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A NEW ROLE FOR THE FDA IN FOOD SAFETY

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I. Introduction

On March 14, 2009, President Obama remarked, “There are certain things that only a government can do. And one of those is ensuring that the foods we eat are safe and don’t cause us harm.”² This is a widespread opinion and has been the prevailing opinion for over 100 years. Beginning in the 1870s and ’80s, there were multiple bills in Congress to get the federal government heavily involved in food safety to effect—as one writer put it—a “dramatic expansion of the federal government’s role in promoting the health and safety of American consumers.”³ At the time, many of problems associated with food safety could be readily classified as a market failure. Pathogenic contamination was rampant, from insanitary plants and poor processing, and there were many compounds added to food that had no business in anyone’s diet. There was generally no judicial remedy as there was almost no way to trace harm to offending products. The government’s role in protecting consumers from risk has increased steadily right through today and, initially, the creation of the FDA saw some early successes in this area.

Yet early successes inevitably have given way to increasing stagnation and inefficiency. At the FDA, institutional arteries defined by informal relationships with stakeholders have hardened, and the supply of readily available science and technological solutions for obvious problems have been replaced by greater uncertainty and inefficiency. The FDA has continued to use the same tools as it did over 100 years ago to try and make food safer but, eventually, it will become obvious to even the most dedicated supporters of food-safety regulation that we cannot make food safer by continuing centuries-old practices. In order to reduce risk, the FDA must take on a new role.

But virtually all recent efforts to make food safer have been headed in the direction of giving the FDA more resources and more authority to continue in the same direction exercising greater control over industry. The FDA has offered a new plan issued under the Bush administration in their “Food Protection Plan: An Integrated Strategy for Protecting the Nation’s Food Supply.”⁴ This plan is composed of three core elements: prevention, intervention, and response. Central to the plan is an attempt to address the GAO’s criticism of the lack of coordination between federal, state, and industry partners.⁵ Such coordination, coupled with risk-based inspections, would in principle allow the FDA to operate more effectively without having full responsibility for all

¹ Although all errors are mine, I would like to thank Dan Claybaugh for his help in producing this paper as well as Kevin Rollins and Bob Scharff.

² Barack Obama, “Weekly Address: Reversing a Troubling Trend in Food Safety,” March 14, 2009. <http://www.whitehouse.gov/blog/09/03/14/Food-Safety/>.

³ Anthony Gaughan and Peter Barton Hutt, “Harvey Wiley, Theodore Roosevelt, and the Federal Regulation of Food and Drugs,” Harvard Law School, Winter 2004, p.3. <http://leda.law.harvard.edu/leda/data/654/Gaughan.pdf>.

⁴ Department of Health and Human Services and Food and Drug Administration, *FDA Food Protection Plan: An Integrated Strategy for Protecting the Nation’s Food Supply*, November 2007, http://www.nap.edu/openbook.php?record_id=12892&page=419.

⁵ GAO, Federal Oversight of Food Safety: FDA’s Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical, January 29, 2008.

enforcement activities. A more elaborate version than the FDA's plan is offered in a report entitled, *Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System.*⁶ Both of these documents suggest that a greater role is necessary at all government levels for food safety, with a primary emphasis on the central role of the federal government. But the history of the FDA suggests that this is the wrong direction. This discussion will begin with the early history of successes that the FDA enjoyed with early regulations. Next, there will be a discussion of how early successes evolved into diminishing regulatory effectiveness. Following that there will be a discussion of the complex world that the FDA now tries to regulate and inspect and what the modern approach has been to try and deal with this universe. Finally, there will be a discussion of new directions that are likely to be more effective at reducing food-borne disease.

II. Early History

The beginnings of federal involvement with food safety began with a writer who set out to write an exposé of the working conditions in meat packing plants. In his 1906 novel *The Jungle*, Upton Sinclair horrified Americans as they were told that rats were running freely over meat and, among other unknown items, ended up being part of the meat.⁷ Sinclair sought to bring about a socialist reform to the nation by using food safety as the vehicle. "For Sinclair, food safety was barely an afterthought for the author."⁸ The work was first published as a serial in 1905 and reprinted as a novel in 1906 and was responsible primarily for the Meat Inspection Act. At the same time that the novel was being published, Harvey Wiley, a food reformer, was publishing his first paper on adulteration using glucose.⁹ Wiley worked in the Chemistry Division of the USDA and from that position began to advocate for government regulation to prevent food adulteration. Both Wiley and Sinclair were arguing that the federal government needed to solve fairly obvious problems, including "questionable ingredients or additives in food" and cleaning up filthy plants.¹⁰

The third player was the most important one, Teddy Roosevelt, who despised both Sinclair and Wiley. He considered Sinclair a "crackpot" and did not want to align himself with Sinclair, who was a known socialist.¹¹ Roosevelt, although favoring regulation as giving a "square deal" to common man, equally disliked the publicity-seeking Wiley. At the USDA, Wiley was forming his now famous "Poison Squad" (a group of volunteers who ate compounds to see if they would make themselves sick) and became so popular with the public that he earned himself a nickname, "Old Borax."¹² Wiley was investigating intentionally added substances that, as evidenced by his

⁶ Michael R. Taylor and Stephanie David, "Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation's Food Safety System." Department of Health Policy, School of Public Health and Health Services, George Washington University, <http://www.scribd.com/doc/14519426/Stronger-Partnerships-for-Safer-Food-Report-by-Michael-R-Taylor-and-Stephanie-D-David>.

⁷ Upton Sinclair, *The Jungle* (New York: Doubleday, Page and Company, 1906).

⁸ <http://www.kirjasto.sci.fi/sinclair.htm>

⁹ Gaughan, 4.

¹⁰ The President's Council on Food Safety comment before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Senate Committee on Governmental Affairs, August 4, 1999. <http://www.fda.gov/NewsEvents/Testimony/ucm115043.htm>

¹¹ http://en.wikipedia.org/wiki/The_Jungle

¹² Gaughan, 9.

poison squad, made people sick. These substances were both fillers (sawdust) and compounds that might disguise spoilage. For example, lead salts were added to candy and cheese, textile inks were used as coloring agents, brick dust was added to cocoa, and copper salts were added to peas and pickles.¹³ Even prior to Wiley, Frederick Accum wrote the *Treatise on the Adulteration of Food* which began to uncover some of these practices in 1820.¹⁴ Although Roosevelt was disinclined to intervene in the affairs of business, he became convinced by the reports from both Wiley and Sinclair and ended up supporting the Pure Food and Drug Act of 1906. It was this act that formed the Food and Drug Administration and Harvey Wiley was made its first director.

The formation of a new regulatory body is typically the result of a perceived crisis (that at least part of the time has real consequences) that is nurtured by both media and reformers. In the case of food safety, there had been previous attempts to establish a food safety bureau but it was *The Jungle* that put it over the top. Opposition to new laws was ultimately overcome by public fervor and the fact that Roosevelt's own agents inspected the conditions at meat packing plants.

Once in place, it was relatively easy for the FDA to address intentional neglect, (e.g., failure to control for obviously visible rats) and intentional poor production practices (such as adding in compounds that do not belong in food). Of at least as much consequence, there had been an enormous breakthrough in food-safety science in the latter part of the 19th century. While a number of scientists deserve credit, it was Louis Pasteur who put forth the theory that bacteria could make people sick. German scientist Robert Koch went on to show how microorganisms in a sick animal can be cultivated and injected in a well animal that makes the animal sick.¹⁵ With the science in hand, Pasteur went on in 1864 to show that heat killed these microorganisms as a way to improve wine. This key finding ultimately led to a law for the FDA, the Grade A Pasteurized Milk Ordinance (PMO) in 1923 which requires, among other things, that milk sold interstate be pasteurized.¹⁶ Arguably, this enduring law and the regulations that implemented it are one of the huge accomplishments of the early Food and Drug Administration. It wasn't necessarily easy, there were many arguments about the merits of pasteurization despite the fact that raw milk accounted for up to 25 percent of all food- and water-borne illnesses before pasteurization became common.¹⁷ At the time, some thought that thunderstorms were the cause of milk spoiling; others thought pasteurization might induce scurvy.¹⁸ One could argue that these same types of forces have aligned more recently to battle against irradiation and genetically

¹³ Food History, "History of Food Safety," <http://www.world-foodhistory.com/2009/02/history-of-food-safety.html>.

¹⁴ John D. Floros et al., "Feeding the World Today and Tomorrow: The Importance of Food Science and Technology," *Comprehensive Reviews in Food Science and Food Safety* 9, no. 5 (2010): 7.

¹⁵ CliffsNotes.com, *A Brief History of Microbiology*. September 13, 2010, http://www.cliffsnotes.com/study_guide/topicArticleId-8524,articleId-8406.html.

¹⁶ Cornell University, "Heat Treatments and Pasteurization," <http://www.milkfacts.info/Milk%20Processing/Heat%20Treatments%20and%20Pasteurization.htm>.

¹⁷ Sally Fallon and Thomas Cowan, "Fight the Pasteurization Myth," *Alive*, http://www.alive.com/371a1a2.php?subject_bread_cramb=455. See also, Nickel K. Gall, "The Milk Wars – 'Raw' or Pasteurized," *Food CEO*, June 8, 2010, <http://foodceo.com/articles/2010/08/the-milk-wars-raw-or-pasteurized/>.

¹⁸ Joseph H. Hotchkiss, "Lambasting Louis, Lessons from Pasteurization," in *Genetically Modified Food and the Consumer*, ed. Allan Eaglesham, Steven G. Pueppke, and Ralph W.F. Hardy, (Ithaca, NY: National Agricultural Biotechnology Council, 2001).

modified foods.¹⁹ The discovery of pathogenic bacteria and heating foods to kill them was a giant leap forward for food safety.

