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| Florida state university |
| Foodborne Illness and Policy in the United States |
| Capstone Paper, Part 1 |
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The Problem: Foodborne Illness

Foodborne illness (also known as food poisoning, foodborne infection, or foodborne disease) is a term used to describe a group of more than 250 illnesses caused by the consumption of contaminated foods or beverages. Bacteria, parasites, viruses, toxins, and poisonous chemicals can all cause foodborne illness. With foodborne illness, the contaminant (e.g. bacteria or virus) enters the body through the gastrointestinal tract and can cause a variety of symptoms including vomiting, diarrhea, abdominal cramping, and nausea.[[1]](#footnote-1) Symptoms typically appear within 12 to 72 hours of eating contaminated food, but can occur as quickly as 30 minutes or as long as 4 weeks later.[[2]](#footnote-2)

Foodborne illness is a major public health problem. Every year approximately 1 in 6 Americans, or about 48 million people, get sick after consuming contaminated foods or drinks. In addition, 128,000 people are hospitalized and 3,000 die because of foodborne infections. While anyone can contract a foodborne illness, some populations, such as pregnant women, the elderly, the very young, and people with weakened immune systems, are at higher risk for severe infections.[[3]](#footnote-3) People with weakened immune systems may include transplant patients and those with chronic conditions, such as HIV/AIDS, cancer, and diabetes. People in these high-risk groups have an increased change of contracting foodborne illness, as well as an increased chance of complications associated with the illness.[[4]](#footnote-4) Complications may include kidney failure, chronic arthritis, brain and nerve damage, and death.[[5]](#footnote-5)

Foodborne illnesses can occur as isolated cases or in outbreaks, where two or more people become ill from the same pathogen. Eight pathogens account for a majority of foodborne illness, hospitalization, and death: the bacteria [***E.coli***](http://www.cdc.gov/ecoli/) **(STEC) O157,** nontyphoidal *Salmonella*, *Clostridium perfringens,* ***Campylobacter spp***[**.**](http://www.cdc.gov/nczved/divisions/dfbmd/diseases/campylobacter/)**, *Staphylococcus aureus***,*Listeria monocytogenes*;the parasite ***Toxoplasma gondii***;and Norovirus. Norovirus causes the majority of foodborne illness, and nontyphoidal *Salmonella* causes the majority of hospitalizations and deaths.[[6]](#footnote-6) Aditionally, *Salmonella* (34% of reported outbreaks)and Norovirus (35%) are the most common cause of foodborne outbreaks.[[7]](#footnote-7)
 Pathogens occur almost everywhere, and they can contaminate food during any step of the production and preparation process. Many pathogens that cause foodborne illness occur naturally in the gastrointestinal system of healthy animals, and meat can be contaminated during the slaughtering process by contacting the intestines. Fruits and vegetables can be contaminated if they are washed or irrigated with water that encountered human or animal feces. Infected food handlers can introduce pathogens to food if they do not practice proper hygiene. Cross-contamination – using the same cutting board or utensil on different foods – is a common way to transfer pathogens from one food or surface to another.[[8]](#footnote-8) Because there are so many ways pathogens enter the food supply, it is difficult to ensure food safety and prevent outbreaks. The foods most associated with foodborne illness include: raw animal products, such as raw meat, eggs, or shellfish and unpasteurized milk; foods that mix the products of different animals, such as ground beef; and raw fruits and vegetables.[[9]](#footnote-9)

The Role of Experts, Policy Analysis Groups, and Policy Entrepreneurs/Advocates

Over the last 60 years, there have been many calls for the reorganization of the food safety system. The Government Accountability Office has documented food safety “problems resulting from the fragmented, balkanized nature of the federal food safety system”[[10]](#footnote-10) and recommends food safety statutes be restructured and enforcement powers be merged under one agency. A 1998 report from the Institute of Medicine and National Research Council determined that the lack of a single, federal agency primarily focused on food safety leads to poor surveillance, low quality regulations, a lack of consumer knowledge, inadequate resources, and a lack of enforcement of current, minimal standards. The committee that created the report went on to recommend “the integration of food safety oversight into a single, independent agency.” [[11]](#footnote-11)

## U.S. Senator Dick Durbin (D-IL) began his fight for increased food safety and became a policy entrepreneur in 1993 after receiving a letter from a grieving mother, Nancy Donley. Donley’s son Alex died of food illness at the age of six after eating a hamburger containing the bacteria *E. coli.* Donley’s letter inspired Durban to write legislation aimed at improving food safety and protecting the public.[[12]](#footnote-12) Senator Durbin went on to introduce S.510, the FDA Food Safety Modernization Act, to the Senate on March 3, 2009. Representative Betty Sutton (D-OH) introduced the bill in the House as HR2751 on June 8, 2009, and the House passed the bill on June 9, 2009. The bill passed the Senate with an amendment on November 30, 2010. The House agreed to Senate amendments on December 21, 2010, and the bill became Public Law No: 111-353 on January 4, 2011. [[13]](#footnote-13) [[14]](#footnote-14)

