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A CRITICAL EVALUATION OF THE LEGAL SAFEGUARDS OF AMERICA'S FOOD SAFETY SYSTEM

by

Dennis D. DiMarzio*

I. INTRODUCTION

While America is currently engaged in ongoing conflicts abroad and the Country struggles to navigate through a major economic crisis at home, it has yet more on its plate which must be addressed. Literally, it is the safety of the food that America puts on its plates that merits prime attention. The purpose of this paper shall be to present a critical evaluation of the legal safeguards of America's food safety system.

As the title of this paper clearly suggests, America's food safety system is "broken" and it needs to be "fixed." However, any complete and meaningful evaluation of the food safety system must necessarily trace its evolution. Therefore, a brief historical overview of America's food safety system will first be presented. Substantial attention will then be given to identifying the shortcomings of the current dysfunctional food safety system. Next, remedies available to victims of unsafe food will be discussed. Finally, possible steps that could be and are being taken to make America's food safety system safe again will be presented.

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II. BRIEF HISTORICAL OVERVIEW OF AMERICA'S FOOD SAFETY SYSTEM

The initial and yet foundational federal law that was designed to address food safety in America was enacted at the turn of the last century. The Pure Food and Drugs Act¹ was passed in 1906, and the Federal Meat Inspection Act² was passed in 1907. The Bureau of Chemistry administered the Food Act and the Bureau of Animal Industry administered the Meat Act.³ (The bifurcated statutory framework remains in place yet today.) In 1927, Congress separated the Chemistry Bureau's research and enforcement responsibilities and assigned the latter to a new Food, Drug, and Insecticide Administration (FDIA), still within the USDA.⁴ In 1930, the USDA deleted the "I" from the agency's name, leaving it as the FDA, the title that is used today.⁵

The reorganization of the food safety system continued over time. In 1940, President Roosevelt transferred the FDA from the USDA to the Federal Security Agency.⁶ Meanwhile, the 1938 Federal Food, Drug, and Cosmetic Act was enacted.⁷ It enlarged the FDA's food authority by allowing it to inspect factories,⁸ to set safety tolerances for unavoidable poisons,⁹ to create identity and safety standards,¹⁰ and to require manufacturers to label food ingredients.¹¹ In 1953, the FDA was moved to the Department of Health, Education and Welfare (HEW).¹² In 1980, HEW was altered to create the Department of Health and Human Services (HHS) where the FDA remains today.¹³

"As the 20th Century progressed, FDA's scientists and those in the emerging food processing industry slowly built a food safety infrastructure for the United States that enabled us to claim that we had the safest food supply in the world."¹⁴ In that earlier time, Americans grew much of their own food,

processed foods were rare, and some of the most lethal bacterial pathogens such as E Coli were unknown to nature.¹⁵ Food imports were rare, and food safety inspections and enforcement tools were adequate for that time.¹⁶

Under the law, the FDA could pursue prosecution of a violating business's chief executive, seek an injunction against that business to keep it from selling contaminated food, and it had the authority to seize food found to be contaminated.¹⁷ Generally, the FDA reacted to contaminated food already in the market place rather than taking preventive steps to safeguard the public. In fact, even with contaminated food already in the market place, the FDA had no mandatory recall power. (The lack of FDA mandatory recall power persists yet today).¹⁸

The United States Department of Agriculture (USDA) regulated meat, poultry, and various dairy products, and it had a continuous inspection and approval process in place that proved successful. "That system remains largely unchanged today ...",¹⁹ and it explains why those food products are generally safer yet today.²⁰

Over time, other federal agencies became involved with food regulation. The Environmental Protection Agency (EPA), the Department of the Treasury, the Department of Commerce, the Centers for Disease Control and Prevention, the National Marine Fish Service, the Federal Trade Commission (FTC), the Alcohol and Tobacco Tax and Trade Bureau, and the Department of Homeland Security are just some of the more prominent federal agencies that work with over 3000 state and local agencies to oversee America's food safety.²¹ Today, there are fifteen federal agencies with food safety responsibilities and at least 30 statutes that govern the area.²²