The founding of the FDA and its early successes were based on a food production system that the public found “intolerable” and at least one key scientific discovery. In fact, this new technology drives most of the successful regulation by the Food and Drug Administration. As Bernstein put it over 50 years ago, “The agency of regulation is created at the peak of organized fervor for reform.”²⁰ Similarly, one could argue that it was Rachael Carson’s *Silent Spring* that created a widespread perception of an endangered environment that which led President Nixon to create the Environmental Protection Agency (out of the Ash Council) in 1970.²¹

Food-safety problems continued to plague the United States. During the Spanish and American War, canning was done so poorly that, although 379 soldiers died in combat, more than 1,000 died from spoiled canned meat.²² Between 1906 and 1963 there were 219 cases of botulism from commercial foods.²³ In 1971, the Bon Vivant Soup company recalled 6,444 cans of vichyssoise soup, although ultimately only five cans of soup were found to contain botulinum toxin.²⁴ Nevertheless, this event led to another effective food-safety regulation: the low-acid canned-food processing regulations in 1973 that ensured that these foods are adequately heated (i.e., pasteurized) to kill pathogens.²⁵ Since then, the risk from low-acid canned foods, particularly commercially packed cans, is low enough that it is not considered a significant food-safety problem.²⁶

Although helpful at the time they were promulgated, good manufacturing practices (GMPs), which established baseline practices for safe food processing, are now somewhat antiquated. Modern-day food manufacturers have much more sophisticated processing procedures and, in fact, have begun to design and use equipment that is less likely to harbor pathogens that may be a key method to reduce exposure to pathogens. There is no regulation requiring such innovation, however.

¹⁹M.T. Osterholm and M.E. Potter, “Irradiation Pasteurization of Solid Foods: Taking Food Safety to the Next Level,” *Emerging Infectious Disease* 3, no. 4 (1997).

²⁰Marver H. Bernstein, *Regulating Business by Independent Commission* (Princeton, New Jersey: Princeton University Press), 76.

²¹ Environmental Protection Agency, *Douglas M. Costle: Oral History Interview*, January 2001, <http://epa.gov/history/publications/print/costle.htm>.

²² Food-Safety-and-You.com, “History of Food Safety: A Commentary,” <http://www.food-safety-and-you.com/HistoryofFoodSafety.html>.

²³ Karen P. Penner, “*Clostridium Botulinum* and Foodborne Illness,” Fadi Aramouni and Karen Blakeslee MF-2171 Kansas State <http://www.ksre.ksu.edu/library/fntr2/mf2171.pdf>.

²⁴ Wikipedia contributors, “Botulism,” *Wikipedia, The Free Encyclopedia*, <http://en.wikipedia.org/wiki/Botulism> (accessed June 8, 2010).

²⁵ Wikipedia contributors, “Botulism,” *Wikipedia, The Free Encyclopedia*, <http://en.wikipedia.org/wiki/Botulism> (accessed June 8, 2010).

²⁶William Sperber, “Testing: Shifting the Emphasis from Product Testing to Process Testing,” *Food Safety Magazine*, April/May 2010.

III. Diminishing Regulatory Effectiveness

The discovery of filthy, pest-ridden food facilities, intentional addition of obviously harmful substances, and a miraculous cure for recently discovered harmful pathogens were all contributors to early risk-reduction success at the FDA. Over time, however, the FDA has suffered from what might be termed “diminishing regulatory effectiveness.” That is, over time, the FDA has continued to promulgate many new regulations of food processing without any noticeable decrease in food-safety risk. The causes of the FDA’s inability to succeed fall into three categories: organizational, institutional, and scientific. The first issue is the general organizational decline that we expect to see in any organization when they age. A general rule for organizations and governments was expressed by Ridley, “Empires, indeed governments generally, tend to be good things at first and bad things the longer they last.”²⁷ More specific to regulatory agencies (as opposed to private firms), “The static quality of regulation and the inertia and apathy that gradually overtake the regulatory process contrast sharply with the dynamic development of industry and technology and the productive ingenuity of American industrial enterprise.”²⁸

Even private firms eventually develop “organizational senility and rigidity.”²⁹ In fact, “only a tiny percentage of firms ever reach 40 years, probably less than 0.1 percent.”³⁰ Because they become inefficient, competition drives them out of business. At 104 years old and without any competitive pressure, is it possible that the FDA remains an “efficient” organization?

Institutionally, the FDA has developed a set of informal relationships with both the regulated industry and food activists that create a system of political rewards that has little to do with food safety. Over time, the bureaucratization starts to operate and regulation becomes less and less efficient over time.”³¹ Regulatory agencies create institutions that tend to favor narrow constituencies such as command-and-control regulations.³² This system of “rent seeking” not only pushes the FDA away from solving food-safety problems, it also generate certain types of regulations, primarily those that require specific actions (command and control) that tends to reward rent-seeking firms, and these types of regulations are also favored by food-safety activists. There is a vast literature on how agencies become captured, first by industry and, in some cases, by the combination of industry and public-advocacy groups. This combination produces the famous “bootleggers and Baptists” situation.³³ In a sense, it was this combination that produced the 1938 Food, Drug, and Cosmetic Act that created food standards that benefited both incumbent firms by reducing competition for quality, and consumer groups, by keeping

²⁷ Matt Ridley, *The Rational Optimist: How Prosperity Evolves* (New York: Harper Collins, 2010), 182.

²⁸ Berstein, p. 100.

²⁹ C.I. Stubbart and M.B. Knight, “The Cast of the Disappearing Firms: Empirical Evidence and Implications,” *Journal of Organizational Behavior*, 7 2006, p. 88.

³⁰ Horvath, Schivardi and Waswaste, p.91.

³¹ David Martimort, “The Life Cycle of Regulatory Agencies: Dynamic Capture and Transactions Costs,” *The Review of Economic Studies* 66, no. 4 (1999): 932.

³² Bruce Yandle, “Rethinking Protection of Competition and Competitors, in 21st Century Regulation: Discovering Better Solutions for Enduring Problems, Mercatus Center at George Mason University, January 2009, pp 55-67.

³³ Bruce Yandle, “Bootleggers and Baptists: The Education of a Regulatory Economist,” *Regulation* 7, no. 3 (1983): 12-16.

foods produced “like mother used to make.”³⁴ Even Harvey Wiley noted, “It is hardly necessary to add that all the conferences, indulgences, and collaborations with vested interests which thereafter were resorted to as a means of defeating the purpose of the law have effectively nullified the efficiency of the standards originally established.”³⁵ Over time, it became clear that food standards were ensuring that the original recipes (which prescribed minimum fat levels) were not necessarily the healthiest.

To continue to use the FDA to their advantage, the food industry, particularly larger firms, has become better organized to obtain regulations that help them competitively. In fact, the food industry regularly lobbies Congress to give more funding and more authority to the FDA. The FDA is rewarded by becoming larger and more powerful. The organizational problem these institutional arrangements present is that solving problems now becomes secondary to the system of seeking and granting rewards. For industry, more regulation is favored if it benefits incumbents, particularly large incumbent firms that restrict entry. Regulation can serve to reduce product differentiation competition as well as raising smaller rival’s costs.³⁶ This kind of rent seeking tends to increase over time as there appear to be increasing returns because, for example: 1) there are fixed cost of setting up rent seeking systems, and 2) offense creates a defense.³⁷ Of course, it also serves to keep out those who choose to sell substandard products which can cause consumers to lose confidence in entire classes of products.

Finally, we have the science problem which is that, without new scientific breakthroughs, solutions become more difficult.

The discovery of the germ theory coupled with the innovation of pasteurization had the ability to make huge inroads in food-borne disease. It was fairly obvious that requiring filthy, pest-ridden plants be cleaned and that the intentional addition of known poisons should be prohibited. Both the problems and the solutions were fairly homogeneous across the industry so that broadly applied regulations work. In other cases, where there were specific problems, it was fairly obvious whom to target and fairly easy to spell out those targets in a rule. This was certainly the state of food safety and the FDA in the first 50 or so years.

To some extent, absent emerging risks, this pattern of easy problems to solve for a newly created organization is consistent with trying to reduce smaller and smaller risks. As smaller and smaller risks are addressed, the marginal costs of action increase and marginal benefits decrease. In some cases, the knowledge of what the actual risk is becomes less certain so that the likelihood of having a positive effect is decreasing. In addition, as we decrease these small risks, other risks may be increasing (risk/risk trade-offs) so that it is possible that net risk is increasing.³⁸ If, as argued here, the FDA addressed the biggest, most-obvious problems first, the remaining

³⁴Richard A. Merrill and Earlyi Collier, “Like Mother used to Make: an Analysis of FDA Food Standards of Identity,” *Columbia Law Review* 74 (1974): 561.

³⁵Wiley, Harvey M., *The History of a Crime Against the Food Law*, Harvey Wiley, MD. Publisher, Chapter 3, 1929.

³⁶Stephen Salop, “Raising Rivals Costs,” *American Economic Review* 73, no. 2 (1983): 267-71.

³⁷Kevin M. Murphy et al., “Why is Rent-Seeking so Costly to Growth?” *American Economic Review* 83, no. 2 (1993): 409.

³⁸Richard A. Williams and Kimberly M. Thompson, “Integrated Analysis: Combining Risk And Economic Assessments While Preserving the Separation of Powers,” *Risk Analysis* 24, no. 6 (2004).

problems are going to necessarily be some combination of smaller and/or less-certain risks and without inexpensive, effective solutions.

Without new science or easy problems to solve, the FDA’s approach to food safety in the last 30 years can be characterized as the FDA asserting its control over how food is processed. The rules that the FDA produced demonstrate both institutional and scientific issues as well as organizational decline that reflects the inability of the organization to creatively solve food-safety problems.

The FDA received more funding and began to make a strong push in the 1990s for food safety and three large rules characterized that drive (see table 1).

Table 1: Growth in FDA Funding for Food Safety

Year	Amount (in thousands)	Center FTEs	Field FTEs	Total FTEs
1997	\$191,183	790	1,436	2,226
1998	\$203,830	809	1,409	2,218
1999	\$235,203	811	1,464	2,275
2000	\$279,717	869	1,509	2,378
2001	\$287,504	879	1,566	2,445
2002	\$401,582	907	1,928	2,835
2003	\$406,824	950	2,217	3,167
2004	\$430,220	910	2,172	3,082
2005	\$435,517	884	2,059	2,943
2006	\$438,721	812	1,962	2,774

Two of the rules in particular were borrowed from an industry creation known as “Hazard Analysis Critical Control Points” (HACCP). The FDA decided to make these process controls mandatory and under the FDA’s supervision for the seafood and juice industries. A third rule required extensive Good Manufacturing Practices for the dietary supplement industry.

Prior to the introduction of first HACCP rule for the seafood industry, Commissioner David Kessler announced in 1993 that “Three years ago, FDA’s seafood program was under attack. Since then, FDA’s seafood inspections have been stepped up. Now the agency’s seafood program is stronger, more vital, and respected for its leadership and innovation. Three years ago, FDA’s seafood program was funded \$22.5 million a year. Now it receives \$44 million annually and all program activities have been strengthened.”³⁹ The reason for this announcement was that Congress was considering transferring the seafood program from the FDA to the USDA, a move that the FDA’s bureaucracy had to respond to vigorously.

