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High Crimes Not Misdemeanors: Detering the Production of Unsafe Food

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## **HIGH CRIMES, NOT MISDEMEANORS: DETERRING THE PRODUCTION OF UNSAFE FOOD**

By Rena Steinzor<sup>1</sup>

*ABSTRACT: In the fall of 2008, Minnesota public health officials became alarmed by an unusually high number of illnesses and deaths caused by salmonella poisoning. Federal and state regulators and the news media eventually traced the outbreak back to products supplied by the Peanut Corporation of America (PCA). Employees shipped batches that tested positive for salmonella from a plant with a leaking roof, mold growing on ceilings and walls, rodent infestation, filthy processing receptacles, and feathers and feces in the air filtration system. Under an agreement with the Food and Drug Administration (FDA), Georgia state inspectors visited the PCA plant nine times in 2006-2008 but took no effective action to terminate any of these conditions. When called to testify before Congress, Stewart Parnell, PCA’s chief executive officer, invoked his Fifth Amendment rights, and the company itself is under criminal investigation. Food-borne illness causes 5,000 deaths, hospitalizes 325,000, and sickens 76 million annually. Incidents like those at PCA have spurred Congress to draft comprehensive legislation to strengthen FDA’s food safety programs, which cover 80 percent of the American diet. (The Department of Agriculture has jurisdiction over meat and poultry.) Yet under the leading piece of Senate legislation, such egregious conduct would remain punishable as a misdemeanor, triggering at most 0-6 months in jail if the Department of Justice even considered prosecuting those crimes. Industry groups like the Grocery Manufacturers of America oppose enhanced criminal and civil penalties, urging the FDA to focus on cooperative efforts to achieve compliance. The paper argues that the nation cannot afford to forego the substantial deterrent effects provided by severe criminal penalties, especially under the “responsible corporate officer” doctrine that applies to violations of the Food, Drug, and Cosmetics Act. That doctrine holds responsible any corporate officer who should know illegal practices are occurring and is in a position to stop them. In an era when regulatory agencies responsible for protecting health and safety cannot afford to inspect their way out of trouble, high profile enforcement is critical to efforts to improve the safety of the food supply.*

Enron is indicative of nothing. There’s always people who do something they shouldn’t and you’ll never be able to legislate against it. This stuff happens.

Alan Greenberg, Chairman, Executive Committee,  
Bear Stearns<sup>2</sup>

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<sup>1</sup> Rena Steinzor is a professor at the University of Maryland School of Law and the president of the Center for Progressive Reform, [www.progressivereform.org](http://www.progressivereform.org). She appreciates the energetic research assistance provided by Ryan Sweigard and James Getz and the expert editing provided by research librarian Susan McCarty.

<sup>2</sup> Steven Pearlstein, *Debating the Enron Effect; Business World Divided on Problem and Solutions*, WASH. POST, Feb. 17, 2002, at A1.

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FDA regulates food manufacturers’ safety practices by relying on companies’ self-interest in producing safe products, and by working with the industry to improve production practices.

Geoffrey Becker, Congressional Research Service<sup>3</sup>

The FDA needs the ability to criminally prosecute quickly and effectively when needed. If someone is convicted of a felony in the criminal justice system, they go to prison and are not allowed to vote. But, if you poison Americans via their food supply what are the consequences? You pay a fine and keep producing? Is this right? Is this what we as Americans want?

Peter Hurley, police officer, Portland, Oregon and father of surviving salmonella-poisoned child<sup>4</sup>

## OVERVIEW

In the fall of 2008, Minnesota public health officials became alarmed by an unusually high number of illnesses and deaths caused by salmonella poisoning. Using the tedious and time-consuming “traceback process,” which involves interviewing victims in detail about their eating habits to discover common foods,<sup>5</sup> graduate students employed by the state part-time and jokingly referred to as the “Diarrhea Squad” eventually focused in on peanut products supplied to schools, nursing homes, and other institutions by the Peanut Corporation of America (PCA). PCA had two processing plants: one in Blakely, Georgia and a second in Plainview, Texas. As the mainstream media demanded details about the outbreak, which ultimately killed nine and

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<sup>3</sup> GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 2 (2009), available at <http://www.nationalaglawcenter.org/assets/crs/RS22600.pdf> [hereinafter CRS PRIMER].

<sup>4</sup> Mr. Hurley is the father of Lauren, 5, Jacob, 3, and Alyssa, 8 months. Jacob was sickened by Austin peanut butter crackers in January 2009, but survived. *The Salmonella Outbreak: The Continued Failure to Protect the Food Supply: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce, 111th Cong.* (Feb. 11, 2009) [hereinafter *The Salmonella Outbreak: The Continued Failure*] (testimony of Peter K. Hurley), prepared statement available at [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_hurley.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_hurley.pdf), at 5.

<sup>5</sup> For a description of this methodology, see *The Salmonella Outbreak: The Continued Failure*, supra note 4, (Testimony of Stephen F. Sundlof, Dir., Center for Food Safety and Applied Nutrition, Food and Drug Administration), prepared testimony available at [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_sundlof.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_sundlof.pdf), at 2-5 [hereinafter *Sundlof Testimony*].

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sickened 660, federal, state, and congressional investigators swarmed to these facilities.<sup>6</sup> Within weeks, both plants closed and the company declared bankruptcy.<sup>7</sup> The combination of media accounts and congressional oversight hearings revealed several shocking facts about the facility and the absence of any effective government oversight of its operations:

- Plant operators shipped peanut products that had tested positive for salmonella, justifying their activities by retesting to get a negative result.<sup>8</sup>
- The Texas plant had operated unlicensed and without inspections for nearly four years.<sup>9</sup> Testing in February 2009 indicated possible salmonella contamination of the facility, and the company closed it voluntarily, after former employees told the *New York Times* that the facility was “disgusting.”<sup>10</sup>
- The Georgia plant was awash in outright safety violations and unwise management practices including a leaking roof, mold growing on ceilings and walls, rodent infestation, filthy nut processing receptacles, feathers and feces in its air filtration system, and workers who wore their uniforms from work to home and back again.<sup>11</sup>

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<sup>6</sup> See, e.g., Karla Cook, *Peanut Recall's Ripples Feel Like a Tidal Wave for Some Companies*, N.Y. TIMES, Feb. 26, 2009, at B6.

<sup>7</sup> Andrew Martin, *Troubled Peanut Company Files for Bankruptcy Protection*, N.Y. TIMES, Feb. 14, 2009, at B2.

<sup>8</sup> The most notorious e-mail exchange, between PCA president Stewart Parnell and Joe Valenza, the Vice President for Finance and Administration of the King Nut Companies, reads:

Parnell to Valenza: “Joe, I’m sure it’s something we did.”

Valenza to Parnell: “Now my heart is really in my throat. I think I’m going to church tonight.”

This exchange was quoted by Representative Bart Stupak. *The Salmonella Outbreak: The Role of Industry in Protecting the Nation’s Food Supply: Hearing Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy & Commerce*, 111th Cong. (Mar. 19, 2009) (opening statement of Chairman Stupak), prepared opening statement available at [http://energycommerce.house.gov/Press\\_111/20090319/stupak\\_open.pdf](http://energycommerce.house.gov/Press_111/20090319/stupak_open.pdf), at 2 [hereinafter *Stupak Opening Statement*]. See also Gardiner Harris, *Salmonella Was Found at Peanut Plant Before*, N.Y. TIMES, Jan. 29, 2009, at A15 (noting that PCA shipped foods that retested negative for salmonella twelve times in 2007 and 2008).