Critics have repeatedly called for the consolidation of government control in the area of food safety.²³ As early as 1949, the Hoover Commission Report²⁴ recommended that the FDA be made part of the USDA. The Commission stated that the system "... creates great overlap and also confuses the public."²⁵ Again in 1977, the Senate Government Affairs Committee unanimously concluded that all federal food regulatory functions should be consolidated.²⁶ Even today, there is proposed legislation calling for consolidation of food regulatory powers.²⁷

Many things have changed in America in the last century, but the Country's food safety system has remained largely unchanged since its foundational laws were enacted back in 1906. However, recent major food contamination recalls, and the circumstances that preceded those recalls suggest that change could be in the air.

III. AMERICA'S CURRENT DYSFUNCTIONAL FOOD SAFETY SYSTEM AND ITS SHORTCOMINGS

Perhaps, the strongest evidence that America's food safety system is dysfunctional and that change could be near is reflected in the number and severity of food contamination outbreaks. In a recent radio address, President Obama stated that "... the average number of outbreaks from contaminated produce and other foods ... (is) 350 a year up from 100 a year in the early 1990s."²⁸ "The Centers for Disease Control and Prevention (CDC) estimates that as many as seventy-six million people suffer from food poisoning each year. Of those individuals, approximately 325,000 will be hospitalized, and more than 5,000 will die."²⁹ It is estimated that the overall negative economic impact of food borne illness may be as high as \$83 billion dollars per year in the United States.³⁰

Several severe food contamination outbreaks have occurred in recent years. In 2006, there were nationwide food borne illnesses and subsequent food recalls involving spinach, peanut butter, and chili. Spinach farmers reported losing \$350 million.³¹ In 2007, contaminated pet food imported from China resulted in the estimated death of 4,000 American pets and sickened thousands of other pets.³² In 2008, a recall involving contaminated tomatoes resulted in \$500 million dollars in losses to Florida farmers.³³

However, the 2009 peanut butter food contamination case stands out as a classic illustration of how truly dysfunctional the current food safety system is in America. The Peanut Corporation of America sold peanut butter contaminated with salmonella, which is believed to have sickened more than 637 people and led to nine deaths. To date, more than 200 companies have recalled more than 2000 products.³⁴ The FDA had not inspected the plant in 8 years. While Georgia inspectors noted only minor violations, the Company ignored 12 positive test results showing the presence of salmonella in their peanut butter. The Company continued to ship its products to customers. The Company did not report these positive tests to the FDA nor did the law require them to do so.³⁵

NestlA©'s inspectors, considering whether to buy products from the Peanut Corporation, sent its own inspectors to Company plants in Georgia and Texas. They observed rat droppings, dead insects, sanitary problems and other evidence of food contamination. NestlA© refused to buy any products, but it failed to notify the FDA or other customers about the food contamination.³⁶

The Kellogg's Company hired American Institute of Baking International, the biggest inspection firm in the country

to audit the Peanut Company's facilities. Those audits resulted in a "superior" rating and even a "certificate of achievement award."³⁷ Meanwhile, The Peanut Corporation has closed all three of its facilities in Georgia, Texas, and Virginia because of salmonella contamination and it has filed for Chapter 7 Bankruptcy. Kellogg Company has lost \$70 million dollars in food recalls, and it along with other Peanut Corporation products buyers are being sued for the contaminated food they sold.³⁸ The FDA in conjunction with the Justice Department has undertaken a criminal investigation of the Peanut Corporation, its president, and other executives.³⁹ The Texas Department of State Health Services assessed a \$14.6 million fine against the Texas plant owned by the Peanut Corporation of America for violations involving unsanitary conditions and product contamination.⁴⁰

The Peanut Corporation of America case is more disturbing yet again because it apparently sold contaminated products to the USDA and FEMA Departments. The USDA is recalling food packets it sent to 3 or 4 states for a free lunch program for poor children.⁴¹ FEMA is recalling food packets it sent to tornado victims in Arkansas and Kentucky.⁴²

The troubling facts involved in the Peanut Corporation of America case and the aforementioned other recent food contamination outbreaks clearly indicate the magnitude of the problem that America has with its food safety system. To say that the system is dysfunctional is an understatement. The profoundly simpler characterization presented earlier, that America's food safety system is "broken" better describes the sad current state of affairs.