Because of pressure from large seafood exporters who could not export to the European Union without federal oversight, the FDA decided to create a voluntary HACCP oversight program for the seafood industry. However, the FDA quickly came under pressure from those same large processors to make this program mandatory and included small, non-exporting processors. The large fixed costs of HACCP put the smaller processors at a competitive disadvantage (fixed costs are the same for large and small firms, meaning they must be paid for by small firms over a smaller sales base). Nevertheless, the FDA dismissed the problem facing small firms: “There are prerequisite sanitation requirements, but no allowance for size of firm because small firms can obtain assistance.”⁴⁰ The proposed regulation was first published in December 1985 and became effective in 1997. Food-safety activists also pressured FDA as popular polls showed that people believed that seafood was responsible for a great many more illnesses than is actually the case. Testifying to a House committee in 1996, Michael Friedman described the FDA’s (HAACP) initiative which had already been embodied in seafood regulation:

HACCP has seven basic steps. It begins with an in depth analysis of potential hazards, followed by identification of points in the processing operation (critical control points) where the failure to control the hazard is likely to result in illness or injury to the consumer. Steps three and four are the establishment of critical limits associated with each identified critical control point and delineation of procedures to monitor the limits. The firm identifies corrective action procedures to be taken when monitoring indicates that a critical limit has been exceeded. Then, an effective recordkeeping system must be in place to document the HACCP system. Finally, the HACCP system should be verified to assure that it is functioning properly. (Friedman 1996)⁴¹

Each step of HACCP is unique to the plant and requires in-depth, plant-specific knowledge. Even farms are unique. A food-safety manager at a California farm said in a tour, “There are unique risks at every farm.”⁴² As an effective creation by and for the food industry, it is unclear what value the FDA believed it could add by requiring and overseeing it. At best, the FDA can (and did) publicize hazards that individual firms may not know are associated with their particular product. While the FDA has touted the success of its seafood HACCP program, it has had almost a negligible effect on safety. The FDA identified 33,000 illnesses per year directly associated with seafood with most of the serious illnesses associated with the consumption of

³⁹ David A. Kessler, “Seafood Safety: The Next Steps” (speech, National Fisheries Institute Annual Convention, Washington, DC, November 4, 1993), <http://www.fda.gov/NewsEvents/Speeches/ucm106917.htm>.

⁴⁰ Phillip C. Spiller “Status of Seafood HACCP,” *Food and Drug Law Journal* 52 (1997): 327.

⁴¹ House Committee on Agriculture, *Inspection of Seafood Products*, 104th Cong., 2nd sess., May 22, 1996.

⁴² Interview with Fernando Fernandez, Lakeside Organic Gardens, Watsonville, CA, 9/27/2010.

raw shellfish.⁴³ The most serious illness associated with seafood, which accounted for about 50 percent of the estimate benefits of the rule, was the pathogen *Vibrio vulnificus*, which is found mainly in raw oysters from the Gulf of Mexico. But reducing those illnesses from consumption of raw shellfish could never have been realized by imposition of a HACCP system. To date there is no evidence in fact that this system has been effective at reducing any illnesses, no matter what the cost.

The key to HACCP is that a company must identify a critical point in processing where a hazard can either be reduced or eliminated. For an oyster that comes out of the water already containing high enough levels of a pathogen to cause illness and then is consumed raw, there simply is no control intervention to reduce the levels. With the exception of icing after harvest, which only reduces the growth of pathogens, there simply is no “control point” to control the problem. Yet the FDA estimated that somehow, magically, that 50 percent of the problem would be solved.⁴⁴ The FDA promised in its final rule to revisit the public-health success or lack thereof after implementation but, not surprisingly, has never done this.

In fact, the person credited with first utilizing HACCP while at Pillsbury in the early 1970s, William Sperber, says that HACCP has been “oversold.”⁴⁵ He argues that, “Despite the widespread use of HACCP in the food industry, many outbreaks of food borne outbreaks still occur. However, these food safety failures are rarely HACCP failures. Rather they are frequently failures of cleaning and sanitation practices or the lack of management awareness and commitment to provide the necessary training and resources.”⁴⁶

The FDA went on to mandate a government-inspected HACCP system for raw juice products.⁴⁷ In this case, once it became more broadly known that unpasteurized apple and orange juice products were making children sick, primarily due to fecal contamination from apples which had fallen into animal feces, the juice industry began to either pasteurize or cease production entirely.⁴⁸ Pasteurization effectively kills the pathogens so that all of the HACCP steps were redundant. Nevertheless, the FDA moved forward with the complex regulation. A look at just a small part of the rule is illustrative of this problem:

Each processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food hazards that are reasonably likely to occur during processing, as described in § 120.7. The HACCP plan shall be developed by an

⁴³ <http://www.foodsafety.gov/~lrd/searule2.html> (FDA Proposal 1995: Seafood HACCP)

⁴⁴ FDA used a “panel” of its own scientists to make these determinations without explaining precisely how they would be obtained. See footnote 1, to Table 6A in the Final Regulatory Impact Analysis on page 65185. Food and Drug Administration, Final Rule, “Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products,” *Federal Register* 60, no. 242 (December 1995): 65095-65202.

⁴⁵ W.H. Sperber, “HACCP does not work from Farm to Table,” *Food Control* 16 (2005): 511-514.

⁴⁶ Sperber, 513.

⁴⁷ Hazard Analysis and Critical Control Point (HACCP) Systems, *Code of Federal Regulations*, title 21, sec. 120.1 (2003), http://edocket.access.gpo.gov/cfr_2003/apr/qtr/pdf/21cfr120.1.pdf.

⁴⁸ The fact that FDA went out quickly mandating a warning label on raw juice quickly pushed the industry to make these changes.

individual or individuals who have been trained in accordance with § 120.13 and shall be subject to the recordkeeping requirements of § 120.12.⁴⁹

When pasteurization easily solves the problem, the reason for going ahead with a complex regulation can only be explained by non-risk related reasons. This explains a problem with many regulations; they are done because an agency has pressures that are not necessarily in line with its organic mission. By the time the juice HACCP regulation was finalized, the problem had already been effectively solved, although food-safety activists continued to push for the rule. In the seafood HACCP case, the FDA was heavily influenced by the large seafood processors as well as food-safety activists to go forward with a rule that could not solve the biggest problem (shellfish).

When mandated by government, HACCP is not a solution; it is government admitting that it does not have a solution to a problem. In the two cases above, there was no new technology to be implemented and the problems, particularly with meat (USDA HACCP rule), poultry, and seafood had been around for a long time. The rather small risk with juice products was solved by the old technology, pasteurization, not by process controls. It was not until 2010 that a group of food safety experts at the National Academy of Sciences admitted that “most interventions to minimize food hazards have only limited effects in decreasing the prevalence of pathogens, and for some foods, such as those sold raw, few interventions are possible.”⁵⁰

The last process rule that reflects all of these problems and more is the Good Manufacturing Practices for Dietary Supplements rule.⁵¹ In this case, Congress granted (but did not require) the FDA the authority to regulate how dietary supplements were processed, but did not give FDA the authority to regulate ingredients. This regulation was certainly favored by pharmaceutical companies who were already in compliance with strict drug manufacturing requirements and saw a way to raise rival’s costs on those firms who only manufactured dietary supplements. Although dietary supplements were already covered by the generic Good Manufacturing Practices for food, the FDA proceeded with a much more stringent set of rules that were that were much closer to those required to manufacture pharmaceuticals. The FDA’s estimates of costs and benefits tell the story:

We estimate that, once it is fully implemented, the annual quantified benefits from the final rule will be \$8 million to \$64 million, with a mean estimate of \$44 million. However, there are potentially large benefits of the rule that we were not able to quantify. The annual costs will be \$104 million to \$322 million, with a mean estimate of \$164 million.⁵²

⁴⁹ Hazard Analysis and Critical Control Point (HACCP) Systems, *Code of Federal Regulations*, title 21, sec. 120.7 (2003), http://edocket.access.gpo.gov/cfr_2003/apr/qtr/pdf/21cfr120.7.pdf.

⁵⁰ Institute of Medicine, p. 2-7

⁵¹ Food and Drug Administration, Final Rule, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” *Federal Register* 72, no. 121 (June 2007): 34751-34958.

⁵² Food and Drug Administration, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” 34932.

The FDA’s belief that there are “potentially large benefits of the rule that we were not able to quantify, was clearly stated just to be in compliance with Executive Order 12866 which requires that costs be ‘justified’ by benefits.”^{53 54} In fact, after years of searching, the FDA simply could not find any real risks associated with the processing of dietary supplements. In cases where there might have been pathogen contamination from herbals manufactured directly from crops in the field, the industry was found to be quietly irradiating them to ensure no problems. But the agency could not resist a chance to expand into the relatively unregulated industry while aiding the pharmaceutical manufacturers. In this case, it is not that the FDA did not have a solution, it did not have a problem (there was virtually no systemic risk from the manufacture of dietary supplements).

These three rules represented the FDA’s largest food-safety efforts in the 1990s and the early part of the next decade. Was there a notable decrease in unsafe food during this period? The evidence fairly convincingly demonstrates that there was not as shown in table 2. In fact, although it appears that there was a jump in 1998 in the numbers of outbreaks and illnesses, PulseNet came on line in 1997 which greatly increased the numbers of outbreaks that could be detected.

Table 2: Outbreaks and Illnesses 1990–2006

Year	Outbreaks	Illnesses
1990	533	19,231
1991	531	15,052
1992	411	11,083
1993	514	14,080
1994	690	16,995
1995	645	13,497
1996	602	15,421
1997	806	18,802
1998	1,314	26,719
1999	1,344	25,286
2000	1,417	26,043
2001	1,238	25,035
2002	1,332	24,971
2003	1,072	22,791
2004	1,319	28,239
2005	982	20,179
2006	1,247	25,659

Numbers drawn from CDC Summary Statistics for Foodborne Outbreaks.
See spreadsheet appendix for listing of reports.

⁵³ Food and Drug Administration, “Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements,” 34933.