<sup>9</sup> Gardiner Harris, *After Tests, Peanut Plant in Texas Is Closed*, N.Y. TIMES, Feb. 11, 2009, at A14.

<sup>10</sup> *Id.*

<sup>11</sup> Vivid descriptions of these conditions, and photographs that document them, were entered into the congressional record by Representative Bart Stupak. *Stupak Opening Statement*, *supra* note 8, at 3. See also Michael Moss,

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- Under an agreement with the Food and Drug Administration (FDA), Georgia state inspectors visited the PCA plant nine times in 2006-2008 but took no effective action to terminate any of these conditions. They tested only once for salmonella, despite widespread news reports at the time regarding a comparable outbreak at a ConAgra plant seventy-five miles away in Sylvester, Georgia;<sup>12</sup> the test came up negative.
- Georgia employs sixty field inspectors to cover 16,000 facilities, ranging from processing plants to food storage warehouses.<sup>13</sup>
- The Georgia plant had received a “superior” rating from a private audit firm, American Institute of Baking International (AIB), barely a year before the outbreak, although a second auditing team hired by its customer Nestlé Inc. had turned in such a damning report that Nestlé stopping buying products from PCA.<sup>14</sup>
- When called to testify before Congress, Stewart Parnell, PCA’s chief executive officer, invoked his Fifth Amendment right not to incriminate himself.<sup>15</sup> The company became the subject of a criminal investigation that is not yet complete as this article goes to press.<sup>16</sup>

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*Peanut Case Shows Holes in Food Safety Net*, N.Y. TIMES, Feb. 9, 2009, at A1 [hereinafter *Holes in Food Safety Net*].

<sup>12</sup> The ConAgra outbreak occurred in 2007 and sickened more than 600 people, but no one died. ConAgra’s total business dropped twenty percent during the seven months the peanut butter was off the shelves. Kim Severson, *Who’s Sticking with Us?*, N.Y. TIMES, Feb. 4, 2009, at D1. See also Moss, *Holes in Food Safety Net*, *supra* note 11.

<sup>13</sup> *The Salmonella Outbreak: The Continued Failure*, *supra* note 4 (testimony of Oscar S. Garrison, Ass’t Comm’r, Consumer Protection Division, Georgia Department of Agriculture), *prepared testimony available at* [http://energycommerce.house.gov/Press\\_111/20090211/testimony\\_garrison.pdf](http://energycommerce.house.gov/Press_111/20090211/testimony_garrison.pdf), at 1.

<sup>14</sup> Andrew Martin, *Peanut Plant Says Audits Declared It in Top Shape*, N.Y. TIMES, Feb. 5, 2009, at B10; Lyndsey Layton, *Nestlé’s Inspectors Saw Rat Droppings, Rejected Peanuts*, WASH. POST, Mar. 20, 2009, at A2.

<sup>15</sup> Gardiner Harris, *Peanut Foods Shipped Before Testing Came In*, N.Y. TIMES, Feb. 12, 2009, at A24.

<sup>16</sup> Rob Stein, *FDA Investigating Peanut Company Behind Recall, Firm Could Face Criminal Charges*, WASH. POST, Jan. 31, 2009, at A2. Corporations targeted for criminal prosecution are not jailed, of course, but are liable for fines.

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- The outbreak resulted in the recall of some 2100 products containing PCA peanuts.

It cost the peanut industry \$1 billion and uncounted hundreds of millions more were spent by its customers, large and small manufacturers of everything from cereal to health store granola bars.<sup>17</sup>

Outbreaks of food-borne illness cause 5,000 deaths, hospitalize 325,000 Americans, and make 76 million people sick annually, according to a 1999 estimate by the Centers for Disease Control.<sup>18</sup> The Government Accountability Office (GAO) puts these numbers considerably higher, estimating in 1996 that food-borne illness kills 9,100 people and makes 81 million people sick.<sup>19</sup>

The 2009 peanut scandal propelled Congress to put food safety at the top of its legislative agenda; the House of Representatives passed legislation in July 2009, and Senate leaders seem poised to follow suit.<sup>20</sup> Focused on programs implemented by the Food and Drug Administration (FDA), the bills would adopt stricter regulatory approaches and increase the FDA's funding. Yet, in one of the most perplexing instances of legislative underreaction to a public health crisis in recent memory, the Senate bill does not strengthen the existing criminal penalties available for such violations. Those provisions render even the egregious conduct of Stewart Parnell punishable as a misdemeanor, with a maximum penalty of not more than one year in jail and a \$1,000 fine.<sup>21</sup> The legislation passed by the House would raise this penalty to a

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<sup>17</sup> Emily Fredrix, *Salmonella Recall Could Cost Peanut Producers \$1 Billion*, INS. J., Mar. 12, 2009, <http://www.insurancejournal.com/news/national/2009/03/12/98635.htm>.

<sup>18</sup> These widely cited figures are from a 1999 report by the Centers for Disease Control. See Paul S. Mead et al., *Food-Related Illness and Death in the United States*, 5 EMERGING INFECTIOUS DISEASES 607 (1999).

<sup>19</sup> U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO/RCED-96-96, FOOD SAFETY: INFORMATION ON FOODBORNE ILLNESSES 4 (1996), available at <http://www.gao.gov/archive/1996/rc96096.pdf>.

<sup>20</sup> Gardiner Harris, *Bipartisan Group Demands Overhaul on Food Safety*, N.Y. TIMES, Mar. 12, 2009, at A20.

<sup>21</sup> See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 333(a)(1) (2006). Repeat violators are liable for up to three years in jail and a \$10,000 fine. *Id.* § 333(a)(2).

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felony for comparable future acts, punishable by up to ten years in jail<sup>22</sup> and a fine determined under the provisions of Title 18 of the U.S. Code. Those provisions cap individual assessments at \$250,000 and corporate assessments at \$500,000 unless the pecuniary benefit to the defendant is greater than those amounts, in which case the person can be compelled to pay twice the gross amount of the gain.<sup>23</sup> At a time when regulatory agencies are being asked to do much more with less and the nation as a whole is reaping the bitter harvest of unregulated misconduct by financial institutions and their managers, why has Congress neglected the relatively inexpensive and demonstrably effective approach of imposing stringent liability for the worst violators and relying on deterrence-based enforcement to inspire compliance with the law?

This article attempts to answer those questions, which have implications beyond food safety. The article contends that the Senate omissions reflect a profound ambivalence among lawmakers regarding the prosecution of white collar crime. During an era when victims defrauded by the largest Wall Street Ponzi scheme in history were marching in the street to ensure that Bernard Madoff would never emerge from jail, this attitude is baffling and seems remote from public sentiment.<sup>24</sup>

The article opens with a brief diagnosis of why the existing food safety system is dysfunctional. It explores the fundamental theories behind deterrence-based enforcement and rebuts the arguments made against those principles in a white collar context. It concludes with a proposal for enhancing the penalty provisions in pending legislation.

