUNSEL.COM, (2016),

https://www.foodindustrycounsel.com/2016/09/doj-and-fda-say-criminal-prosecution-of-food-companies-is-a-priority/ (last visited Nov. 15, 2017).

¹⁵¹ No. 1:13-CR-12, 2013 U.S. Dist. WLS 2387714 (M.D. Ga., May 30, 2013).

¹⁵² FORMER PEANUT COMPANY OFFICIALS SENTENCED TO PRISON FOR THEIR ROLES IN SALMONELLA-TAINTED PEANUT PRODUCT OUTBREAK, DOJ 15-1214.

¹⁵³ *Id*.

¹⁵⁴ *Id*.

¹⁵⁵ Id.

products that Mr. Parnell knew were tainted."¹⁵⁶ The corporate officers were found guilty and were criminally punished.¹⁵⁷

While cases are still seeing mixed results since the salmonella outbreak, the overall trend is imposing or at least charging for criminal punishment when a corporate officer could have prevented contaminated food from entering the stream of commerce. Another example of the justice system seeking criminal liability with regard to foodborne illness was with brothers Eric and Ryan Jensen. He Jensen brothers owned a farm in Colorado. A listeria outbreak was traced back to their corporation. The brothers pleaded guilty to charges brought on after around three dozen people died from listeria resulting from mishandled food and sanitation guidelines. The Jensen brothers asked the judge for probation, as federal guidelines had been recently put into place that would minimize a repeat tragedy. The judge in the case ordered restitution and probation for the Jensen brothers, but no incarceration time. He Jensen brothers were ultimately found guilty for their crime, but did not serve any time for punishment.

In *United States v. DeCoster*, 828 F.3d 626 two members of the DeCoster family, who were corporate dignitaries in supervisory positions claimed lack of knowledge of any wrongdoing and were held liable for contamination of eggs that tested positive for harmful bacteria. ¹⁶⁶ The men were sentenced to

¹⁵⁶ Alan Blinder, *Georgia: 28-Year Sentence in Tainted Peanut Case*, N.Y. TIMES, Sept. 22, 2015, at A20.

¹⁵⁷ Dan Flynn, *Parnell Brothers Finally in Prison for Deadly Peanut Butter Outbreak*, FOODSAFETYNEWS.COM (2016)

http://www.foodsafetynews.com/2016/02/123674/#.WdZ5SjPMzVo (Former Peanut Corporation of America CEO Stewart Parnell was sentenced to twenty-eight years in prison, and his brother, Michael Parnell was sentenced to twenty years).

¹⁵⁸ See legal analysis generally.

¹⁵⁹ Mary Beth Marklein, *Cantaloupe farmers get no prison time in disease outbreak* usatoday.com (2014),

https://www.usatoday.com/story/news/nation/2014/01/28/sentencing-of-colorado-cantaloupe-farmers/4958671/.

¹⁶⁰ *Id*.

¹⁶¹ Id.

¹⁶² Ray Sanchez, *At sentencing, cantaloupe growers apologize for deadly listeria outbreak*, CNN.COM (2014), http://www.cnn.com/2014/01/28/justice/cantaloupe-listeria-deaths-sentencing/index.html (last visited Nov. 15, 2017).

¹⁶³ Marklein, *supra* note 159.

¹⁶⁴ Sanchez, *supra* note 162, Marklein, *supra* note 159.

¹⁶⁵ Marklein, *supra* note 159.

¹⁶⁶ Collin Woodard, Notorious egg seller 'Jack' DeCoster gets jail time for salmonella outbreak, PRESSHERALD.COM (2015),

http://www.pressherald.com/2015/04/13/maine-businessman-jack-decoster-gets-jail-for-selling-tainted-eggs/ (last visited Nov. 15, 2017); United States v. DeCoster, 828 F.3d 626 (2016).

prison and appealed the Eighth Circuit Court of Appeal's ruling. ¹⁶⁷ On appeal to the Supreme Court, the DeCosters planned to argue that the Court should overrule the holdings in *Dotterweich* and *Park*. ¹⁶⁸ The Supreme Court denied certiorari, upholding the appellate court. ¹⁶⁹