⁵⁴ <http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866.pdf>

As the FDA's regulatory effectiveness has declined, the industries that the FDA is charged with overseeing have changed making the job much more difficult. First, the FDA is now faced with an industry that is vastly larger than it was in its first few decades and much more complex. It certainly makes a "one-size-fits-all" style of command-and-control regulation much less likely to be effective. The diversity of food plants, retail service, and other places that the FDA is charged with regulating is breathtaking. From an oyster harvesting boat in the Gulf of Mexico, to a vegetable canning plant in Chicago, to a Mississippi cruise boat, to an egg farm in Minnesota, to a deli in California, to an apple presser in Virginia, the FDA's reach extends far and wide. To be able to pass effective regulations, the FDA would have to have in-depth knowledge of the thousands of combinations of foods, processing, and packaging. In a modern-day supermarket, it is not unusual to find 30,000 different kinds of foods. The FDA's charge covers farms, trucks, trains, airplanes, processing plants, packers, repackers, labelers, boats, restaurants, nursing homes, prisons, schools, universities, supermarkets, military bases, prisons, cruise ships, warehouses, and mailed foods. As Welch and Mitchell stated, "No period of time has seen such rapid advances in food and beverage processing as the 20th century."⁵⁵ Just a few of the innovations include quick freezing, irradiation, and *sous vide* packaging. FDA cannot be in a position to understand even a small fraction of the many different kinds of issues associated with food production, warehousing, and distribution today.

Even if the FDA were somehow able to obtain such knowledge, outbreaks are often attributable to unique conditions which do not lend themselves easily to be remedied by regulation. For example, there might be a problem a bagged salad contaminated with *listeria monocytogenes*. For illnesses to result, there would first have to be a sufficient number of colony-forming units (CFUs) (levels of *listeria*) in order to make someone sick, perhaps as high as 100,000 CFUs of *listeria* per gram of food. Next, there would need to be a failure to clean the lettuce sufficiently with an antimicrobial wash (assuming the contamination is not on the inside of the lettuce) and, finally, for severe illness to occur, it would have to be eaten by someone who is immunologically impaired. Processing failures that lead to high levels of contamination are fairly rare and the actual causes of contamination may also be unique. Assuming that 310 million U.S. consumers eat three meals per day with 3 servings each meal, that means that only about 1 out of every 10,000 servings has a problem (with 76 million illnesses per year). Consumer handling may account for about half of these problems as, for example, cross contamination (cutting vegetables on the same wooden cutting board that was used to cut meat), or improper cooling or heating of foods. The FDA's difficulties trying to regulate an industry that is rapidly growing more complicated is only half of the problem; they also are charged with overseeing a much larger industry and enforcing rules that are all considered to be equally important.

IV. Inspections

Over the last 100 years plus, the FDA has continued to pass rules, some effective at the outset but much less so as time goes on. There are two additional reasons the FDA regulations are not as efficient as they may have been in the past: the large volume of existing rules and the number of entities that must be inspected. The first reason, the large volume of existing rules, affects

⁵⁵Welch, RW and Mitchell, PC, "Food Processing: A century of Change," British Medical Journal, 56(1) 1-17 cited in Floros, John D., et. Al. "Feeding the World Today and Tomorrow: The Importance of Food science and Technology," Comprehensive Reviews, 0 (2010), p. 7.

both the FDA and the regulated firms. It becomes difficult for the FDA or the regulated parties to know which ones are important. The very first OMB Report to Congress identified this problem for all regulations: “Some regulations are critically important (such as safety criteria for airlines or nuclear power plants); some are relatively trivial (such as setting the times that a draw bridge may be raised or lowered). But each has the force and effect of law and each must be taken seriously.”⁵⁶ When there are too many rules, companies tend to either flout the rules or focus exclusively on religiously following the rules to the detriment of focusing on the problems the rules were intended to address.⁵⁷ The FDA could try to prioritize these rules but must deal with Congress who periodically calls the FDA officials to testify why they have not been enforcing their favorite rules, even if old and no longer effective.

While it is important to prioritize rules, the FDA must be able to enforce the rules they choose to enforce and that problem is perhaps the most severe challenge. This problem is strongly similar to trying to sample foods with low contaminations rates. Many scientists and statisticians have argued for years that it is not possible to sample (for statistically rare pathogens) your way to safety as the number of samples that would be needed to detect pathogens is too large to be done with any reasonable number of samples. The problem with enforcement is exactly the same; there are simply too many inspections that would need to be taken to be effective.

For regulations to be effective, firms must believe both that there is a high enough probability that non-compliance will be detected and the penalty for non-compliance is larger than the cost of compliance. There are two possible effects of inspections, actually finding a problem as it occurs and deterring actions (or lack of actions) that might cause a future problem. Table 2 presents an overview of FDA’s regulatory universe suggests both are difficult.

Table 3: The FDA’s Universe

Domestic Food Facilities ¹ (food manufacturing)	136,000 (50,000)
Cosmetics ²	14,000
Restaurants ¹	935,000
Dietary Supplements ³	4,250
Supermarkets, grocery stores and other food ¹	114,000

⁵⁶ Office of Management and Budget, “Report to Congress on the Costs and Benefits of Federal Regulations,” 1997, <http://www.whitehouse.gov/omb/inforeg/chap1.aspx>.

⁵⁷ Andrew Hale, “Railway Safety Management: The Challenge of the New Millennium” (keynote address, Occupational Safety & Health Conference of the Union Internationale des Chemins de Fer, Paris, France, September 1999), 7-8, and Jack N. Barkenbus, “Is Self Regulation Possible?” *Journal of Policy Analysis and Management* 2, no. 4 (1983): 578.

Farms³

Produce (Domestic)¹ 184,000

Egg¹ 96,000

Foreign Firms Exporting to U.S¹ 189,000

¹ FDA Food Protection Plan 2007: An integrated strategy for protecting the nation's food supply
<http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>

² House Committee on Energy and Commerce, Discussion Draft of the "Food and Drug Administration Globalization Act" Legislation: Device and Cosmetic Safety, 110th Cong., 2nd sess., May 14, 2008.

³ Federal Register Interim Final Rule - 72 FR 34959 June 25, 2007: Petition to Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements [Federal Register: June 25, 2007 (Volume 72, Number 121)] [Rules and Regulations] [Page 34959-34969] From the Federal Register Online via GPO Access ais.access.gpo.gov [DOCID:fr25jn07-22]

For all food, cosmetics, and dietary supplement products, the FDA conducted 5,700 inspections, surveillance, or other enforcement activities in 2002. More recently, the Office of Inspector General reported, "FDA identified 51,229 food facilities that were subject to inspection and were in business from the start of FY 2008 until the end of FY 2009. Of these, 56 percent were not inspected at all, 14 percent were inspected a single time and the remaining 30 percent were inspected two or more times."⁵⁸ Suppose the FDA determined that, just for food processors, it needed to inspect once a week to be effective. The number of inspections would have to jump from 5,700 to about 2.5 million. Is it possible that, at the current level of inspections for all of these plants, or any conceivable increase in the number of federal inspections, the FDA is likely to either detect a problem on the spot or generate any realistic level of deterrence?

Beyond the number of facilities, there is the number of regulations to contend with. Until recently, the FDA treated all regulations the same for enforcement priority instead of, for example, being risk-based. Although the FDA has not addressed which of their regulations are most likely to be effective, they have begun to address firm risk. Unfortunately, the FDA's risk-based inspection efforts may not account for a key factor; market relationships including private food-safety contracts between firms and private enforcement inspections to enforce those contracts.⁵⁹

There are at least two reasons why there might be a difference in food risk on an individual firm basis. One is reputation. Although many food safety problems are difficult to tie back to a firm's product because of the lag time between consumption and illness (*listeria*, for example, may have a two-month lag between consumption and an effect on an unborn fetus), the

⁵⁸ Office of Inspector General, DHHS, "FDA Inspections of Domestic Food Facilities," April 2010, OEI-02-08-00080

⁵⁹ Food and Drug Administration, *Managing Food Safety: A Regulator's Manual For Applying HACCP Principles to Risk-based Retail and Food Service Inspections and Evaluating Voluntary Food Safety Management Systems* (2006), chap. 2, <http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Regulators/ucm078169.htm>.

possibility of such a tie could potentially affect a firm in three ways: recall costs, loss of brand reputation, and tort payments to the injured parties. These costs can be substantial. But a more significant reason may be private inspections. As will be discussed later on in this paper, there are millions of private contracts and private inspections of these contracts.

It may be impossible to provide a deterministic probability as to the efficacy of the FDA’s food-safety inspections, either real-time detection or future deterrence, but the evidence so far does not provide much comfort for those who believe that an increase in regulation and inspection by the FDA is a key component to making food safer.

Both theoretically and empirically, it appears that the FDA cannot and has not been effective at reducing food-borne disease. Of course, one can argue that the FDA is underfunded, and that is a perennial plea to Congress. In the mid-1990s there were heightened calls for an initiative to reduce risk from food-borne pathogens. In response, the Clinton administration pushed through a “Food Safety Initiative” which included funding for more regulation and surveillance of food producers and preparers.⁶⁰

Since 1997, the FDA’s food-safety programs have seen an increase in budget from \$191 million a year to nearly \$440 million. FDA food-safety staff swelled from 2,226 in 1997 full time equivalents (FTEs) to a high of 3,167 in 2003 and then back down to 2,774 in 2006. Most of the growth was in field staff and this staff remains 548 persons larger than in 1997 as shown in table 4.

Table 4: Growth of Federal Government Support for Food Safety 1997–2006

Year	Amount (in thousands)	Center FTEs	Field FTEs	Total FTEs
1997	\$191,183	790	1,436	2,226
1998	\$203,830	809	1,409	2,218
1999	\$235,203	811	1,464	2,275
2000	\$279,717	869	1,509	2,378
2001	\$287,504	879	1,566	2,445
2002	\$401,582	907	1,928	2,835
2003	\$406,824	950	2,217	3,167
2004	\$430,220	910	2,172	3,082
2005	\$435,517	884	2,059	2,943
2006	\$438,721	812	1,962	2,774

Data from FDA Budget Reports, Comparable Program Tables, 1999–2008

V. Market Failures

Although we had seen massive expansions of regulations of the economy in Teddy Roosevelt’s progressive era and later on by the New Dealers in the 1930s, it wasn’t until the 1950s that

⁶⁰ House Committee on Government Reform and Oversight, *The Need for FDA Regulatory Reform to Protect the Health and Safety of Americans*, 104th Cong., 1st sess., June 9, 1995.

economists found reasons why these interventions were theoretically justified from an economic standpoint. Francis Bator is credited with developing this theory in 1958.⁶¹ As government regulations were intended to change the underlying market institutions and incentives, Bator reasoned that they must be doing this because markets had “failed.” The original theory was rapidly expanded upon to cover every perceivable undesirable outcome. Recognition of the market-failure theory led President Clinton to require a description of the market failure in regulatory impact analyses that would justify federal intervention into markets.⁶²

If consumers do not know enough about the safety of the food they are buying (i.e., enough so that more knowledge would affect their purchase behavior), then manufacturers will have insufficient incentives to produce safe food, and unsafe food will be overproduced. That is, at least some food-borne illnesses result from failures of the market to incorporate all of the costs of the product into the price of the product. Food safety is termed a so-called “credence attribute,” one cannot ascertain it before it is sold nor necessarily discover it (experience it) after consuming the product.⁶³ Based on this theory, governments may be able to improve markets by directly ensuring that the credence attribute (characteristic) is of some minimal quality.