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<sup>22</sup> Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 134 (2009).

<sup>23</sup> 18 U.S.C. § 3571 (2006).

<sup>24</sup> Kevin McCoy, *Victims' Anger Shifts Past Madoff; Criticism Turns to Role SEC and Others May Have Played and How They'll Be Repaid*, USA TODAY, June 30, 2009, at 1B.

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Although problems in the Department of Agriculture’s food safety programs, which govern the production of meat, poultry, and eggs, are very important, and have direct implications for the FDA’s failures, they are beyond the scope of this discussion. The details of the FDA’s regulatory programs, now and under the pending legislation, are also given short shrift, including the agency’s use of its civil penalties authority to deter wrongdoing. Regulatory approaches are instead discussed primarily to provide a general context for the central propositions advanced here: Congress should embrace stringent criminal liability provisions because misconduct in certain areas of food production has mortal consequences for consumers. Globalization of the economy, which has produced a surging market for imported foods, means that federal and state agencies will never succeed if their sole focus is inspecting their way out of trouble. Rather, the nation must create negative incentives for larger food processors to address both deliberate and negligent malfeasance in their supply chain. Expansive criminal liability for individuals and corporations should become a weapon of first resort for policymakers because small numbers of well-publicized prosecutions have tremendous potential to create and maintain those incentives.

### **REGULATORY DYSFUNCTION AT THE FDA**

The U.S. population spends “more than \$1 trillion on food each year, nearly half of it in restaurants, schools, and other places outside the home.”<sup>25</sup> An estimated 15% of the food Americans eat is imported, much of it from countries without any effective food safety

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<sup>25</sup> CRS PRIMER, *supra* note 3, at 1. Roughly two-thirds of this amount pays for domestically produced farm foods; imports and seafood account for the remainder. CRS identifies the USDA’s Economic Research Service as its source for these statistics, with data accessed January 2008 at the “Food Sector” web page at <http://www.ers.usda.gov/Browse/FoodSector/>.

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regulation.<sup>26</sup> The FDA is responsible for regulating 80% of that food;<sup>27</sup> everything other than meat and poultry fall within its jurisdiction, although other agencies share responsibility for eggs, fish, and pesticide residues on produce.<sup>28</sup> The FDA has jurisdiction over more than 44,000 U.S. food manufacturers, as well as over 100,000 additional registered food facilities including warehouses and grain elevators.<sup>29</sup> Some 200,000 foreign food facilities have filed FDA registrations, but given the highly decentralized structure of food production and processing in developing countries like China, it is difficult to imagine that this figure comes close to an accurate estimate of the number of places where imported food originates.<sup>30</sup>

As is the case with other health and safety agencies, FDA food safety programs are undermined by three severe problems: (1) acute funding shortages, (2) outdated statutory authority, and (3) the enormous challenges posed by imported food. These crippling conditions are well-documented in a series of reports by the National Academies’ Institute of Medicine,<sup>31</sup> the agency’s own independent science advisory board,<sup>32</sup> the Congressional Research Service (CRS),<sup>33</sup> the Government Accountability Office (GAO),<sup>34</sup> former FDA officials who are now

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<sup>26</sup> *Id.* at 2.

<sup>27</sup> U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO-02-47T, FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD (2002), available at <http://www.gao.gov/new.items/d0247t.pdf>.

<sup>28</sup> For a succinct summary of FDA jurisdiction, see CRS PRIMER, *supra* note 3, at 2.

<sup>29</sup> *Id.*

<sup>30</sup> *Id.* For an insightful discussion of China’s food industry, see GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, FOOD AND AGRICULTURAL IMPORTS FROM CHINA (2008), available at <http://www.fas.org/sgp/crs/row/RL34080.pdf> [hereinafter CRS CHINESE IMPORTS].

<sup>31</sup> See COMM. TO ENSURE SAFE FOOD FROM PROD. TO CONSUMPTION, INST. OF MED. AND NAT’L RESEARCH COUNCIL, ENSURING SAFE FOOD FROM PRODUCTION TO CONSUMPTION (1998).

<sup>32</sup> See FDA SCI. BD., SUBCOMM. ON SCI. AND TECHNOLOGY, FDA SCIENCE AND MISSION AT RISK: REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY (2007).

<sup>33</sup> See CRS PRIMER, *supra* note 3; GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, FOOD SAFETY ON THE FARM: FEDERAL PROGRAMS AND SELECTED PROPOSALS (2009); GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES (2009); CRS CHINESE IMPORTS, *supra* note 30; GEOFFREY S. BECKER, CONGRESSIONAL RESEARCH SERVICE, SANITARY AND PHYTOSANITARY (SPS) CONCERNS IN AGRICULTURAL TRADE (2006).

<sup>34</sup> The following list is not all-inclusive of GAO reports on food safety, but rather singles out those most relevant to the FDA’s contribution to this mission. U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-09-523,

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members of the academy,<sup>35</sup> and public interest groups,<sup>36</sup> as well as a self-analysis written by FDA staff during the administration of George W. Bush.<sup>37</sup>

In 2007, the GAO decided to include federal government oversight of food safety on its “high-risk series” list, where it remains.<sup>38</sup> The high-risk list was initiated in 1990 as a tool for identifying government programs that urgently need reform, either because they are subject to

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INFORMATION TECHNOLOGY, FDA NEEDS TO ESTABLISH KEY PLANS AND PROCESSES FOR GUIDING SYSTEMS MODERNIZATION EFFORTS (2009), *available at* <http://www.gao.gov/new.items/d09523.pdf> (explaining problems with the agency’s computerized data analysis systems); U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-435T, FEDERAL OVERSIGHT OF FOOD SAFETY, FDA’S FOOD PROTECTION PLAN PROPOSES POSITIVE FIRST STEPS, BUT CAPACITY TO CARRY THEM OUT IS CRITICAL (2008), *available at* <http://www.gao.gov/new.items/d08435t.pdf> [hereinafter GAO CAPACITY] (explaining that the FDA must have more money, legal authority, and political will to implement the Bush Administration proposed plan for improving its food safety programs); U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-909T, FEDERAL OVERSIGHT OF FOOD SAFETY, FDA HAS PROVIDED FEW DETAILS ON THE RESOURCES AND STRATEGIES NEEDED TO IMPLEMENT ITS FOOD PROTECTION PLAN (2008), *available at* <http://www.gao.gov/new.items/d08909t.pdf> (criticizing the FDA for failing to report in sufficient detail on its progress in implementing the Bush Plan); U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-08-794, FOOD SAFETY, SELECTED COUNTRIES’ SYSTEMS CAN OFFER INSIGHTS INTO ENSURING IMPORT SAFETY AND RESPONDING TO FOODBORNE ILLNESS (2008), *available at* <http://www.gao.gov/new.items/d08794.pdf> (highlighting efforts in Europe and Canada to implement more effective food safety systems); U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-05-549T, OVERSEEING THE U.S. FOOD SUPPLY, STEPS SHOULD BE TAKEN TO REDUCE OVERLAPPING INSPECTIONS AND RELATED ACTIVITIES (2005), *available at* <http://www.gao.gov/new.items/d05549t.pdf> [hereinafter GAO SIMPLIFICATION] (urging the consolidation and simplification of the nation’s food safety laws and the administrative structure employed to implement them); U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-05-51, FOOD SAFETY, USDA AND FDA NEED TO BETTER ENSURE PROMPT AND COMPLETE RECALLS OF POTENTIALLY UNSAFE FOOD (2004), *available at* <http://www.gao.gov/new.items/d0551.pdf> [hereinafter GAO RECALLS] (concluding the recalls are always voluntary and poorly supervised, with the result that many are ineffective in removing contaminated food from homes); U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO-04-246, FOOD SAFETY, FDA’S IMPORTED SEAFOOD SAFETY PROGRAM SHOWS SOME PROGRESS, BUT FURTHER IMPROVEMENTS ARE NEEDED (2004), *available at* <http://www.gao.gov/new.items/d04246.pdf> (explaining the problems that undermine efforts to supervise the safety of imported fish), U.S. GEN. ACCOUNTING OFFICE, REP. NO. GAO/RCED-98-103, FOOD SAFETY, FEDERAL EFFORTS TO ENSURE THE SAFETY OF IMPORTED FOODS ARE INCONSISTENT AND UNRELIABLE (1998), *available at* <http://www.gao.gov/archive/1998/rc98103.pdf> [hereinafter GAO FOOD IMPORTS] (exploring the difficulties the FDA has had as a result of a small inspection force, increasing imports, and the difficulty of verifying that other countries effectively assure safety of their exports).