Finally, in 2014, three higher-ups of the Rancho Feeding Slaughter House were sentenced to prison time. ¹⁷⁰ This case presented facts that show there was an actual intent to deceive the public by processing meat from cattle that were known to have eye cancer. ¹⁷¹ Jesse Amaral, owner of Rancho, directed his supervisory staff to sell meat condemned by the United States Department of Agriculture veterinarian. ¹⁷² The supervisory staff instructed their employees to carve out the 'condemned' branding and to sell the meat. ¹⁷³ The court found that these corporate individuals should be held accountable. ¹⁷⁴

More regularly in recent cases, there has been criminal prosecution of corporate individuals in court proceedings. ¹⁷⁵ While this appears to act as a stern warning to promote deterrence for the inaction on behalf of corporate individuals, the question that is presented now is whether it goes far enough to meet the intent of the FSMA. ¹⁷⁶ The general trend appears to answer this in the affirmative. ¹⁷⁷ The FSMA was signed into legislation in 2011, with the instruction that all guidelines will need to be implemented by 2015, however, compliance dates appear to have been extended to early 2018. ¹⁷⁸ Since being signed into law, the number of cases per year has been on a general decline

¹⁶⁷ DeCoster v. United States, 137 S.Ct. 216 (U.S. Supreme Court), *petition for cert. filed*, 85 U.S.L.W. 3551 (U.S. May 22, 2017) (No. 16-877).

¹⁶⁸ *Id*.

¹⁶⁹ *Id*.

¹⁷⁰ Paul Payne, *Defendants in Rancho Feeding Corp. scandal sentenced*, PRESSDEMOCRAT.COM (2016), http://www.pressdemocrat.com/news/5320689-

^{181/}petaluma-slaughterhouse-defendants-sentenced (last visited Nov. 15, 2017). 171 *Id.*

¹⁷² Petaluma Slaughterhouse Owners And Employees Charged In Scheme To Distribute Adulterated Meat, JUSTICE.GOV (2014),

https://www.justice.gov/usao-ndca/pr/petaluma-slaughterhouse-owners-and-employees-charged-scheme-distribute-adulterated-meat (last visited, Feb. 20, 2018). ¹⁷³ *Id.*

¹⁷⁴ Payne, *supra* note 170.

¹⁷⁵ See generally Part IV. A.

¹⁷⁶ Fact Sheets and Presentations, FDA.GOV (2016),

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm (last visited Nov. 15, 2017).

¹⁷⁷ See generally Part IV. A.

¹⁷⁸ Compliance Date Extensions and Clarifications for FSMA Final Rules, FDA.GOV (2016),

https://www.fda.gov/food/guidanceregulation/fsma/ucm517545.htm (last visited Nov. 15, 2017).

with the exception of 2016.¹⁷⁹ The goals of the Food Safety Modernization Act with respect to extension of criminal liability to corporate officers makes a great deal of sense when examining the broad public policy purposes justifying our criminal justice system.¹⁸⁰

The criminal justice system was established by the early founders for fundamentally noble reasons, including to protect the rights of the innocent. ¹⁸¹ Those basic purposes include: deterrence of future criminal conduct, either for the individual or for the public as a whole; retribution on behalf of society and the victims of crime, incapacitation, punishment, and rehabilitation of the offender. ¹⁸²

Of all the traditional purposes, perhaps the most compelling reason behind the imposition of the agencies stronger regulations is deterrence. One of the fundamental goals of the FDA is to protect the public, so this in accord with the basic public policy purpose behind the FDA, the protection of the public. Has is effectuated by punishing those who did not keep their promise to society to ensure that safe food/consumables were going to be hitting the market. The state must redress imbalances caused by those people who take illegal advantage of another or diminish their human dignity. The state must redress imbalances caused by those people who take illegal advantage of another or diminish their human dignity.

B. Congress Should Avoid Technical Challenges by Creating Clearer Guidelines

A clearer and more focused law is more enforceable and less likely to be disputed.¹⁸⁷ Making laws consistent with fundamental fairness and which are not vague helps ensure fewer constitutional challenges.¹⁸⁸ To best avoid these challenges, the FSMA should establish more stringent guidelines that affirmatively describe who will and who will not be found in violation of the

¹⁷⁹ See Outbreak Investigations supra note 6.

¹⁸⁰ Interview with Rachel Hill, Adjunct Professor, San Joaquin College of Law in Fresno, Cal. (2017).