The existence of food-borne illness is, by itself, not a market failure. A person who chooses to accept increased risk in exchange for a lower price can be operating in a completely rational and efficient manner; assuming the person is aware of the risk she is taking. Evidence shows that consumers both under- and overestimate risks associated with food. For example, consumers overestimate risks associated with pesticides and with seafood (generally) but may underestimate the risk associated with undercooking foods such as ground beef or eggs.⁶⁴

There are potentially two kinds of food-safety information problems: deliberately withholding information from consumers (asymmetric information) and (everyone having) insufficient information. In the latter case for example, while CDC estimates that there are 76 million cases of food-borne illness annually, the majority of these cases are of “unknown” origin.⁶⁵ Of course, if the information is not known by anyone, it is incomplete information but there also may not be any government intervention that is effective (other than requiring production).

The former problem, asymmetric information, occurs when producers have information about safety that consumers would benefit from knowing and would be willing to pay for, but do not have. In this case, producers could theoretically cut costs by having lax safety standards and knowingly deceive consumers about product safety. In fact, it is always the case that producers have more information about their production processes than consumers. If high-quality firms cannot differentiate themselves from low-quality firms, reputation externalities could,

⁶¹Francis M. Bator, “The Anatomy of Market Failure,” *The Quarterly Journal of Economics* 72, no. 3 (1958):351-379.

⁶² President, “Executive Order 12866,” *Federal Register* 58, no. 190 (October 1993),

http://www.whitehouse.gov/omb/inforeg_riaguide/.

⁶³ M.R. Darby and E. Karni, “Free competition and the optimal amount of fraud,” *Journal of Law and Economics*, 16, 67-88.

⁶⁴ See, for example, Fein, S, J Lin, and AS Levy. Food-borne Illness Perceptions, Experience, and Preventive Behaviors. *Journal of Food Protection* 1995;58:1405-1411 and Nancy Kraus, T Malmfors, and Paul Slovic, “Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks,” *Risk Analysis*, 12(2), 1992, pp. 215-232.

⁶⁵ Centers for Disease Control and Prevention, “Foodborne Illness,” 2005, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodborneinfections_g.htm#criticalproblems.

theoretically, lead to adverse selection, where bad firms push out good firms. Whether such a regime develops depends on whether *ex post* incentives exist to force firms to maintain safe practices.

For asymmetric information problem to manifest itself that would warrant intervention, there are two necessary conditions. First, food-safety problems are not traced back to offending firms. In addition, firms have no way to signal quality differences in practices. Second, where information on these problems is available to the market, it is too costly for consumers to obtain (unlike brand names which are readily available).

In the past, both manufacturers and retailers have been somewhat “judgment proof” in that it has been too difficult to tie an outbreak to any particular food or firm. In some cases, the difficulty is still too great as with, for example, *listeria Monocytogenes* that can manifest itself up to 60 days after consumption. But in recent years, enhanced technologies have been employed to tie food firms to problems. First, new technologies such as Pulsed Field Gel Electrophoresis (PFGE) allow scientists to match the DNA fingerprint between an infected individual and any remaining samples from contaminated batches of food.⁶⁶ Pathogens, like all living creatures, have unique DNA patterns that can be mapped and, when the DNA in a contaminated food is matched with a sample from a specific plant, there is no question where the contamination originated.

Helping this technology to be effective, PulseNet is a federal system that keeps fingerprint samples from public-health laboratories (that take them from patients) at the national, state, and local level that can be used to help make these matches from food manufacturing plants.⁶⁷ In addition, tracebacks are becoming increasingly sophisticated with on-line electronic systems and product bar codes. Use of radio frequency identification devices (RFID) that use radio waves to track items with active or passive tags, systems with 2D bar codes and laser etching are all technologies which are being used to facilitate tracebacks.⁶⁸ Finally, there is FoodNet which is an active surveillance program that collects data on illnesses from food-related pathogens in selected states and can be useful in uncovering root causes of food-safety problems.⁶⁹ Although food-safety outbreaks are never likely to be tied 100 percent to the offending party, it is only necessary that the probability of being detected is high enough to provide firms with sufficient incentives to utilize proper care in their facilities. Once identified, it is not just government that works to identify offending firms; there has been a fairly dramatic increase in third-party suppliers of this information.

One of the first third-party information suppliers was Harvey Wiley. He realized after he got out of government that government oversight wasn't going to be sufficient to solve all food-safety problems. He realized that markets could solve “market failures” before anyone had thought of the concept of market failure. So after leaving government, he went to work for *Good*

⁶⁶ <http://www.cdc.gov/pulsenet/whatis.htm#limitations>

⁶⁷ <http://www.cdc.gov/pulsenet/>

⁶⁸ Jennifer C. McEntire et al., “Traceability (Product Tracing) in Food Systems: An IFT Report Submitted to the FDA, Volume 1: Technical Aspects and Recommendations,” *Comprehensive Reviews in Food Science and Food Safety* 9 (2010): 112-115.

⁶⁹ <http://www.cdc.gov/foodnet/>

Housekeeping magazine and continued his work exposing poor food-safety practices.⁷⁰ What *Good Housekeeping* began in 1900 has continued on today.⁷¹ There are many, many sources of food safety information on the web today as shown in box 1.

Given that technology and third-party suppliers are now making it increasingly likely that firms can be and are tied to food-safety problems, the second issue is whether the information is accessible to consumers at a low enough cost. One source of information that has always been available to consumers is brand names. More recently the advent of the web and the internet has greatly reduced the cost of supplying this information in the last decade. It is likely that, any problem for a food manufacturer or retailer now is likely to be the subject to publicity more than ever before. As Moorhouse says, “if a lack of information is a major justification for government consumer protection, the case for government intervention may be seriously weakened by the dramatic increase in the availability of consumer information on the Internet. This technology makes low-cost, up-to-date information readily available to consumers.”⁷² He also says that “Internet technology has shifted the margin of effectiveness between private and public sources of consumer information. The Internet provides up-to-date consumer information about an incredible array of goods and services at very low cost.”⁷³

For example, the internet has made finding out about recalled products even easier and more up-to-date. On the US Recall News website, there is a page listing each of the brands and their products that are being recalled.⁷⁴ The site has Really Simple Syndication (RSS) that allows a person to subscribe to a newsfeed that updates whenever news about recalls emerges. Interestingly, a check on October 8, 2010 listed advertisements for salmonella-free eggs and for personal injury lawyers.⁷⁵ A “widget” allow individuals to embed these feeds into their own homepage. Alternatively, one can subscribe to the site’s email news service.

An Amazon.com search (1/29/09) for “food” in “magazines” gave 264 results. Some of the top hits included consumer publications such as *Food Network Magazine* and *Everyday Food*, as well as industry publications such as *Food Manufacturing*.

Table 5 shows the number of stories that contained the one or more of the following search terms in Google News. These numbers demonstrate that there is an active effort by the media to alert consumers to food-safety issues.

⁷⁰ Good Housekeeping, “The Original Man of the House,” <http://www.goodhousekeeping.com/product-testing/history/about-harvey-wiley> (accessed June 8, 2010).

⁷¹ Good Housekeeping, “The History of the Good Housekeeping Research Institute,” <http://www.goodhousekeeping.com/product-testing/history/good-housekeeping-research-institute-history> (accessed June 8, 2010).

⁷² John C. Moorhouse, “Consumer Protection Regulation and Information on the Internet,” in *The Half-Life of Policy Rationales*, ed. Fred E. Foldvary and Daniel B. Klein (New York, NY: New York University Press, 2003), 126.

⁷³ *Ibid.*, 136

⁷⁴ <http://www.usrecallnews.com/section/recalled-food>

⁷⁵ [http:IBID](http://IBID).

Table 5: Food Safety Terms in News Stories

Year	“foodborne”	“food borne”	“food safety”	“food recall”
2008	1,410	8,430	84,700	18,200
2007	1,900	8,200	88,700	21,500
2006	1,650	7,150	80,100	13,000
2005	1,660	7,450	81,000	11,600
2004	1,410	6,840	68,800	11,000
2003	1,250	6,020	57,300	10,500
2002	1,060	4,930	46,100	8,050

These numbers are from Google News on 1/29/2009.

The result of both government and third parties being able to link firms to food-safety problems and publishing that information at very low cost is that firms are now held accountable by markets through sales and recall costs as well as by legal action for their food-safety practices.

Given that the probability of being tied *ex post* to a food-safety problem is rising, it is also necessary that firms have a way to signal differentiation of their food-safety practices. It is neither necessary nor desirable that food manufacturing firms signal consumers about safety practices other than through their branding. The cost to consumers of having to absorb this information would simply be prohibitive and is not necessary to inform their food choices. In fact, food manufacturing firms primarily distinguish their food safety practices to buyers, including upstream buyers and retailers (and insurers) who are in a position to monitor them.

With firms being tied to food-safety problems *ex post*, being able to signal their differences to producers, and food-safety information that is readily available at low cost to consumers, what were once market failures have now turned into market opportunities. In their paper on internet markets, Boettke and Steckbeck argue that information asymmetries create profit opportunities: “Akerlof’s lemons model suggests the fragility of market arrangement in the face of informational asymmetries and thus the problems identified should be prevalent in . . . markets. But as we have shown, the apparent problems in these markets today are simply tomorrow’s profit opportunities as actors possess strong pecuniary incentives to adjust their behavior to ameliorate these problems and realize the gains from exchange.”⁷⁶ The authors cite the growth in e-commerce as an example. In this instance, every product purchased is an “experience good” meaning that its quality can be assessed only after purchase. Yet the number of disappointed purchases has become vanishingly small and this market has boomed.