<sup>35</sup> MICHAEL R. TAYLOR & STEPHANIE D. DAVID, STRONGER PARTNERSHIPS FOR SAFER FOOD: AN AGENDA FOR STRENGTHENING STATE AND LOCAL ROLES IN THE NATION’S FOOD SAFETY SYSTEM (2009), *available at* <http://www.rwjf.org/files/research/20090417foodsafetyfinalreport.pdf>; TOWARD SAFER FOOD: PERSPECTIVES ON RISK AND PRIORITY SETTING (Sandra A. Hoffmann & Michael R. Taylor eds., 2005).

<sup>36</sup> TRUST FOR AMERICA’S HEALTH, KEEPING AMERICA’S FOOD SAFE: A BLUEPRINT FOR FIXING THE FOOD SAFETY SYSTEM AT THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (2009), *available at* <http://healthyamericans.org/assets/files/2009FoodSafetyReport.pdf> (the FDA is housed at the department).

<sup>37</sup> INTERAGENCY WORKING GROUP ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY (2007), *available at* <http://www.importsafety.gov/report/actionplan.pdf>.

<sup>38</sup> U.S. GOV’T ACCOUNTABILITY OFFICE, REP. NO. GAO-09-271, HIGH-RISK SERIES: AN UPDATE 5 tbl.3 (2009), *available at* <http://www.gao.gov/new.items/d09271.pdf> [hereinafter GAO HIGH RISK].

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significant waste and fraud or because they need “broad-based transformation to address major economy, efficiency, or effectiveness challenges.”<sup>39</sup> To keep the implications of inclusion on the list appropriately dire, the GAO has targeted only thirty programs as of January 2009. The list includes areas of well-publicized and widespread concern, such as creation of the Department of Homeland Security” (listed in 2003, shortly after Congress created the department) and coverage offered by the National Flood Insurance Program (listed in 2006, as the implications of Hurricane Katrina became clear). The GAO’s impeccable reputation for objectivity and freedom from political interference should catapult programs to the top of the executive and legislative branches’ priorities for reform, although some particularly intractable problems—for example, supply and weapons acquisition at the Department of Defense—have remained on the list since its inception.

The GAO was characteristically blunt in explaining its reason for listing food safety as a high priority risk:

[GAO added food safety in 2007] because 15 agencies collectively administer 30 food-related laws. Since then, the largest food-borne outbreak in the last 10 years was linked to *Salmonella* in fresh produce. Also, high levels of imported foods underscore the urgency to revamp this system. About 15 percent of the overall U.S. food supply is imported, as is about 60 percent of fresh fruits and vegetables and over 80 percent of seafood.

....

... Federal expenditures on food safety are not based on the volume of foods regulated by the agencies or consumed by the public. FDA is responsible for about 80 percent of the food supply and yet accounts for about 24 percent of expenditures.<sup>40</sup>

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<sup>39</sup> *Id.* at unnumbered “Highlights” page.

<sup>40</sup> *Id.* at 71.

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The FDA fields approximately 1,900 inspectors in regional offices throughout the U.S., and has a staff of some 900 at its Washington D.C. headquarters.<sup>41</sup> As indicated by the PCA peanut saga, state and local agencies also inspect food production facilities, although the quality of their inspection and enforcement programs are often sub-par. Information on the frequency of FDA inspections is somewhat inconsistent. The CRS reports that “various estimates of unannounced compliance inspections of domestic establishments by FDA officials range from once every five years to once every ten years, on average, although the agency *claims* to visit about 6,000 so-called high-risk facilities on an annual basis.”<sup>42</sup> The FDA inspects only about two percent of foreign food imports.<sup>43</sup>

In FY 2009, the FDA had a \$649 million budget for the regulatory apparatus that supervises eighty percent of the food people consume in this country, plus another \$137 million for the regulation of animal drugs and feeds.<sup>44</sup> The Department of Agriculture’s budget for food safety was \$972 million in appropriated funds, plus an estimated \$140 million in industry user fees.<sup>45</sup> President Obama’s budget for FY 2010 would add \$259 million to the FDA budget, strengthening the FDA’s ability to promulgate new rules if Congress approves the various reform bills that are pending—staff at headquarters would grow to 854 Full-time Equivalents, or FTEs, and regional offices would field 2,165 inspectors.<sup>46</sup> These increases would allow the agency to

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<sup>41</sup> CRS PRIMER, *supra* note 3, at 2.

<sup>42</sup> *Id.*

<sup>43</sup> GAO FOOD IMPORTS, *supra* note 34, at 5.

<sup>44</sup> *Id.* at 1-2.

<sup>45</sup> *Id.* at 1.

<sup>46</sup> For the granular detail of how the FDA would spend these amounts, see U.S. FOOD & DRUG ADMINISTRATION, FY 2010 EXHIBIT FOR CONGRESSIONAL APPROPRIATORS, *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM153496.pdf> (last visited Oct. 6, 2009).

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inspect high-priority domestic facilities more frequently, but would make little dent in its limited supervision of foreign imports.

The FDA does not have authority to order recalls and must instead rely on the cooperation of food manufacturers, processors, wholesalers, and retailers to accomplish the arduous and expensive job of extracting contaminated food from commerce, and the agency's legal impotence was noted by press covering the peanut scandal.<sup>47</sup> Consumer groups and independent experts have sharply criticized the FDA's lack of mandatory recall authority, and pending House and Senate reauthorization legislation would give the agency this authority.<sup>48</sup>

Some prominent members of the food industry and FDA career staff have argued that mandatory recall authority could interfere with the cooperative spirit of voluntary recalls, an ingredient essential to the efficacy of the recall remedy, making FDA a less valuable partner in corporate efforts to encourage consumers to turn in tainted food.<sup>49</sup> Congress has thus far decided to ignore these arguments, which reflect a long-standing and deep-seated view that the food industry is already well-motivated to prevent contamination of its products because of the severe effects such incidents have on consumers' brand, or type of food, loyalty.