¹⁸¹ The U.S. Criminal Justice History Resource Page, CRIMINALJUSTICEDEGREE.NET (2016), http://www.criminaljusticedegree.net/resources/the-us-criminal-justice-history-resource-page/ (last visited Nov. 15, 2017).

¹⁸² Interview with Rachel Hill *supra* note 180.

¹⁸³ Valerie Wright, Ph.D, Deterrence in Criminal Justice, THE SENTENCING PROJECT, https://www.sentencingproject.org/wp-content/uploads/2016/01/Deterrence-in-Criminal-Justice.pdf.

¹⁸⁴ Frieden, *supra* note 104.

¹⁸⁵ Lierberman, *supra* note 76.

¹⁸⁶ *Id*.

¹⁸⁷ Mark L. Rienzi & Stuart Buck, Federal Courts, Overbreadth, and Vagueness: Guiding Principles for Constitution Challenges to Uninterpreted State Statutes, (2002) UTAH L. REV. 381.

¹⁸⁸ *Id*.

current FSMA regulations. 189 Issues that regularly arise with vagueness include arbitrary enforcement and inadequate notice. 190 Every person, seemingly including corporations, are guaranteed certain protections. 191 The Fourteenth Amendment states that "nor shall any State deprive any person of life, liberty, or property without due process of the law."192 Criminal defendants have relied on the "void for vagueness" doctrine to be liberated from charges against them because the average person should not have to guess what the enactment encompasses. 193 When a law is vague it could lead to prosecution of otherwise innocent persons. 194 "Where the conduct in question is at the margins of the meaning of an unclear statute, however, it will be struck down as applied."195

Under the new guidelines and funding under the FSMA, were they to be implemented by this administration, there would be more FDA agents conducting domestic inspections and sending warning letters letting a corporation know when it is either A) at risk of falling out of compliance or B) out of compliance. 196 This, paired with the fact that technology is much more efficient now than before, and it is easier for food safety tests to be done, the reasons to not punish corporate overseers would begin to diminish. 197

To avoid injustice the FSMA should revise and incorporate an informational plain letter language rule set for corporate dignitaries who cannot understand the language of the current regulations and guidelines. This will also reduce any risk of a fundamental fairness defense to the regulations. 198 The FSMA should punish those responsible for sickness and death by continuing to hold irresponsible corporate officers criminally liable so that there is a clear

¹⁸⁹ Ralph W. Aigler, Legislation in Vague or General Terms, (1923) MICH, L. REV. 21: 831-51.

¹⁹⁰ Rienzi, *supra* note 187.

¹⁹¹ Everyone Has Certain Basic Rights, No Matter Who Is

President, NILC.ORG (2016), https://www.nilc.org/issues/immigration-

enforcement/everyone-has-certain-basic-rights/ (last visited Nov. 15, 2017).

¹⁹² U.S. Const. amend. XIV, § 1-Due Process.

¹⁹³ Cantwell v. Connecticut, 310 U.S. 296, 308 (1940).

¹⁹⁴ Musser v. Utah, 333 U.S. 95, 97 (1948).

¹⁹⁵ Procedural Due Process Civil, LAW.JUSTICIA.COM,

https://law.justia.com/constitution/us/amendment-14/05-procedural-due-processcivil.html#fn-1096 (last visited Apr. 04, 2018), citing United States v. National Dairy Products Corp., 372 U.S. 29 (1963).

¹⁹⁶ Joseph A Levitt, et al., FDA's Changing Culture: What Every Food Company Needs to Know, FOODSAFETYNEWS.COM (2013),

https://www.foodsafetymagazine.com/magazine-archive1/aprilmay-

^{2013/}fdae28099s-changing-culture-what-every-food-company-needs-to-know/ (last visited Nov. 15, 2017).

¹⁹⁷ See Anderson supra note 12.