⁷⁶Mark Steckbeck and Peter Boettke, “Turning Lemons Into Lemonade,” in *Markets, Information and Communication*, ed. Jack Birner and Pierre Garrouste (New York, NY: Routledge, 2004), 221.

Box 1: Examples of Private Food-Safety Organizations

Partnership for Food Safety Education
Consumer Federation of America

International Association for Food
Protection(

Food Allergy and Anaphylaxis Network

Institute of Food Technologists

Food Safety Magazine

Center for Science in the Public Interest

Safe Tables Our Priority

The Center for Food Safety

As the world has changed around the FDA and market failures are seen to be fading because of private market activities, the FDA and other observers have attempted to chart out a more ambitious case for food safety regulation. Unfortunately, the “modern” approach is just more of the same type of activity.

VI. The “Modern” Approach

The FDA has offered its vision for the future of food safety in its “Food Protection Plan: An integrated strategy for protecting the nation’s food supply;” a plan issued under the Bush administration.⁷⁷ This plan was composed of three core elements: prevention, intervention, and response. Central to the plan was an attempt to address the GAO’s criticism of the lack of coordination between federal, state, and industry partners. Such coordination, coupled with risk-based inspections, will, it is assumed, allows the FDA to operate effectively without having full responsibility for all enforcement activities. A similar but more elaborate version than FDA’s plan is offered in a report entitled, “Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local roles in the Nation’s Food Safety System” (hereafter referred to as “Partnerships”).⁷⁸ Both of these documents suggest that a greater role in food safety is necessary at all government levels, with a primary emphasis on the central role of the federal government. The new vision, put forward in the aforementioned reports, is that government regulation and inspection can achieve safer food only if there is greater integration of efforts across all levels of

⁷⁷ U.S. Food and Drug Administration, *Food Protection Plan 2007* (2007),

<http://www.fda.gov/food/foodsafety/foodsafetyprograms/foodprotectionplan2007/default.htm>.

⁷⁸ Michael R. Taylor and Stephanie David, “Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation’s Food Safety System,” (report, George Washington University, Washington, DC, 2009), <http://www.scribd.com/doc/14519426/Stronger-Partnerships-for-Safer-Food-Report-by-Michael-R-Taylor-and-Stephanie-D-David>.

government and industry. Recently, this kind of system has been given a name, “regulatory capitalism.”

Regulatory capitalism is a name given to a vision of capitalism that explicitly incorporates an expanding role of government as a regulator of markets that grows along with the size and complexity of the market. It defines a new role for government as a regulator of private production rather than one that produces goods (socialism or state capitalism).⁷⁹ One definition of regulatory capitalism is “a political, economic, and social order where regulation, rather than direct provision of public and private services, is the expanding part of government.”⁸⁰ It is a view of regulation in which, everyone regulates everyone else at all levels of society.⁸¹ This view of comprehensive regulation includes industry as partner regulators where, for example, upstream firms inspect supplier firms using regulations derived from government (and reported up to government). Of course, the incentives to provide government with this information are never made clear. In fact, there is probably a strong incentive not to provide this information if private firms view risks in a neutral way as opposed to a government view that is more “precautionary.” Others, such as non-governmental organization, may also play a role in enforcing rules. Finally, there is a role for enforcement within the firm from workers who wish to blow the whistle on firm violations. This view of networked governance goes further, and suggests that there is a need for international networking of rules. However, for national rules, there is no question where the role of ultimate power should reside, at the federal level. The justification for this, apparently, is that the federal government can supply meta-government and has superior democratic accountability.⁸²

This vision of an expanded regulatory state is advanced in the previously cited report on partnerships.⁸³ While acknowledging the role that state and local governments must play in food safety, the organizing principle again is to bring all state and local agencies involved in food safety under federal control. It states that “policy makers are now realizing that federal agencies sit at the *top of a much larger pyramid of state and local agencies* working on food safety.”⁸⁴ Specifically, it recommends “a strengthened federal leadership role on food safety (that) must empower state and local agencies.” It is interesting from a federalist perspective that the document assumes that state and local agencies must be *empowered* in order to do their job by the federal government not to mentioned that *strengthened federal leadership* will shift power from the states to the federal government. In order for this vision to be accomplished the report recommends, for example:

- Establishment of an inter-governmental Food Safety Leadership Council chaired by the Secretary of the federal Department of Health and Human Services (DHHS).

⁷⁹ Iam Bremmer, *The End of the Free Market: Who Wins the War between States and Corporations*, 2010.

⁸⁰ David Levi-Faur, foreword to *Regulatory Capitalism: How It Works, Ideas for Making It Work Better*, by John Braithwaite (Cheltenham, UK: Edward Elgar, 2008), viii.

⁸¹ Levi-Faur, 11.

⁸² Levi-Faur, 205.

⁸³ Taylor and David, “Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation’s Food Safety System.”

⁸⁴ *Ibid.*, 6.

- A five-year plan by to integrate federal, state, and local food-safety efforts.
- Federal funding of state and local agencies (line item in FDA’s budgets).
- State and local funding that is consistent with “agreed criteria and benchmarks for food safety capacity and performance.”⁸⁵
- A federally established leadership and training institute (with the above-mentioned council as a “partner).”
- A network of federally funded food-borne outbreak response centers.
- Congressionally mandated traceability requirements.

A review of the plan suggests coordination only so far as it fits within the FDA’s traditional view of food safety. For example, the plan suggests new direct controls, supplementation of FDA inspections with state and third-party inspections, and authority to issue mandatory recalls. Little in the plan references using government to enhance the ability of the market or the legal system to deter unsafe practices.

The proponents of regulatory capitalism note that we live in an information economy and that “an information economy cannot be centrally planned; it can only be centrally facilitated and coordinated.”⁸⁶ While coordination of regulations that are enforced by different levels of government and private actors may reduce costs for firms who are responding to multiple sets of rules, a more important question is whether this kind of massive coordination of efforts will actually achieve the stated goal of making food safer. In fact, this kind of coordination is both costly and it may actually crowd out expenditures that are dedicated to finding solutions to food safety problems. Whether or not there is a link between firms who are not in complete compliance with the thousands and thousands of federal food-safety rules and food-safety problems has not been demonstrated. It is therefore unclear whether coordination to ensure compliance will actually lead to anything other than more firms being in greater compliance with more federal rules.

As noted earlier, studies in numerous fields document the adverse effects from having too many rules.⁸⁷ Hale examines the general approach of adding more and more rules and finds:

The second line of defense in many systems, if the human could not be eliminated, has been to try to turn the human into a robot by specifying rules and imposing them rigidly. The railway industry has been one of the main protagonists of this approach, alongside the nuclear, and to lesser extent, the chemical industries. Accidents were then analyzed up to the point where it became clear that someone had broken a rule (at which point discipline was appropriate) or that there was no rule for this eventuality (in which case a new one was made). In this way rulebooks continually grew and never diminished. This rules-fix is also a hankering after certainty. Ultimately we get a rule for everything and safety is seen as something which requires no thinking any longer,

⁸⁵ Taylor and David, “Stronger Partnerships for Safer Food: An Agenda for Strengthening State and Local Roles in the Nation’s Food Safety System,” 44.

⁸⁶ Braithwaite, *Regulatory Capitalism: How it Works, Ideas for Making it Work Better*, 4.

⁸⁷ Richard Williams, *Federal Rulemaking and the Regulatory Process*, House Judiciary Committee, 111th Cong., 2nd sess., July 27, 2010.

but simply good training, a prodigious memory, a large safety manual or computer to refer to, and an iron discipline. Management does not need to do any more thinking or planning, because it is all fixed in the rule system. Reason (1990, 1997), among others has shown clearly how this approach ossifies an organization and forces its staff into being habitual and professional violators of rules, just to get their work done.⁸⁸

Coordination to either enforce the large number of existing rules or an increase of more top-down rules is unlikely to produce safer food. Overall, these two plans, while ambitious, are going in the wrong, which is to say the same, direction.

In sum, there are a number of reasons to believe that pursuing more coordination and more regulation and inspection is unlikely to produce safer food. These reasons include:

- 1) As the food industry has grown more complex, solutions are more likely to be specific to firms or subsectors making national regulation less applicable. The diversity of processing, packaging and sale of foods is harder to make “one-size-fits-all” regulation that is effective.
- 2) As the institutions surrounding the FDA, and the FDA itself, have become entrenched in rent seeking reward informal rules and relationships (including “Bootlegger and Baptist” situations), regulations will continue to benefit the few rather than solving social problems. This is evidence by two of the larger regulations that the FDA promulgated in the later part of the 20th century (Seafood HACCP and Dietary Supplement GMPs).
- 3) Mandating solutions that don’t work creates an opportunity cost for firms if expenditures to comply with federal rules crowds out their own research and development.
- 4) With so many rules now in existence, it is difficult to prioritize them and firms end up focusing on the rules, either to avoid or follow rote-like and lose the ability to manage new situations.
- 5) The FDA no longer has the ability to inspect the numerous facilities for which it has oversight and no realistic increase in funds is likely to make it realistic. As mentioned earlier, if, for inspections to be efficient, food firms needed to be inspected once a week, FDA would have to increase the number of inspections from 5,700 to about 2.5 million.⁸⁹

VII. Market Food Safety

Predictably, as food-safety problems have been increasingly tied to individual companies leading to higher probabilities of recalls and tort actions, institution of private standards and inspections

⁸⁸ Andrew Hale, “Railway Safety Management: The Challenge of the New Millennium” (keynote address, Occupational Safety & Health Conference of the Union Internationale des Chemins de Fer, Paris, France, September 1999), 7-8.

⁸⁹ With about 50,000 food manufacturing firms, the number of inspections would be $50,000 \times 52 = 2.6$ million.

have replaced and exceeded government rules and inspections. Referring back to the quote at the beginning of the paper from President Obama that, only the government can “ensur(e) that the foods we eat are safe and don’t cause us harm” is most likely not the case. Given the political problems associated with regulations and the ineffectiveness of inspections, it is likely that the reason that food is as safe as it is has more to do with private than government efforts. In fact, there are likely many millions more inspections of food plants in the private sector than are done by the FDA or even the combination of federal, state, and local governments. Perhaps the majority are done by upstream buyers.⁹⁰ Manufactured foods that are complex products involve buying ingredients from multiple firms, and it is likely that most of these upstream manufacturers have their own inspection programs for ingredient manufacturers.