A. An Under-funded and Understaffed Food Safety System

To ultimately remedy America's food safety system, one must first identify its specific shortcomings and then collectively address them. That the FDA is grossly under-funded and understaffed is not debatable. While the FDA is accountable for regulating 80% of the nation's food, it receives 24% of the food safety funding.⁴³ The Agency is only able to inspect about 5% of the domestic food outlets per year.⁴⁴ Worse yet, less than 0.2% of imported foods are subjected to FDA laboratory testing.⁴⁵ An FDA inspector estimated that at the current pace, it would take the FDA 1900 years to check all of the food outlets in the world.⁴⁶ The FDA recently tested a Chinese herbal supplement with a \$150,000 machine known as a mass spectrophotometer at a lab in San Francisco. The test revealed such high levels of mercury that the machine had to be sent away for two weeks for proper cleaning.⁴⁷

More workers with advanced scientific training and more advanced technology for food testing are required. This is necessary to better identify food contamination and then to trace the source of that contamination. The added expense for the government will be enormous, and it might require added fees for the food industry. Another possibility is that the government could authorize and hire independent food auditing firms⁴⁸ to assist them in carrying out their fundamental duty to protect the public health and safety.

B. An Outdated Food Safety System That Lacks Coordination, Communication, And Sufficient Regulation

While more funding for staff and technology would help improve America's food safety system, there are other major shortcomings that must be addressed to properly protect our food. Specifically, the System is outdated, and there is a

lack of coordination, communication, and sufficient food regulation. The essential framework of the regulatory legislation was enacted in 1906. In those earlier times, it was much easier to trace food from "the farm to the table." The food system today is far more complex. There are dramatically more food outlets, and food typically travels longer distances and "...through many hands and into many finished products."⁴⁹ It is now a global food system with 50% of our food being imported, including 60% of produce and 80% of seafood.⁵⁰ This is particularly troubling in today's world, where bioterrorism is an ongoing threat and other countries food safety systems are even worse than our own flawed system.

There are fifteen federal agencies with food responsibilities and at least 30 statutes that govern the area.⁵¹ The two primary agencies are the USDA and the FDA. While there has long been a movement for consolidation, that would likely prove too costly and too complicated to accomplish any time soon.⁵² Immediately, there is a strong push to concentrate more food regulatory powers into a central food agency.⁵³ That centralization of food safety authority in combination with proper coordination and timely communication between all parties in the food safety network would go far in improving food safety.⁵⁴

Furthermore, more rigorous food regulation, especially with an eye toward imports and threats of bioterrorism, would improve food safety and the public's confidence in that safety. Currently, the FDA has no mandatory recall power in food contamination cases. It lacks a safety network sufficient to monitor imports. The Chinese pet food contamination outbreak that killed 4,000 American pets illustrates the problem. In 2007, because of ongoing drug and food contamination problems, the Chinese Government executed the top official of their own Food and Drug Administration.⁵⁵ While the

Bioterrorism Act of 2002 requires importers and foreign exporters of food to give advance notice to the FDA of specific shipments and requires them to maintain written records so that food traces can be accomplished,⁵⁶ the Agency still lacks a sufficient presence on foreign soil, and it does not properly monitor food processing employee backgrounds.⁵⁷

The FDA lacks rigorous safety standards, including industry testing and reporting requirements. A lack of rigorous across the board safety standards negatively impacts home grown and imported food safety. Not requiring internal testing and FDA reporting of food contamination has contributed to countless food contamination outbreaks.

Finally, the FDA, in conjunction with the Justice Department and state authorities, ought to have stronger civil and criminal penalties in food contamination cases. Current penalties rarely result in jail time.