¹⁹⁸ See generally 21 U.S.C. § 301 et seq. (2011).

punishment. This will help to deter the inaction of said dignitaries and give redress to the victims affected and their loved ones. 199

C. Opposition to the Food Safety Modernization Act

The FSMA is without doubt a controversial legislative reform, especially to farmers who see it as an expensive regulation that imposes a financial burden upon small farms and farmers.²⁰⁰ Some farmers argue that imposition of the regulations would result in: the reduction in the availability in safe and healthy food; difficulty for farms to diversify; excessive water testing; and an over-regulation of new food.²⁰¹

The need for the FSMA outweighs the inconveniences for farmers when it protects lives versus the inconvenience to livelihood.²⁰² While no act can be perfect, the FSMA provides much needed safeguards, and the nuisance is slight compared to the burden on corporations.²⁰³ Foodborne illnesses cause sickness and death and are also costly to the United States economy, being estimated at about \$15.6 billion annually.²⁰⁴ There may be portions of the FSMA that might not survive criticism, however certain regulations of the FSMA, specifically, criminal liability, should be enforced.²⁰⁵

V. RECOMMENDATIONS

A. The United States as a World Leader.

"International food [safety] agreements provide a reasonably uniform level of protection in terms of public health and food standards." Many countries

Fails, CAROLINAFARMSTEWARDS.ORG (2015),

https://www.carolinafarmstewards.org/food-safety-modernization-act-2-fixes-and-fails/ (last visited Nov. 15, 2017).

¹⁹⁹ See No. 1:13-CR-12, 2013 U.S. Dist. WLS 2387714 (M.D. Ga., May 30, 2013).

²⁰⁰ Food Safety Modernization Act 2; Fixes and

²⁰¹ *Id*.

²⁰² See generally Part I. A.

²⁰³ See supra Part II. B.

²⁰⁴ Dan Flynn, *USDA: U.S. Foodborne Illnesses Cost More Than \$15.6 Billion Annually*, FOODSAFETYNEWS.COM (2014),

http://www.foodsafetynews.com/2014/10/foodborne-illnesses-cost-usa-15-6-billion-annually/#.WgzMHLaZNAY (last visited Nov. 15, 2017).

²⁰⁵ Ryan M. Gembala, Esquire, Martyn & Associates, *Ignorance Is No Excuse:* Criminal Liability in the Produce Industry, FOOD ONLINE (Feb. 24, 2016) https://cals.arizona.edu/agliteracy/sites/cals.arizona.edu.agliteracy/files/Article-Ignorance-is-No-Excuse-Criminal-Liability-in-the-Produce% 20Industry.pdf. ²⁰⁶ Simon Jol, et al., A Country-by-Country Look at Regulations and Best Practices in the Global Cold Chain, FOODSAFETYNEWS.COM (2006),

http://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2006/a-

follow guidelines set out by the World Trade Organization (WTO.)²⁰⁷ The code standards established by WTO are called the Codex Alimentarius.²⁰⁸ The Codex Alimentarius, or "Food Code," is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission.²⁰⁹ "The Commission, also known as CAC, is the central part of the Joint The Food and Agriculture Organization of the United Nations (FAO)/WHO Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade."²¹⁰

Members of the World Trade Organization (WTO) recognize Codex Alimentarius standards as the basic standards upon which national measures will be judged.²¹¹ These are known as the Recommended International Code of Practice General Principles of Food Hygiene.²¹² While these are guidelines set to maintain uniform food safety, they are not requirements.²¹³

Canada has recently expanded on criminal liability and penalties by "increas[ing] criminal penalties for violations of their corollary act of the FSMA, the Safe Food for Canadians Act (SFCA.)²¹⁴ For example, under their newer guidelines, penalties for convictions under the act increased from \$50,000 fine and/or six months imprisonment to \$250,000 fine and/or six months imprisonment."²¹⁵ Canada, however, did not impose any criminal liability for one of its most serious foodborne illness outbreaks in their country's history.²¹⁶ A 2008 outbreak of listeriosis was eventually credited to Maple Leaf Foods.²¹⁷ Just a year later, the company agreed to settle all wrongful death claims with a \$27 million dollar settlement.²¹⁸ This led to a

country-by-country-look-at-regulations-and-best-practices-in-the-global-cold-chain/ (last visited Nov 15, 2017).

²⁰⁷ Id.

²⁰⁸ What is the Codex Alimentarius?, FAO.ORG (2016), http://www.fao.org/fao-who-codexalimentarius/en/ (last visited Nov. 15, 2017).

²⁰⁹ Jol et al., *supra* note 206.

²¹⁰ What is the Codex Alimentarius?, supra note 208.

 $^{^{211}}$ Id

²¹² Jol et al., *supra* note 206.

²¹³ *Id*.