In a groundbreaking discussion of these types of standards, primarily for European countries, Henson and Humphrey found that “four drivers combine to create an environment in which businesses are under more pressure to deliver food safety and to maintain the integrity of their brands . . . in the face of increasingly globalised and complex food supply chains that cut across multiple regulatory jurisdictions.”⁹¹ These private controls are driven by food risks, heightened interest by consumers and businesses, globalization of the food supply, and the fact that “responsibility for ensuring food safety has been devolved from the state towards the private sector.”⁹² The paper highlights various benefits of private standards:

1. They can and do respond much more quickly to address new issues.
2. They are often more stringent or more extensive about the outcome to be achieved than public standards.
3. They may increase the scope of coverage, vertically or horizontally.
4. They provide businesses with claims for differentiation, particularly claims about “credence”⁹³ goods.
5. Private standards “package” multiple international and national standards and guidance and fill in the voids.
6. Market forces make (private) standards *de facto* mandatory and there are both second and third party monitoring and enforcement.
7. Private standards provide “clear instructions as to how rules are to be implemented, monitored, and enforced.”

⁹⁰ A study of HACCP adoption in the United Kingdom found that while “meeting legal requirements” was the most important factor for the average company, HACCP adoption was driven almost as strongly by upstream buyers, and desire for internal controls on production quality and wastage. Spencer Henson and John Humphrey, “The Impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Processes,” *Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, 32nd sess.*, (Rome, Italy: 2009).

⁹¹Henson and Holt 2000) p. iv.

⁹² Henson and Humphrey, “The Impacts of Private Food Safety Standards on the Food Chain and on Public Standard-Setting Processes,” iv.

⁹³ Credence attributes are attributes which cannot be detected before or after consumption by consumers.

8. They include traceability provisions.⁹⁴

In addition to manufacturers inspecting their suppliers, some supermarkets also perform inspections for certain kinds of products, e.g., seafood. Supermarkets have consolidated in recent years giving them “significant leverage to bargain . . . for . . . safety standards.”⁹⁵ Besides supermarkets, many insurance companies have food-inspection programs that they do as part of establishing eligibility and rates for food-plant insurance. Finally, there are food-safety audits where firms inspect themselves. A food-safety audit is an audit by a third party at the request of the firm itself. It is a planned, independent, and documented assessment to determine whether agreed upon requirements are being met. Audits are conducted against standards, whether set by government or private organizations. These standards could include government regulations, private rules, and general auditing standards such as those found in the ASQ Auditing Handbook. An example of this is the “Servsafe” program for restaurant managers.⁹⁶ For other retail operations, there is “Supersafemark” owned by the Food Marketing Institute.⁹⁷ This program also trains food-safety managers.

The rise of private standards and enforcement is finally forcing some government institutions to notice. Given the institutional monopoly that government food-safety agencies enjoy, it is not surprising that they will not relinquish this power easily. For example, “Within Codex, significant anxiety has been expressed that the rapid pervasion of private food safety standards is serving to undermine the Commission’s role.”⁹⁸

VIII. Recommendations for a New Role for FDA

The FDA is an antiquated organization by the type of standard that is emerging in the 21st century. First, the evidence shows that the structure of corporate America is changing.⁹⁹ In traditional firms such as IBM, Sun, and GE and newer firms like Ebay and eClass229, corporations are decentralizing.¹⁰⁰ Instead of top-down management picking winners and making large investments based on their expertise, corporations are increasingly turning to structures that allow for smaller investments in creativity knowing that it is becoming increasingly difficult for a small group at the top to choose which investments are likely to pay

⁹⁴ Ibid.

⁹⁵ Institute of Medicine, “Enhancing Food Safety, the Role of the Food and Drug Administration” (Washington, DC: National Academies P, 2010) p. 2-2.

⁹⁶ <http://www.servsafe.com/foodsafety/>

⁹⁷ http://www.fmi.org/forms/store/ProductFormPublic/search?action=1&Product_productNumber=2245

⁹⁸ Henson and Humphrey, p. 1. The Codex Alimentarius (or food code) Commission is an international organization created in the 1960’s by the World Health Organization to create international food safety standards, among other things.

⁹⁹ Alan Murray, “The End of Management,” *Wall Street Journal*, August 21, 2010, http://online.wsj.com/article/SB10001424052748704476104575439723695579664.html?mod=WSJ_hp_mostpop_read.

¹⁰⁰ Ori Brafman and Rod A. Beckstrom, *The Starfish and the Spider: The Unstoppable Power of Leaderless Organizations*, Penguin Books, Ltd., London, England, 2006.

off. Instead, they make many smaller investments and wait to see which ones will work and that the market will adopt.¹⁰¹

In many cases, new small firms are emerging to stay as small firms rather than the traditional model of growing into large monoliths. In the economic theory of the 20th century, firms were created to lower the transactions costs of organizing resources for production. However, the web has greatly decreased the costs of organizing and contracting so that it becomes less and less necessary to organize as a firm in order to cooperatively produce.¹⁰² In the U.S. today, about three-quarters of all private firms have less than one employee.¹⁰³

A rigidly controlled with a vertical management structure is an odd fit for a scientific organization. In particular, health, safety, and environmental bureaucracies differ fundamentally from so-called economic agencies, they are about science. One on-line journal about the nature of sciences describes science this way:

Science is a process for producing knowledge. The process depends both on making careful observations of phenomena and on inventing theories for making sense out of those observations. Change in knowledge is inevitable because new observations may challenge prevailing theories. No matter how well one theory explains a set of observations, it is possible that another theory may fit just as well or better, or may fit a still wider range of observations. In science, the testing and improving and occasional discarding of theories, whether new or old, go on all the time. Scientists assume that even if there is no way to secure complete and absolute truth, increasingly accurate approximations can be made to account for the world and how it works.¹⁰⁴

Scientists are by their nature inventors and innovators who are constantly seeking to improve on yesterday's theories. In the FDA, however scientists are made fully aware that they are bureaucrats and success and advancement can be threatened for the individual scientist who challenges existing policies. Simply put, new ideas are not encouraged. Many writers have insisted that bureaucracies will always devolve into such rigid structures¹⁰⁵ In the FDA's case, that has certainly proved true. One question is whether or not it is possible for the FDA to change, whether the FDA can move to an organization that is more decentralized and entrepreneurial in spirit.

One thing holding the FDA back in the food-safety arena is that it tries to accomplish its mission, creating safer food, by regulation and inspection, which requires that it have policies. Beyond all

¹⁰¹ Murray, "The End of Management."

¹⁰² Clay Shirky, *Here Comes Everybody: The Power of Organizing Without Organizations* (New York, NY: Penguin Press, 2008).

¹⁰³ Federal Reserve Bank of Minneapolis, "Nonemployer Firms as a Percent of Total Firms, 2004," *Fedgazette*, http://www.minneapolisfed.org/publications_papers/fedgazette/ (accessed June 8, 2010).

¹⁰⁴ American Association for the Advancement of Science, "Chapter 1: The Nature of Science," *Science for All Americans Online*, <http://www.project2061.org/publications/sfaa/online/chap1.htm?txtRef=&txtURIOld=/tools/sfaaol/chap1.htm> (accessed June 8, 2010).

¹⁰⁵ See Ludwig von Mises, *Bureaucracy* (New Haven: Yale UP, 1944), or James Q. Wilson, *Bureaucracy: What Government Agencies Do and Why They Do It* (New York: Basic Books, 1989).

of the theoretical and empirical problems that were previously discussed, the FDA will always have difficulty becoming a more innovative organization if it continues to stick with this 100 year old strategy. In regulation it is important to stay with precedent, both because of the organizational culture and because repetition is more likely to succeed in courts. Government attorneys, who have become increasingly powerful at the FDA and its parent agency, the Department of Health and Human Services, understand that for the FDA to maintain any kind of deference in courts, it must continue to have a strong winning percentage. This means building carefully on precedents (this also helps the personal careers of these attorneys). But this type of strategy is the antithesis of a decentralized, innovative organization.

A move away from regulation and inspection for the FDA to help solve food-safety problems would allow the FDA to free its scientists from frozen policies to one in which they are empowered to find new solutions. Thus, rather than continually etching policies in stone for its scientists and regulated industry, the FDA should:

1) Decentralize and empower scientists to innovate for food-safety solutions. With such a radical change in bureaucratic philosophy, the FDA could move toward being a highly flexible, horizontal organization that focuses on problem solving rather than policy dictation. Not just internally, the FDA could become a sponsor of prizes for solutions to food-safety problems.

That is, for a relatively small part of its budget, the FDA could create incentives for anyone to come up with solutions that could then release those solutions as public information. An example of this is given by the XPrize Foundation.¹⁰⁶ On its website, the foundation describes itself as an “educational nonprofit organization whose mission is to create radical breakthroughs for the benefit of humanity.”¹⁰⁷ The FDA could set the terms and describe the particular issue that needs to be solved. Alternatively, or in addition, the FDA could host a wiki, not unlike Wikipedia or TaxAlmanac.org, that allows everyone to contribute to solutions.¹⁰⁸ This would allow many solutions to emerge for heterogeneous problems, rather than homogeneous regulations which becoming obsolete.

For the FDA to be a contributor to scientific discovery, it would have to open its culture to encourage scientists to be entrepreneurial. Currently, scientists at the FDA are discouraged from investigating controversial subjects, like genetically modified foods, by insisting that any research go through multiple levels of review by policy officials. Yet these are the areas where there is most uncertainty and where there can be the most benefit from innovative research. By relieving scientists of having to maintain the regulatory policy line, they would be free to exchange ideas with external scientists. In this type of organization, all policies would be considered “organic” and ready to change as science evolved. The FDA’s primary mission then becomes assembling multiple scientific disciplines to discover new solutions through research, laboratory, field work, risk analysis, and economic analysis. It would become a contributor to food-safety solutions, not a dictator.

¹⁰⁶ <http://www.xprize.org/>

¹⁰⁷ IBID.

¹⁰⁸ Ori Brafman, p. 171.

In a sense, the FDA could actually become a more important entity in food safety because it has a unique blend of social and physical scientists whose only mission would be advancement of the science and discovery of food-safety solutions and it could attract some of the best scientists. The FDA would be seen as a place where they would be free to explore their science and make real-world policy differences in real time.