Among other considerations, this rationale does not take into account the short-term economic pressures—and even sheer laziness or malfeasance—that can provoke food producers to cut corners, all of which were on full display in the PCA peanut incident. Kellogg, a major customer of PCA, clearly understood the implications for its business if peanut paste was contaminated by salmonella, and the company made an effort to forestall this kind of problem by

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<sup>47</sup> Gardiner Harris, *Peanut Product Recall Took Company Approval*, N.Y. TIMES, Feb. 3, 2009, at A13.

<sup>48</sup> Food Safety Enhancement Act, H.R. 2749, 111th Cong. § 111 (2009); FDA Food Safety Modernization Act, S. 510, 111th Cong. § 206 (2009).

<sup>49</sup> VANESSA K. BURROWS, CONG. RESEARCH SERV., THE FDA'S AUTHORITY TO RECALL PRODUCTS 3 (2007), available at <http://www.nationalaglawcenter.org/assets/crs/RL34167.pdf>.

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deploying third party inspectors to PCA’s Georgia plant.<sup>50</sup> However, the inspector, who was paid by PCA and not Kellogg, was not only incompetent but overly friendly with the target of his efforts, sending a note by electronic mail announcing cheerfully, “You lucky guy. I am your AIB auditor. So we need to get your plant set up for any audit. . . . Thanks and Merry Christmas and Happy New Year to you and your family.”<sup>51</sup> The inspector subsequently cleared the dates of the audit with plant personnel.<sup>52</sup>

In any event, the unfortunate reality is that even in the best of circumstances, recalls are notoriously difficult to implement and are not an effective substitute for preventive regulation. Because products are relatively inexpensive and purchases are so numerous, retailers rarely have easy access to the names and contact information of their individual customers. Even if such information is available, recalls involving millions of units are daunting to implement. The GAO reported in 2004 that “most recalled food is not recovered,” estimating that food recalls supervised by the FDA in 2003 recovered 36% of covered products.<sup>53</sup>

Of course, the fact that consumers do not take the trouble to return products to stores does not mean that contaminated food is consumed. During the 2009 peanut scare, 28 million people visited the FDA web site giving information about affected products,<sup>54</sup> indicating that national press attention motivates extensive public interest and suggesting that many consumers simply toss contaminated food in the trash.<sup>55</sup> If these assumptions are correct, the real threats to public

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<sup>50</sup> See *supra* note 14 and accompanying text.

<sup>51</sup> E-mail exchange between Pete Hatfield, AIB inspector, and Sammy Lightsey, PCA plant manager (Dec. 22, 2008 to Dec. 31, 2008), *available at*

[http://energycommerce.house.gov/Press\\_111/20090319/Email%20exchange%20Hatfield%20Lightsey%20December%2031%202008.pdf](http://energycommerce.house.gov/Press_111/20090319/Email%20exchange%20Hatfield%20Lightsey%20December%2031%202008.pdf) (background material for *The Salmonella Outbreak: The Role of Industry*, *supra* note 8).

<sup>52</sup> *Id.*

<sup>53</sup> GAO RECALLS, *supra* note 34, at unnumbered “Highlights” page.

<sup>54</sup> See *Sundlof Testimony*, *supra* note 5, at 9.

<sup>55</sup> Caroline Smith DeWaal, ???

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health lie in food consumed before researchers trace back the contamination and the multiple instances of small-scale contamination that do not receive intensive national coverage. Further, the monetary losses from contamination episodes are often steep and are magnified by the Internet, which is capable of communicating information to consumers about potentially affected products rapidly and at little cost.

As a result of the growing threats to public health and steep costs to the food industry, the full spectrum of participants in the food safety debate agree that FDA regulators must emphasize programs that prevent outbreaks of contamination through the mandatory implementation of “food safety plans” that assess the risks posed by the processing that occurs at covered facilities. The House and Senate bills both have provisions requiring owners, operators, or agents of such facilities to prepare such plans under guidance issued by the FDA and to update them periodically.<sup>56</sup> To ensure that the FDA has a credible presence in policing compliance with these plans, the bills take the unusual step of mandating how often covered facilities must be inspected. The House-passed legislation is more specific and therefore stronger than the most prominent Senate bill. The House would require that the FDA rank facilities as “Category 1/high-risk,” “Category 2/low-risk,” or as a “Category 3/facility that holds food.”<sup>57</sup> The House directs the FDA to randomly inspect Category 1 facilities at least every six-twelve months, Category 2 facilities at least every eighteen months to three years, and Category 3 facilities at least every five years. In contrast, the Senate would require inspection of “high-risk” facilities every two years during the first two years after the date of enactment, and every year following

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<sup>56</sup> H.R. 2749, 111th Cong. § 101 (registration); § 102 (hazard analysis and risk-based preventive controls) (2009); S. 510, 111th Cong. § 102 (registration); § 103 (hazard analysis and risk-based preventive controls) (2009).

<sup>57</sup> H.R. 2749, 111th Cong. § 105 (2009).

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that initial period, while “non-high-risk” facilities must be inspected at least once every four years.<sup>58</sup>

These mandatory timetables are an important reform for an agency that exhibits such acute dysfunction. But if Congress does not deliver the funding necessary to meet these aggressive schedules, the provisions will degenerate into symbolic law. The bills do not contain so-called “citizen suit” provisions that would allow concerned parties to take the agency to court in the event of failed deadlines. These provisions are common in the federal environmental laws<sup>59</sup> and court orders have played an important role in pressuring the Environmental Protection Agency to ask Congress for the funds needed to implement statutory mandates.

As for imports, neither bill would adopt the most aggressive reform proposed by the GAO and other independent observers.<sup>60</sup> Before meat and poultry are imported to this country, the U.S. Department of Agriculture must conduct an evaluation determining that the source country has a regulatory system in place that is basically equivalent to the system we have in the United States.<sup>61</sup> This so-called “equivalency authority” allows American regulators to “transfer the primary food safety responsibility to the exporting country,” in effect leveraging their own resources by evaluating programs periodically rather than posting hundreds, even thousands, of inspectors at U.S. ports.<sup>62</sup> As they began their consideration of food safety legislation in January 2009, House and Senate leaders apparently concluded that they could not muster enough political support to overcome strenuous industry resistance to such a system and that the money needed to

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<sup>58</sup> S. 510, 111th Cong. § 201 (2009).

<sup>59</sup> See, e.g., 33 U.S.C. § 1365 (2006) (authorizing citizen suits for violations of the Clean Water Act).

<sup>60</sup> See, e.g., GAO FOOD IMPORTS, *supra* note 33, at 21–26.

<sup>61</sup> See generally OFFICE OF INTERNATIONAL AFFAIRS, FOOD SAFETY INSPECTION SERVICE, U.S. DEP’T OF AGRICULTURE, PROCESS FOR EVALUATING THE EQUIVALENCE OF FOREIGN MEAT AND POULTRY FOOD REGULATORY SYSTEMS (2003), available at <http://www.fsis.usda.gov/OPPDE/IPS/EQ/EQProcess.pdf> (detailing the legal authority requiring and process for performing equivalency evaluations).

<sup>62</sup> GAO FOOD IMPORTS, *supra* note 34, at 24.