## Nancy Donley, the woman who sparked Durbin’s interest in food safety, became President of STOP Foodborne Illness, a nonprofit dedicated to preventing foodborne illness and death.[[15]](#footnote-15) STOP assists people impacted by foodborne illness, advocates for better food safety policies, and raises public awareness about foodborne illness. Foodborne illness victims, friends, and family members founded the organization in the early 1990s in the wake of an *E. coli* outbreak that left four children dead and sickened hundreds. STOP has been instrumental in raising public awareness about foodborne illness, educating Congress on the issue, and lobbying for new laws and regulations. STOP worked closely with Congress to introduce the Safe Food Act of 2005 and advocated for the passage of the FDA Safety Food Modernization Act, the first major change to food safety legislation since the 1930s. [[16]](#footnote-16)

Saliency, Agenda Setting, & the President

A recent outbreak of *Salmonella* linked to cucumbers imported from Mexico has grabbed headlines and the attention of the public in recent weeks. As of September 15, 2015, there were at least 418 cases of *Salmonella*, including 2 deaths and 91 hospitalizations, and the outbreak had reached 31 states. The Centers for Disease Control and Prevention continues to investigate this outbreak and additional cases are possible.[[17]](#footnote-17) When outbreaks occur, saliency is high, but the public’s attention to foodborne illness seems to wax and wane from outbreak to outbreak.

The major roles of the President in the health policy arena include putting items on the agenda and garnering public support for adoption of policy by Congress.[[18]](#footnote-18) The President’s ability to fulfill the second role is largely affected by his political capital, which comes from the president’s popularity, the strength of his party in Congress, and his electoral margin. In 2009, President Obama had a fairly high degree of political capital with majorities in the House and Senate and public approval of 67%. By 2010, Obama’s public approval had dropped to 50%, but his party retained majority in Congress.[[19]](#footnote-19)

According to Weissert and Weissert, one way Presidents attempt to influence Congress is by “going public,” or pleading their case to voters, in the hopes that constituents will pressure their elected officials.[[20]](#footnote-20) Additionally, a president has greater influence when an issue is salient and recent events highlight the need for new policy.[[21]](#footnote-21) President Obama “went public” to introduce his food safety agenda in a weekly address to the American people on March 14, 2009.[[22]](#footnote-22) In addition to the weekly address, President Obama gave interviews on national news programs. President Obama used the “going public” tactic at a time when foodborne illness was highly salient. His public pleas for food safety reform came in the midst of a peanut butter related *Salmonella* outbreak that infected more than 700 people from 46 states and killed nine,[[23]](#footnote-23) making it one of the worst reported outbreaks of food- or waterborne illness in U.S. history.[[24]](#footnote-24) “[F]ood safety is something I take seriously, not just as your President, but as a parent… Protecting the safety of our food and drugs is one of the most fundamental responsibilities government has, and… it is a responsibility that I intend to uphold,”[[25]](#footnote-25) said the President.

The President is usually more successful when his own party controls Congress, as was the case for Obama in 2009-2010 when discussion over food safety law occurred.[[26]](#footnote-26) A friendly Congress, public support, and a triggering event – the recent, deadly *Salmonella* outbreak were powerful tools for the President. Obama and the White House framed the issues surrounding food safety as a threat to families, children, and overall public health, which garnered the support of advocates and the public. Public support “can help convince members of Congress that it is safe to support the president,”[[27]](#footnote-27) thus public support for food safety reform may have decreased resistance from Obama’s adversaries.

In his March 2009 weekly address, President Obama announced the creation of a new Food Safety Working Group (FSWG), citing outdated laws, lack of coordination among government agencies, and a lack of FDA resources as reasons for the country’s food safety problems. The FSWG’s mission was to advise the President on how to upgrade food safety laws, enhance coordination among government agencies, and ensure that new laws are properly enforced.

The FSWG advocated for a public health approach to food safety defined by three core principles: 1) Preventing illness rather than reacting to it, 2) Improving surveillance and enforcement, and 3) Reducing the time between outbreak detection, resolution, and recovery. The FSWG resulted in several executive actions, one of which is to improve the organization of federal food safety responsibilities by modernizing statutes. According to the FSWG, the Administration would work with congress on new legislation that would increase the tools, resources, and authorities available to the FDA and the USDA’s Food Safety Inspection Service.[[28]](#footnote-28)

While the FDA Food Safety Modernization Act became law in 2011, funding problems hinder its success in 2015. Shortly after its passage, the Congressional Budget Office estimated the FDA would need about $580 million from 2011 to 2015 to fulfill the requirements of the Act. As of April 2015, Congress had appropriated less than half of the $580 million, endangering the success of the Act. The FDA is ready to move forward with issuing rules that are crucial to the law, but they lack the money to do so.