If the FDA turned its focus away from rulemaking and toward information provision, this immediately eliminates a social loss that also tends to lock policies in place to protect incumbents—rent seeking. As discussed earlier, firms are constantly investing in lobbying the FDA to create rules that help them and hurt their competitors, either to gain additional rules to disadvantage competitors or to protect those already in place. Incumbent firms have a large investment in the regulatory status quo and are willing to expend resources to ensure that the status quo is maintained. This at least a partial explanation for why the food industry routinely lobbies for more resources for the FDA. Of course, food-industry sectors also gain by having FDA keep out obviously poor actors who turn sales away from all foods within a category, e.g., spinach when there are highly publicized recalls.¹⁰⁹

A radical change like this in the FDA almost certainly would require statutory leadership from Congress and would have to be implemented by an executive strongly attached to the principle of the idea. For one thing, it would imply that changes would need to be made to the traditional GS system of performance and pay which rewards people primarily for longevity. An alternative system would reward scientists, indeed all employees, by the amount to which they add value relative to what they are paid for accomplishing goals. Bonuses would not be based on individual annual salaries or positions in the bureaucratic structure but by whether they exceeded expectations in adding value.

One additional implication is that the FDA cannot be a “safe” place to work in which, as long as you follow orders and do the minimum, you continue to advance. One key role for FDA management would be to continually evaluate contributions and be free to release (fire) those that are not creating value equal to or in excess of their salary. Risk taking would become part of the culture as authority and responsibility is located in the lowest possible level. If such a change in organization could be achieved, the FDA would be well positioned to help make advances in food safety rapidly by publicly announcing solutions that could be quickly adopted, where useful, by food industry participants. This is the second suggestion for a new FDA.

2) The FDA should seek solutions that enhance private-market food-safety contracts.

It should be obvious by now that food is as safe as it is primarily because of private-market contracts and private inspections. Food safety is and must be an integral part of the contract between food sellers and consumers. As firms become more accountable for problems with enhanced tracebacks and widespread consumer information, food safety becomes a competitive margin so that it is now unprofitable not to adopt workable solutions. The FDA can help by discovering food safety root causes and posting them on the web. Certainly one way to do this is to expand FoodNet to help identify sources of problems and expand PulseNet to help tie

¹⁰⁹ Jane Zhang, “Food Makers Get Appetite for Regulation,” Wall Street Journal, September 17, 2007. <http://www.mindfully.org/Industry/2007/GMA-Like-Regulation17sep07.htm>

problems to specific firms. With better traceback institutions, litigation will also be enhanced that also provides strong incentives to adopt food-safety innovations.¹¹⁰ FDA can serve as a host to food-safety solutions from around the world that can be posted and used by any food firms. These kinds of solutions can be rapidly adopted and just as quickly modified or replaced, unlike regulations which take years to put into place and are rarely changed. The most effective kinds of food-safety solutions may come from entirely new technologies; this leads to the third suggestion:

3) The FDA should invest more in quickly approving new technologies and engage in better risk-communication techniques to help that technology to be accepted.

Just as it was at the turn of the 20th century with the discovery of pasteurization, most gains in food safety will come from better technology. This will not happen automatically, particularly if we utilize the “precautionary principle” with respect to new technologies.¹¹¹ The failure of irradiation to take hold, despite the fact that it would likely to have prevented hundreds of thousands of cases of food-borne illness, is well documented. In 1986, a large percentage of the population had not heard of irradiation although, as Sharlin notes, “a common reaction to a new technology is caution or fear.”¹¹² This common reaction was amplified by a small vocal group of citizen organizations who tied food irradiation to nuclear power and nuclear weapons. “It conjured up visions of Hiroshima and Three Mile Island.”¹¹³ But Sharlin found that “FDA scientists were firm in their conviction that the overwhelming mass of research data left no doubt that irradiation of food was safe and wholesome at the approved dose level.”¹¹⁴ Armed with such a conviction, the FDA could have played a much more active role in promoting this technology.

There are two new technologies holding tremendous promise for both food safety and nutrition: biotechnology and nanotechnology. But, as Marchant puts it, “the exotic nature of these emerging technologies, media sensationalism, and activist campaigns create “risk cascades” that sensationalize and amplify the risk of some technologies to the point of stigmatization.¹¹⁵ The precautionary approach to use of these technologies is to insist on a standard this is logically impossible to attain, proof of 100 percent safety. A better standard would be one that compares the risks of having the technology to the risk of not having it.¹¹⁶ Fortunately, there is time to improve the situation, at least with nanotechnology. Cobb and Macoubrie found that “Americans initial reaction to nanotechnology is thus far generally positive, probably rooted in a

¹¹⁰ Although well beyond this paper, more trace back capabilities does seem to imply a necessary legal change. Because some food safety problems are always going to be with us (as pathogens are ubiquitous) and there will always be unique and unpredictable issues, this argues for a “reasonable” or “prudent” man test in law.

¹¹¹ The precautionary principle has multiple meanings but it “generally is regarded as implementing the concept of ‘better safe than sorry’ by requiring proponents of a technology to demonstrate its safety before it can be marketed.” Marchant, p. 9.

¹¹² Sharlin, Harold I, Irradiation of Foods, “Prototype study in conveying health risk issues,” 20 Jun 3 1986.

¹¹³ Sharlin, p.4.

¹¹⁴ Sharlin, p.8.

¹¹⁵ Gary E Marchant, “Lessons for New Technologies” in 21st Century Regulation, Discovering Better Solutions for Enduring Problems, Mercatus Center at George Mason University, January, 2009.
http://mercatus.org/sites/default/files/publication/21st_Century_Regulation.pdf

¹¹⁶ Richard Williams et. al. “Risk Characterization of Nanotechnology” forthcoming in Risk Analysis.

generally positive view of science overall. Their most preferred benefit of nanotechnology is “new and better ways to detect and treat human diseases and they identified losing personal privacy to tiny surveillance devices as the most important potential risk to avoid.”¹¹⁷ There are also potential nanotechnology breakthroughs in food packaging which can alert consumers to spoilage on labels.

There has been at least 30 years of research into risk communication that can be used to inform the FDA how to more actively advance its scientific understanding of new technologies in a way that will help with consumer acceptance.¹¹⁸

In short, the FDA needs to apply more resources and develop better procedures to both speed up approval of new technologies and to engage in modern risk-communication techniques that help these technologies gain rapid acceptance. Finally, the last suggestion, the FDA should not entirely cease its activities as a “food cop.”

4) The FDA should devote its regulatory and inspection regime entirely to “bad actors—those firms who are outside of private contracts and who are perpetual violators. Some of the FDA’s recent efforts to focus on risk-based inspections are headed in the right direction.

There are basic food-safety principles including sanitation and good manufacturing practices that form the basis of any food-manufacturing operation. This applies equally to retail, warehousing, and distribution. The FDA should focus its resources on identifying the most obvious violators of these basic principles who are largely outside of private contracts and private inspection. Clearly, the salmonella outbreak in 2009 associated with the Peanut Corporation of America seems to fit this category. This outbreak sickened 714 people in 46 states and Canada and resulted in 9 deaths. Going all the way back to the problems at the turn of the last century, investigators found dead rodents and rodent excrement in the plant.¹¹⁹ It appears that the firm knowingly shipped contaminated product.¹²⁰ This can be done with better agreements between state and local authorities to divide jurisdictions so that there is no overlap. The FDA should continue to improve its Food Code as well.¹²¹

The Association of Food and Drug Officials (AFDO) reported that states performed 2.3 million inspections and 46,000 investigations of different kinds of food plants in 2003.¹²² Some states utilize the FDA’s Food Code but not all. AFDO reported that in June 2005, 48 of 56 states and

¹¹⁷ Michael Cobb and Jane Macoubrie, “Public Perceptions about nanotechnology: Risks, benefits and trust,” *Journal of Nanoparticle Research* 6, no. 4 (2004): 395.

¹¹⁸ See, for example, Dorothy E. Patton, “The NAS Risk Paradigm as a Medium for Communication” *Risk Analysis*, 14(3) June 1994, pp. 375-378.

¹¹⁹ Bottemiller, Helena, “PCA Exec Back to Work Despite Investigation, Food Safety News, September 09, 2010. <http://www.foodsafetynews.com/2010/09/peanut-exec-under-criminal-investigation-is-back-to-work/> This article cites a CNN.com article (Dead rodents, excrement in peanut processor lead to recall, Feb. 12, 2009).

¹²⁰ Mallove, Zach, “Questions Linger in PCA Salmonella Case,” *Food Safety News*, February 02, 2010. <http://www.foodsafetynews.com/2010/02/questions-linger-in-pca-salmonella-case/>

¹²¹ FDA’s Food Code is a model for retail and food services (e.g., restaurants, grocery stores and nursing homes) designed to assist all levels of government.

<http://www.fda.gov/food/foodsafety/retailfoodprotection/foodcode/default.htm>

¹²² Association of Food and Drug Officials, “AFDO State Food Safety Resource Survey,” <http://www.afdo.org/resources/stateresourcesurvey.cfm#>.

territories have adopted food codes patterned after one of the five versions of the (FDA) Food Code, beginning with the 1993 edition. Those 48 states and territories represent 79 percent of the U.S. population.”¹²³

To determine which bad actors that should be the target of FDA’s inspectional resources, several principles that could be used:

- 1) The violations are serious, that is, lead to human health harms.
- 2) The firms are not inspected at the state or local level.
- 3) The firms do not sell to upstream manufacturers or retailers (or are inspected by insurance agents) who have food safety contracts with them.

Conclusion

If the FDA is to survive and stay effective, it must move reinvent itself as a modern organization, perhaps a new kind of bureaucracy. It must go back to its original focus on science and integrate itself into new market organizations and food safety challenges in a much more innovative way. In some ways, the FDA is holding on to the past to solve the problems of the early part of the last century; somewhat like Minister of War Sukhomlinov characterized in *The Guns of August*:

As war was, so it has remained...all these things are merely vicious innovations. Look at me, for instance; I have not read a military manual for the last twenty-five years.” In 1913 he dismissed five instructors of the College who persisted in preaching the vicious heresy of “fire tactics.”¹²⁴

It will certainly not help the FDA to continue to do more of the same things, regulate, and inspect and try and organize all public and private entities to fall under its jurisdiction in a world of top-down management. The lack of progress in food safety of the last quarter of the 20th century and the beginnings of this century are evidence of that. Unfortunately, there is no evidence to date that a bureaucracy can radically change and become problems solvers, but to do anything else will be a waste of valuable resources.

¹²³ U.S. Food and Drug Administration, “FDA Food Code,”

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/default.htm>.

¹²⁴ Barbara W. Tuchman, *The Guns of August*, Large Print ed. (New York, NY: Macmillan, 1962), 22.