IV. REMEDIES AVAILABLE TO VICTIMS OF FOOD CONTAMINATION

When America's food safety system fails, countless consumers are victimized by food contamination. Those victims or their surviving heirs have litigation rights. One Commentator has accurately summarized their claims as follows: "In general, there are four different types of claims that have been brought against manufacturers: negligence, breach of warranty, strict products liability, and deceptive trade practices."⁵⁸

A. Negligence

A traditional negligence claim requires the victim to establish that the defendant failed to exercise reasonable care,

which rarely proves to be a problem in a food poisoning case. The more difficult task often involves establishing proximate or legal causation.⁵⁹ Of course, if a consumer knew of the food contamination or should have been aware of it, an assumption of the risk or comparative negligence defense could bar or limit recovery.

B. Strict Tort Liability and Express and Implied Warranty Claims

"Breach of warranty claims can be brought for breach of both express and implied warranty under the Uniform Commercial Code, requiring that certain standards be met for a product to be merchantable and punishing those engaged in fraud."⁶⁰ Depending on the facts of a case, a victim might be able to prove a breach of implied warranty of merchantability (food wholesomeness) or a breach of implied warranty of fitness for a particular purpose in addition to a breach of express warranty.

The implied warranty and strict tort claims are "no fault" claims and therefore easier to prove than simple negligence. Strict tort claims require that there be an "unreasonably dangerous" defect in the product, easy enough to prove in a food poisoning case. Proximate cause issues still represent a potentially fatal flaw in the victim's claim. "Disclaimers" might also block a victim's claim. "...A London restaurant has been asking patrons who order hamburgers served rare to sign a disclaimer confirming that they will not sue the restaurant if they develop food poisoning."⁶¹ The disclaimer might have provided the restaurant with a legal victory in court had a lawsuit been filed, but it proved to be a commercial disaster, scaring so many would be customers away that the restaurant ultimately withdrew the disclaimer.

*C. Deceptive Trade Practices, Cruel And Unusual Punishment
And Obesity Claims*

In some states, a victim might successfully bring a statutory deceptive trade practices claim if fraud or false advertising is involved in their case. However, two other types of claims have proven most unsuccessful to date. Prison inmates, who suffer food poisoning while incarcerated, have repeatedly brought Constitutional violation claims⁶² based on cruel and unusual punishment under the 8th Amendment.⁶³ To win in such a case, a claimant must show: “(1) that the deprivation of humane conditions of confinement was ‘objectively, sufficiently serious’ enough to pose a substantial risk of serious harm; and (2) that the prison officials acted with deliberate indifference.”⁶⁴ Yet in other food litigation, some have attempted to hold the fast food industry accountable for their obesity based on false advertising, fraud and negligence.⁶⁵ Again, there have been no recoveries to date in those obesity claims, and there are not likely to be any recoveries in the future.

V. STEPS FOR A SAFER AMERICAN FOOD SYSTEM

The old expression about a bad situation being “desperate, but not hopeless” might well be used to describe America’s current food safety situation. This paper earlier identified major shortcomings in America’s food safety system. Steps to make the system safer necessarily involve addressing those shortcomings and taking appropriate measures to improve the system. There is hope for positive change because the American Government, including the FDA, America’s citizens, and even those food businesses impacted by the system, are quickly moving to improve our desperate situation.

A. American Government Ready For Action

In a recent address, President Obama called our food safety system “...a hazard to public health.”⁶⁶ He pledged a billion dollar investment to upgrade our food safety. Along with announcing top FDA appointments, he said he is “...setting up a Food Working Group, seeking advice from cabinet secretaries and senior officials on strengthening food safety laws, improving coordination among government agencies and enforcing food safety laws.”⁶⁷

It is reported that there are “...about half a dozen food safety reform bills...pending on Capitol Hill.”⁶⁸ The bill which has “...the best chance of passing...”⁶⁹ is sponsored by U.S. Senators Gregg, Durbin, Kennedy and Burr. It is a comprehensive bill and addresses the key shortcomings in America’s food safety system. New Hampshire Senator Gregg has indicated that “...The bipartisan bill focuses on four key areas where FDA’s authorities and resources need to be improved: food-borne illness prevention; food-borne illness detection and response; food defense capabilities; and overall resources.”⁷⁰