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implement it would not be forthcoming. The legislation adopts compromises on imports that are likely to prove far less effective. The House-passed bill authorizes the FDA to require “certification” of food imports if it decides—in its discretion—that the process would assist the agency in deciding whether to admit a potentially risky category of food.<sup>63</sup> Certifications could be performed by “qualified certifying entities,” an opaque term that can include regulators from other countries’ governments or accredited third party inspectors recognized by the FDA.<sup>64</sup> Given the remarkably incompetent performance of national third party inspectors during the PCA peanut scandal and shortcomings of regulatory programs in China and other Asian countries that have become the leading sources of such high-hazard commodities as fish, neither alternative is likely to provide satisfactory protection for quite some time.

The leading Senate legislation is even weaker. It places the burden on importers to “perform risk-based foreign supplier verification activities in accordance with regulations promulgated [by the FDA].”<sup>65</sup> An importer who violates these requirements commits a “prohibited act” under the Senate bill but is liable only for the misdemeanor penalty available under existing law.<sup>66</sup>

### CRIMINAL ENFORCEMENT AS ANTIDOTE TO DYSFUNCTION

#### *The “E(nforcement) Word”*

The FDA’s regulatory dysfunction is the product of two powerful and converging trends. The first is a highly successful campaign to discredit federal regulatory intervention in the so-

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<sup>63</sup> H.R. 2749, 111th Cong. § 109 (2009).

<sup>64</sup> *Id.*

<sup>65</sup> S. 510, 111th Cong. § 301 (2009).

<sup>66</sup> *Id.*; 21 U.S.C. § 331 (2006).

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called “free” market.<sup>67</sup> This campaign, mounted by the nation’s most powerful business interests, began with the election of President Ronald Reagan and peaked during the administration of George W. Bush (“Bush II”). During the entire Bush II period, health and safety laws were left to molder without updating amendments;<sup>68</sup> the White House stifled regulatory proposals that had been in the pipeline for years, including those prompted by non-discretionary statutory mandates;<sup>69</sup> and budgets were slashed with the full cooperation of agency political appointees.<sup>70</sup>

The dynamics that advanced the campaign to deregulate changed with the 2008 presidential election. At present, proponents are waging a ferocious battle to maintain their influence in the wake of the Enron, Worldcom, and Madoff scandals, acute public distress over the global economic recession that began in 2008, conspicuous holes in the regulatory safety net that are manifested as salmonella-laced peanut butter and lead-coated imported toys,<sup>71</sup> and the election of President Obama, who defines government’s role as doing for people what “we

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<sup>67</sup> This word is placed in quotation marks because the economic dynamics of the American and global marketplaces are heavily influenced by government subsidies, tax loopholes, and financial regulation, making the free market described by economists and advocates of deregulation a theoretical construct that has little relationship with reality.

<sup>68</sup> The food safety provisions of the Food, Drug, and Cosmetic Act were last amended in 1997. See Title III of the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, §§ 301-309, 111 Stat. 2296, 2350-56. Other laws in desperate need of change include the Occupational Safety and Health Act of 1970, 29 U.S.C. §§ 651-678 (2006), last amended in 1998, by the Occupational Safety and Health Administration Compliance Assistance Authorization Act of 1998, Pub. L. No. 105-197, 112 Stat. 638, and the Clean Water Act, last amended in 1987, by the Federal Water Pollution Control Act Amendments of 1987, Pub. L. No. 100-4, §§ 301-06, 101 Stat. 29-37.

<sup>69</sup> For example, the Bush II Administration decided to postpone strong regulation of mercury emissions from power plants until 2018. Beth Daley, *EPA Rule Will Limit Power-plant Mercury*, BOSTON GLOBE, Mar. 15, 2005, at A1.

<sup>70</sup> See, e.g., Stephen Labaton, *Safety Chief Is Opposing More Money*, N.Y. TIMES, Oct. 30, 2007, at C1 (describing a request by Nancy Nord, chair of the Consumer Product Safety Commission, that Congress abandon plans to increase her agency’s budget).

<sup>71</sup> See, e.g., Louise Story, *Lead Paint Prompts Mattel to Recall 967,000 Toys*, N.Y. TIMES, Aug. 2, 2007, at C1 (describing recalls of toys coated with lead paint and imported from China).

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cannot do for ourselves.”<sup>72</sup> The president has lent his strong support to food safety reform, in particular with respect to the FDA.<sup>73</sup> These events and the president’s attitudes have clearly slowed the advance of deregulation, although the movement remains quite active in areas like the debate over climate change legislation.

The second converging trend is a systematic underfunding of regulatory agencies by Congress. These budget gaps make the agencies far more susceptible to assertions that they must tread softly in controlling business practices because they lack the resources they need to defend their rules against strong attack, both during the rulemaking process and in court. As serious, shortfalls deprive the agencies of the resources they need to make their enforcement programs appear even minimally credible, as illustrated by the statistics regarding the FDA’s ability to inspect food processing facilities cited earlier.<sup>74</sup> Eventually, this noxious combination of demoralized and underfunded bureaucracy hurts businesses as well as consumers; consider the \$1 billion in losses caused by the PCA peanut scandal just among other producers of peanut products.<sup>75</sup>

Despite the obvious damage to legitimate businesses caused by regulatory dysfunction, corporate executives rarely embrace affirmative reforms. Food safety is a modest, partial exception to this general rule, at least up to a point. Sensing a turning tide of political support, major trade associations have testified before Congress in support of legislation to expand FDA food safety programs. But the most prominent have drawn the line at strengthened penalties and

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<sup>72</sup> Barack Obama, *Obama Closing Argument Speech*, CHICAGO SUN-TIMES, Oct. 27, 2008, [http://blogs.suntimes.com/sweet/2008/10/obama\\_closing\\_argument\\_speech\\_1.html](http://blogs.suntimes.com/sweet/2008/10/obama_closing_argument_speech_1.html) (transcript of speech as delivered at the Canton Memorial Civic Center, Canton, Ohio, Oct. 27, 2008).

<sup>73</sup> Gardiner Harris, *President Plans Team to Overhaul Food Safety*, N.Y. TIMES, Mar. 15, 2009, at A24.

<sup>74</sup> See *supra* notes 41-43 and accompanying text.

<sup>75</sup> Fredrix, *supra* note 17 (describing a cost estimate by Don Koehler, of the Georgia Peanut Commission, of the costs imposed on rural peanut producers by the PCA scandal).

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enforcement. Consider the following statement from Cal Dooley, former president and chief executive officer of the Grocery Manufacturers Association (GMA), which is among the most prominent industry groups participating in the debate:

We also strongly oppose costly new regulatory requirements, including provisions that provide FDA inspectors with broad authority to review the adequacy of food safety plans . . . . While we support the requirement that all food companies have a food safety plan, we believe food companies should be given the discretion to identify appropriate safety controls . . . . Prescriptive, across-the-board new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.