²¹⁴ Comparison of Highlights of Safe Food for Canadians Act (SFCA) and the FDA Food Safety Modernization Act (FSMA) (2012) (Canada)

http://www.sqfi.com/wp-content/uploads/Comparison-of-Highlights-of-Safe-Food-for-Canadians-Act-SFCA-and-the-FDA-Food-Safety-Modernization-Act-FSMA-HL-Memo-12-6-12.pdf.

²¹⁵ *Id*.

²¹⁶ *Listeriosis Outbreak Timeline* (Canada) http://www.cbc.ca/news/listeriosis-outbreak-timeline-1.694467 (last visited Nov. 15, 2017).

²¹⁷ *Id*.

²¹⁸ \$27M settlement reached in Maple Leaf listeriosis suits (2009) (Canada)

circumstance where "[c]laimants who became ill may qualify for up to \$125,000." 219

Similarly, the European Union, under the Food Standards Agency, holds corporations and officers criminally liable for offences. ²²⁰ "Regulation 5 lays down the penalties for the breaches of the articles listed above: on conviction in a Crown Court, a fine or imprisonment for a term not exceeding two years or both." ²²¹ In South Wales in 2005, the largest outbreak of Escherichia coli (E.coli) resulted in the tragic death of a five-year-old boy. ²²² The law in the United Kingdom failed the public by not charging manslaughter against the dignitary and only sentencing him to one year in prison with his imprisonment lasting only a fraction of the sentence. ²²³ The corporate officer was released after serving twelve weeks. ²²⁴

How would these corporations and corporate dignitaries fair against a department of justice with FSMA regulations and enforcement power? Simple, they would likely be serving jail sentences longer than three months. The FSMA, while not perfect, if fully implemented, gives the FDA officers authority to enforce those regulations through warnings, mandates, and actual criminal prosecution. The last three major foodborne illness outbreaks, the United States has charged all of the irresponsible corporate officers involved, and more significant penalties have been imposed than was previously the case. The proviously the case.

The United States has some of the safest food products and cleanest water in the world. The United States has a unique opportunity to become a leader

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http://www.cbc.ca/news/27m-settlement-reached-in-maple-leaf-listeriosis-suits-1.810045 (last visited Nov. 15, 2017).
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https://www.food.gov.uk/enforcement/regulation/foodlaw (last visited Nov. 15, 2017).

²¹⁹ *Listeriosis Outbreak Timeline supra* note 216.

²²⁰ General Food Law (N. Ireland)

 $^{^{221}}Id.$

²²² One Butcher to Blame for Fatal E.coli Outbreak (2009) (United Kingdom) http://www.independent.co.uk/life-style/health-and-families/health-news/one-butcher-to-blame-for-fatal-ecoli-outbreak-1649048.html (last visited Nov. 15, 2017). ²²³ Id.

²²⁴ *Id*.

²²⁵ See supra Part IV. A.

²²⁶ 21 U.S.C. § 301 et seq. (2011).

²²⁷ See supra Part IV. A., (This appears to be due largely to the then existing regulations of the FSMA.).

²²⁸ Food Safety, AMERICANCHEMISTRY.COM,

https://www.americanchemistry.com/Ensuring-a-Safe-and-Plentiful-Food-Supply/ (last visited Nov. 15, 2017).

when it comes to regulating officers in the food industry. ²²⁹ The United States, being a world leader, made a great statement by the passing of legislation in regard to the food safety in the United States and has been recognized as a world leader in food safety. ²³⁰ It is apparent, that when there are insufficient and/or unenforced guidelines for the corporate wrongdoers, the public generally sees an insufficient punishment for crime resulting in serious harm. ²³¹ This author believes that the United States has the chance to send a stern reminder to corporate dignitaries and a message of hope to the public at large. ²³²

As recently as 2016, Chipotle was under investigation for a norovirus outbreak that made 189 customers and eighteen employees ill.²³³ The federal government is in the process of investigating Chipotle for the outbreak.²³⁴ The federal government should use the new authority under the FSMA to prosecute to let consumers understand the government is on their side and has food safety as a top priority.²³⁵ U.S. Attorney Kevin W. Techau of the Northern District of Iowa states the idea clearly, "[t]he message [a foodborne illness related] prosecution and sentence sends is a stern one to anyone tempted to place profits over people's welfare"²³⁶ If the court uses the correct standard created in *Park* there must be criminal liability.²³⁷ Chipotle is alleged to have practiced unsafe food handling in at least one of its stores resulting in foodborne illness.²³⁸ Under *Park*, to be held responsible, a corporate officer must need only to be a person with reasonable responsibility and control and have a violation of current law or regulation occur under their management of the corporation.²³⁹ The lawyer for Chipotle has stated that, "Through these

http://www.foodsafetynews.com/2014/11/canada-ireland-top-food-safety-world-ranking/#.Wgwx27aZPBI (last visited Nov. 15, 2017).