The Bill improves America’s capacity to prevent food safety problems in a variety of ways. First, it “...Requires all facilities to have in place preventive plans to address identified hazards and prevent adulteration, and gives the FDA access to these plans and relevant documentation.”⁷¹ Secondly, in a food emergency, it expands FDA access to food records.⁷² Thirdly, it “...allows the FDA to recognize laboratory accreditation bodies to ensure U.S. food testing labs meet high quality standards and requires food testing performed by these labs be reported to the FDA.”⁷³ Furthermore, it “...allows the FDA to enable qualified 3rd parties to certify that foreign food facilities

comply with U.S. food safety standards.”⁷⁴ Finally, it “...requires importers to verify the safety of foreign suppliers and imported food.”⁷⁵

The Bill dramatically improves America’s capacity to detect and respond to food-borne illness outbreaks. FDA inspections would increase so that there would be annual inspections of high risk facilities and inspections of other facilities at least once every four years.⁷⁶ Surveillance systems would be set up to “...improve the collection, analysis, reporting, and usefulness of data on food-borne illnesses.”⁷⁷ The Bill would require “...the Secretary of HHS to establish a pilot project to test and evaluate new methods for rapidly and effectively tracking/tracing fruits and vegetables in the event of a food-borne illness outbreak.”⁷⁸ Most importantly, the Bill gives the “...FDA mandatory recall authority of a food product when a company fails to voluntarily recall the product upon FDA’s request.”⁷⁹ Finally, the Bill would give the FDA the power to suspend a food facility’s registration “...if there is a reasonable probability that food from the facility will cause adverse health consequences or death.”⁸⁰

Furthermore, the Bill enhances U.S. food defense capabilities, and it increases funding to support the FDA’s food safety activities. Specifically, the Bill “...directs the FDA to help food companies protect their products from intentional contamination and calls for a national strategy to protect our food supply from terrorist threats and rapidly respond to food emergencies.”⁸¹ It also increases funding for FDA’s food safety activities through “...increased appropriations and targeted fees for domestic and foreign facilities.”⁸²

B. The FDA Releases a One Year Summary of Its Food Protection Plan

In December of 2008, the FDA offered a summary of their food protection plan. They identified three core elements in that plan as follows: (1) Prevention, (2) Intervention, and (3) Response.⁸³ If the proposed federal legislation goes through, it would, in fact, enable the FDA to more successfully protect American food and to prevent major future food contamination outbreaks.

Another step that would improve food safety involves more consolidation of the federal agencies that regulate food safety and better coordination and communication among those agencies and state and local governments. Critics, even many within the government itself, have long called for consolidation of government control in the area of food safety.⁸⁴ Ultimately, a bold step involving such a major overhaul of the federal regulatory control of food safety would be most expensive and complicated, but the improved protection of the public health and safety would merit the investment of both money and time.

C. Food Industry Self-Policing and the Public’s Cooperation

The only additional area for food safety improvement would involve better self-policing by the food industry itself and greater public cooperation, whereby food contamination victims quickly report their case and fully cooperate with authorities to trace their food source. The food industry ought to have a record and reporting system in place to prevent the shipment of contaminated food. Food industry employees should be required to report evidence of food contamination to their employer, who should then be required to report that information to the FDA. The food industry ought to encourage and reward employees or members of the public who whistle-

blow or quickly report food contamination. Timely food contamination reports from the food industry and the public would enhance the Government's ability to prevent or to at least better control food-borne illnesses.

VI. CONCLUSION

Perhaps no one better described the current state of America's food safety system than U.S. Senator Durbin when he said it was "...outdated, under-funded and overwhelmed."⁸⁵ Again, it is a "desperate" but not a "hopeless" situation. The American Government has now identified the enormity of the problem, and it will soon be addressed in a bold and new way. If the food industry engages in more rigorous self-policing, and the public lends its full cooperation to the food safety effort, there is every reason to believe that food safety in America will improve in the future. Collectively, the Government, acting in concert with the food industry and a cooperative public, can rise to the challenge of safeguarding America's food.

ENDNOTES

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