While we believe that some facilities deserve greater scrutiny than others, we opposed rigid inspection schedules and instead believe that FDA inspections should be based upon risk. We also strongly opposed needless civil penalties and reinspection fees. *Food companies have powerful incentives to ensure the safety of food products and ingredients and current law already provides a wide range of enforcement tools, including seizure, injunction, and civil and criminal penalties.* Giving FDA the power to assign massive fines and fees will dramatically alter the cooperative relationship between FDA and the food industry and will create a powerful incentive for FDA to find violations regardless of merit.<sup>76</sup>

Dooley’s demand for a “cooperative” relationship with government matches what has happened to enforcement over the course of the deregulatory campaign, when conservatives argued that the country would be better served if government committed resources to “compliance assistance,” a term of art for government programs that seek to educate regulated industries about the elaborate regulatory requirements that apply to their operations.<sup>77</sup> Under Presidents Clinton and Bush, such programs flourished, although efforts to assess their

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<sup>76</sup> *FDA Overhaul: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 110th Cong. (Apr. 24, 2008), prepared testimony available at [http://archives.energycommerce.house.gov/cmte\\_mtg/110-he-hrg.042408.Dooley-testimony.pdf](http://archives.energycommerce.house.gov/cmte_mtg/110-he-hrg.042408.Dooley-testimony.pdf), at 3-4 (testimony of Cal Dooly, president and CEO, Grocery Manufacturers Association) (emphasis added).

<sup>77</sup> See, e.g., Mark Wilson, Heritage Foundation, *Save Lives by Cutting Red Tape: Redefine the Federal Role in Workplace Safety and Health* (Sept. 5, 1995), available at [http://www.heritage.org/research/socialsecurity/upload/89740\\_1.pdf](http://www.heritage.org/research/socialsecurity/upload/89740_1.pdf) (arguing that the OSHA should work cooperatively with businesses by, for example, making compliance assistance a central component of its programs).

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effectiveness are virtually impossible because no one kept reliable statistics on the number of businesses involved, much less the impact of education on the incidence of noncompliance.<sup>78</sup>

The arguments made by Bush II appointees and food industry representatives to the effect that the FDA should not receive mandatory recall authority and instead should continue to rely on voluntary cooperation by companies that produced tainted food are direct descendants of this compliance counseling approach.<sup>79</sup>

The question remains whether Senator Durbin's (D-Ill.) decision to omit any changes to the FDA's authority to impose criminal penalties for food safety violations is also based on these considerations. Senator Durbin introduced S. 510 on March 3, 2009, with ten co-sponsors—five Democrats and five Republicans. The Democrats included Senators Christopher Dodd (D-Conn.), Roland Burris (D-Ill.), Amy Klobuchar (D-Minn.), Edward Kennedy (D-Mass., since deceased), and Tom Udall (D-Utah). The Republicans included Senators Lamar Alexander (R-Tenn.), Richard Burr (R-N.C.), Saxby Chambliss (R-S.C.), Judd Gregg (R-N.H.), and Johnny Isakson (R-Ga.). With the possible exception of Senator Gregg, the Republicans in this group are pointedly conservative and generally supportive of business interests, justifying the speculation that Senator Durbin shaped the content of his bill in order to achieve a bipartisan approach that would speed the legislation's passage. Omitting stronger criminal penalty provisions would serve as a logical trade-off in any logrolling along these lines that may have occurred behind the scenes. The inclusion of strengthening amendments in parallel House legislation, and the prominence of a series of food safety scandals during the period when

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<sup>78</sup> See, e.g., CLAUDIA COPELAND, CONGRESSIONAL RESEARCH SERVICE, REINVENTING THE ENVIRONMENTAL PROTECTION AGENCY AND EPA'S WATER PROGRAMS (1996).

<sup>79</sup> See *supra* note 49 and accompanying text.

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Senator Durbin was drafting S. 510, make it highly unlikely that the decision to omit these reforms was anything but a conscious political choice.

### *Responsible Corporate Officers*

Following the hypothesis that leaving enhanced criminal penalties out of the legislation was accomplished by industry lobbying, what motivates those attitudes? After all, the observation that the misdemeanor punishment is an ineffective deterrent would logically suggest that business executives have little to fear from enforcement of these provisions. Not only are any eventual penalties light, but federal prosecutors are highly unlikely to spend scarce resources on cases that do not bring felony convictions.

Industry’s antipathy to the FDA’s criminal authority undoubtedly is motivated by two prosecutions of purveyors of tainted food that led to landmark Supreme Court decisions changing the fundamental premises of criminal punishment for so-called public welfare offenses.<sup>80</sup> The “responsible corporate officer” doctrine that resulted from these cases holds that executives at the top of a corporate hierarchy, who were not directly involved in committing violations but were in a position to implement policies that would have prevented the offensive conduct, can be held criminally liable to the same extent as their most culpable underlings.

In a classic 1933 article in the *Columbia Law Review*, Professor Francis Bowes Sayre described such cases as the product of an “increasingly complex social order [that] required additional regulation of an administrative character unrelated to questions of personal guilt.”<sup>81</sup> Professor Sayre was scandalized by this development and warned that such prosecutions should

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<sup>80</sup> United States v. Dotterweich, 320 U.S. 277 (1943); United States v. Park, 421 U.S. 658 (1975).

<sup>81</sup> Francis Bowes Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55, 67 (1933).

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be carefully limited to “public welfare offenses involving light penalties.”<sup>82</sup> Whether a federal prosecution commanding a sentence of up to one year in jail would be sufficiently light from his perspective is unclear but, in any event, the Supreme Court did not share his compunction.

The 1943 case involved the prosecution of the Buffalo Pharmacal Company, Inc., along with its president and general manager Joseph H. Dotterweich, under the misdemeanor provisions of the Food and Drug Act for shipping “misbranded drugs”—to wit, “cascara compound” (or “Hinkle Pills”) containing strychnine sulfate.<sup>83</sup> The National Formulary listing of acceptable ingredients for this medication had excluded that chemical in 1939.<sup>84</sup> The specific issue before the Court was whether Dotterweich could be held liable as a “person” under the Act. Justice Frankfurter’s opinion on behalf of 5-4 majority declared that the prosecution was based on a

now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but *standing in responsible relation to a public danger*.<sup>85</sup>

The 1975 case took this departure from traditional *mens rea* requirements to its logical conclusion. *United States v. Park* involved the poor maintenance of a large Baltimore warehouse used to store boxed food products by Acme Markets, Inc., a national retail food chain with 36,000 employees, 874 retail outlets, and 16 warehouses. The warehouse was plagued by rodents, some of which had managed to chew through the food packaging in addition to leaving

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<sup>82</sup> *Id.* at 83.

<sup>83</sup> *United States v. Buffalo Pharmacal Co., Inc.*, 131 F.2d 500, 501-02 (2d Cir. 1942).

<sup>84</sup> The National Formulary is an official publication, issued first by the American Pharmaceutical Association and now yearly by the United States Pharmacopeial Convention, that gives the composition, description, method of preparation, and dosage for drugs. Definition of National Formulary, MedicineNet.com (Dec. 7, 2003), *available at* <http://www.medterms.com/script/main/art.asp?articlekey=25605>.

<sup>85</sup> *Dotterweich*, 320 U.S. at 280-81 (emphasis added).

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feces and urine around the facility, and the company had undergone an initial inspection by FDA officials that lasted for twelve days and produced a letter to company president John R. Park demanding corrective action. He delegated responsibility for this work to his Baltimore division vice president. When FDA representatives returned to reinspect the facility four months later, conditions were improved, but rodent infestation persisted and the government decided to prosecute Park criminally.