In its last five FDA budget requests, the FDA has proposed user fees on the food industry as a way to cover a majority of the FSMA’s costs. Congress has consistently rejected the proposed user fees due to lobbying by the food industry. The budget shortfalls are making it difficult for the FDA to provide assistance to state inspection programs, update its inspection process, train employees to work within the new inspection system, and effectively manage food imports. The FSMA called for the FDA to inspect 600 foreign food facilities in year one and to increase inspections every year after that. The FDA has fallen short of these goals, inspecting only 1,323 of the 4,800 facilities it should have inspected in 2014.[[29]](#footnote-29)

 While the Food Safety Modernization Act is the first wide-sweeping food safety legislation the U.S. has seen in decades, some felt there was more to be done in the food safety arena. The FSMA did not consolidate food safety activities under a single agency, as agencies, advocates, and some politicians hoped it would. In January 2015, Senator Durbin, a food safety policy entrepreneur, and Representative Rosa Delauro (D-Conn.) introduced the Safe Food Act of 2015 in the Senate and House, respectively. The bill calls for the creation of the Food Safety Administration to address the fragmented nature of the current food safety system and to improve the government’s ability to protect the public’s health. Congress has taken no further action on the bill as of September 19, 2015.[[30]](#footnote-30)

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| **Policy Problem** | **Centers for Disease Control and Prevention[[31]](#footnote-31)** | **Government Accounting Office (now Gov. Accountability Office)[[32]](#footnote-32)** | **Center for Foodborne Illness Research and Prevention[[33]](#footnote-33)** | **Other sources** |
| Prevalence, severity, indicators (variations by age, race, income, region, time) | * 48 million Americans (1 in 6) get foodborne illness each year
* Norovirus causes about 5.5 million infections and *Salmonella* causes about 1 million
* Salmonella and Campylobacter cause about 410,000 antibiotic-resistant infections every year in the U.S.
 | * Estimates of foodborne illness are likely low due to underreporting and may be as high as 80 million
* In 1994, the food safety system involved 35 different laws and 12 agencies
 | * 70-80% of sporadic foodborne illnesses and 66% of outbreaks are never linked to a food source.
 | * FDA monitors the safety of more than 80% of U.S. food supply, including a growing amount of imported food. FDA has failed to meet FSMA inspection mandates of foreign facilities from 2012-2015 and is expected to miss the mark again in 2016[[34]](#footnote-34)
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| Consequences (morbidity, mortality, costs, etc) | * 128,000 people are hospitalized and 3,000 die due to foodborne infection each year
* While Norovirus causes the most illness, *Salmonella* causes more hospitalizations (19,336) and deaths (378) than other pathogens
 | * Medical and lost productivity costs due to foodborne illness are estimated to be $17-23 billion per year
 | * Listeria, one of the most lethal foodborne pathogens, kills more than 1/3 of infected young infants and 20% of all people infected.
* E. coli O157:H7 and other shiga-toxin producing foodborne pathogens cause a major portion of kidney failure in children
 | * The estimated cost of foodborne illness is between $51.0 - $77.7 billion[[35]](#footnote-35)
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| Causes, contributing factors | * Many pathogens occur naturally and thrive almost anywhere – this makes it difficult to prevent and predict foodborne outbreaks and illness
* There are still many unanswered scientific questions surrounding foodborne outbreaks, such as “How do the foodborne pathogens spread among the animals themselves, and how can this be prevented?”[[36]](#footnote-36)
 | * FDA lacks resources and enforcement authority to carry out its mission.
* The food safety system is fragmented.
* “The system was not developed under any rational plan but evolved over many years to address specific health threats from particular food products and has been slow to respond to changing health risks.”[[37]](#footnote-37)
 | * Because many foodborne illnesses are not linked to a source, food companies often escape liability.
* The food safety system is reactive, rather than proactive.
 | * Despite the passage of the Food Safety and Modernization Act, which in part intended to improve FDA authority and resources, the FDA still struggles to complete its food safety mission. This is because Congress appropriated only half of the estimated $580 million the FDA needs to implement the FSMA.[[38]](#footnote-38)
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| Rationale for Government Intervention | * We import a large portion of our fruits and vegetables from other countries. Government needs to ensure foreign food products are manufactured at the same level of safety as foods in the U.S.
 | * In order for the food safety system to better protect the public, legislative changes must be made.
* Food safety activities should consolidate under one agency (not a new concept; GAO called for big changes in 1972).
 | * Companies that produce contaminated food should theoretically lose market share when illness occurs, but “when it comes to foodborne pathogens, consumers do not have complete information, so ‘market forces,’ which should drive change, do not work efficiently.” Thus, governments must intervene.
 | * If the FSMA is to truly improve food safety and reduce foodborne illness in the U.S., Congress must appropriate significantly more money to the FDA to complete inspections and enforce new regulations.
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