²²⁹ Lydia Zuraw, *Canada, Ireland Top Food Safety World Ranking* FOODSAFETYNEWS.COM, (2014),

 $^{^{230}}$ Id.

²³¹ See supra, Part II. E.

²³² See generally, Part V.

²³³ Jim Zarroli, *Chipotle Faces A Criminal Investigation Into Its Handling Of A Norovirus Outbreak*, NPR.ORG (2016), http://www.npr.org/sections/thetwo-way/2016/01/06/462147245/chipotle-faces-a-criminal-investigation-into-its-handling-of-a-norovirus-outbrea (last visited Nov. 15, 2017).

²³⁵ Brown *supra* note 9.

²³⁶ Quality Egg, Company Owner and Top Executive Sentenced in Connection with Distribution of Adulterated Eggs, JUSTICE.GOV (2015),

https://www.justice.gov/opa/pr/quality-egg-company-owner-and-top-executive-sentenced-connection-distribution-adulterated (last visited Nov. 15, 2017).

²³⁷ United States v. Park, 421 U.S. 658 (1975).

²³⁸ Zarioli, *supra* note 233.

²³⁹ See generally, United States v. Park, 421 U.S. 658 (1975).

lawsuits we will make sure that Chipotle learns to put the safety of its customers first."²⁴⁰ This statement is quite telling. Shouldn't Chipotle corporate officers put safety first, not due to current lawsuits but because of basic public health policy?²⁴¹

The idea behind food safety agency's main goals can best be summed up by the Food Standards Agency. "Everyone involved in the production and distribution of food has a role to play in ensuring food safety - from food producers to people in their homes. When rare outbreaks such as this occur, we must learn from them and further strengthen our systems." While there are not yet studies on the Act's impact, it appears as though the passage of the FSMA has given a stern warning to corporations that they need to be safer when handling food. Page 1974.

VI. CONCLUSION

Whether it is the threat of actual authority under the RCO Doctrine²⁴⁴ or the visibility of criminal prosecutions against corporate officers, the decline in foodborne illnesses, albeit limited, shows progress and hope in the realm of food safety.²⁴⁵ The Food Safety Modernization Act appropriately provides for criminal prosecution of corporate officers who are found responsible for violating the health and safety provisions under the act.

JOSEPH GOOD²⁴⁶

²⁴⁰ Daniela Galarza, *Chipotle's Norovirus Triggers Lawsuit, Federal Investigation*, EATER.COM (2017) https://www.eater.com/2017/7/27/16050204/chipotles-norovirus-lawsuit-subpoena.

²⁴¹ Brown *supra* note 9.

²⁴² One Butcher to Blame for Fatal E.coli Outbreak, supra note 222.

²⁴³ See Outbreak Investigations supra note 6.

²⁴⁴ United States v. Park, *421 U.S. 658* (1975).

²⁴⁵ Maryn McKenna, *CDC: FOODBORNE ILLNESS IN THE U.S. NOT GETTING BETTER*, WIRED.COM, https://www.wired.com/2014/04/cdc-foodborne-trend/ (last visited Nov. 15, 2017).

²⁴⁶ JD Candidate, San Joaquin College of Law, 2019. I would like to extend my sincerest gratitude to my faculty advisor, Rachel Hill, for her patience and guidance during this process. I would also like to thank the entire editorial board of the San Joaquin Agricultural Law Review for their understanding and willingness to help me and support me during the writing process, especially BreAnne Ruelas and John Soares. Further, I would like to thank Dean Alicia Wrest for her guidance in making early connections with regard to my topic and Jennifer Delarosa for helping me strengthen my Bluebook knowledge. Lastly, this Comment would not have been possible without the unconditional love and support of Robert Cogorno, Jeffrey Nelson, Sara Pena, and Ernesto Aguirre.