Unlike Dotterweich’s modest repackaging operation, which bought drugs wholesale and shipped them to retailers with its own label, Acme’s operations were large and sprawling. Park defended himself on the basis that he was not directly responsible for sanitary conditions at the company’s storage facilities and that he had delegated these tasks to responsible subordinates. The Court of Appeals for the Fourth Circuit reversed his conviction by a jury<sup>86</sup> and the government appealed to the Supreme Court. Alarmed by the implications of the Court’s decision to grant *certiorari*, a broad coalition of industry groups filed amici briefs when the case arrived for hearing at the Supreme Court.

The central issue in the case was whether the trial court judge had erred in failing to instruct the jury that the prosecution must shoulder the burden of proving Park guilty of “wrongful action,” a term that implies affirmative behavior.<sup>87</sup> Writing on behalf of a 6-3 majority, Justice Burger cited substantial precedent concluding that “knowledge or intent were not required to be proved” and that “an omission or failure to act” is a sufficient basis for imposing “a responsible corporate agent’s liability.”<sup>88</sup> “It was enough in such cases that, by

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<sup>86</sup> United States v. Park, 499 F.2d 839 (4th Cir. 1974).

<sup>87</sup> United States v. Park, 421 U.S. 658, 675 (1975).

<sup>88</sup> *Id.* at 670-71.

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virtue of the relationship he bore to the corporation, the agent had the power to prevent the act complained of.”<sup>89</sup>

Regardless of the harshness of the penalties at stake in any given prosecution, the power of the *Park* and *Dotterweich* holdings cannot help but leave every well-informed executive experiencing a combination of resentment and anxiety. In large corporations, the distance between plant or warehouse supervisors is great, from bureaucratic and geographical perspectives. Any lawyer who has counseled clients who belong to the managerial pool in such organizations and are responsible for compliance with complex health and safety regulations—and the author spent seven years engaged in that activity—knows that the mere initiation of a criminal investigation is considered disastrous, no matter what its outcome. Unlike borderline financial practices—and perceptions in that arena are also evolving rapidly—managers cannot defend themselves by arguing that their competitors were engaged in the same activities. Rather, they find themselves accused of a crime that threatens people’s health, spreading an ethical stain that is difficult to escape once the mere fact of the accusation becomes known, even if the knowledge is confined within the corporation.

Two questions remain, however: (1) is anxiety about potentially unfair prosecution based in reality and, as important, (2) should these objections be ignored by policymakers intent on revamping the food safety system in the United States?

*Monster in the Closet?*

Viewed from the perspective of the FDA’s actual track record on enforcement, anxiety about prosecution as a responsible corporate officer is analogous to children’s fear of the monster in the closet. No doubt the terror is real, and no doubt the closet is empty.

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<sup>89</sup> *Id.* at 671.

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Under the *2008 Federal Sentencing Guidelines Manual*, violations of section 331 of the Food, Drug, and Cosmetic Act are characterized as a “Base Offense Level 6,” meaning that they would trigger a sentence of between zero and six months in jail before the “criminal history points” of the individual defendant are considered.<sup>90</sup> Even after those points are added, however, sentencing guidance does not change: the person with the worst history would still be exposed under the guidance to a zero to six month sentence. According to the *Federal Justice Statistics* kept by the U.S. Department of Justice, 89% of defendants were charged with felony offenses in FY 2006 (the last year for which such information is available).<sup>91</sup> In order of priority, 38% were charged with a “public-order offense”, including 20% for immigration violations and 11% for weapons violations, and 37% were charged with a drug offense.<sup>92</sup>

Of course, the Department of Justice cannot prosecute if it does not get case referrals from the FDA. The agency’s statistics reveal an extraordinarily weak track record for criminal investigations and case referrals across-the-board. The FDA’s Office of Criminal Investigations reported 196 convictions in prosecutions for all violations of its statutes in FY 2004; 270 in FY 2005; 279 in FY 2006; 344 in FY 2007; and 369 in FY 2008.<sup>93</sup> The FDA Center for Food Safety and Applied Nutrition (CFSAN) executed two seizures in FY 2008 (the agency does not report how many products or product units were involved) and issued three injunctions.<sup>94</sup>

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<sup>90</sup> U.S. SENTENCING COMMISSION, FEDERAL SENTENCING GUIDELINES MANUAL § 2N2.1 (2008), *available at* [http://www.ussc.gov/2008guid/CHAP2\\_L-X.pdf](http://www.ussc.gov/2008guid/CHAP2_L-X.pdf).

<sup>91</sup> Bureau of Justice Statistics, U.S. Dep’t of Justice, Federal Justice Statistics, Adjudication <http://www.ojp.usdoj.gov/bjs/fed.htm#Adjudication> (last visited Oct. 5, 2009).

<sup>92</sup> *Id.*

<sup>93</sup> FDA, Enforcement Story FY 2008, at 10-18 (2009), *available at* <http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm>.

<sup>94</sup> *Id.* at 4-31. The agency sells the printed version of the document that contains these statistics for a whopping \$327. See FDA, Product Details, Enforcement Story, <http://www.fdanews.com/store/product/detail?productId=26366> (last visited Oct. 5, 2009).

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As for the objections that future application of the responsible corporate officer doctrine to food safety cases would do little more than persecute the well-meaning, potentially driving the worst culprits underground and discouraging small and mid-size businesses from coming forward for compliance assistance, two responses are possible. The enforcement track record in other contexts where the doctrine was applied does not substantiate such claims. Second, the FDA has few alternatives to deterrence-based enforcement in the absence of massive budget increases that seem very unlikely.

The responsible corporate officer doctrine is admittedly stringent and, if applied to insignificant or inadvertent violations, might well strike judges and juries as unfair. However, critics of the doctrine are hard-pressed to find prominent examples of such abuses in the arena of environmental law, where it has been vigorously enforced. For example, during the early years of the Clinton Administration, Professor Richard Lazarus raised the specter of prosecutions for environmental crimes that would punish corporate officers who had tried in good faith to comply with complex, even obscure, regulations. He argued for changes that would circumscribe the government's discretion under what he saw as unduly vague statutory language.<sup>95</sup> Lois Schiffer, assistant attorney general for environment and natural resources, and her colleague James Simon, rebutted these concerns, arguing that the Justice Department operated within a series of institutional constraints unrecognized by Lazarus and did, in fact, exercise its discretion wisely, confining prosecution to cases where conduct was egregious.<sup>96</sup>

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<sup>95</sup> Richard J. Lazarus, *Meeting the Demands of Integration in the Evolution of Environmental Law: Reforming Environmental Criminal Law*, 83 GEO. L.J. 2407 (1995).

<sup>96</sup> Lois J. Schiffer & James F. Simon, *The Reality of Prosecuting Environmental Criminals: A Response to Professor Lazarus*, 83 GEO. L.J. 2531 (1995).

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As for the arguments that strong criminal enforcement will drive culprits underground while cutting off others from compliance counseling, the most compelling response may well be a pragmatic one. The utility for agencies like the FDA of robust criminal enforcement programs grows and intensifies in inverse proportion to their resources. When funding is plentiful and the number of industry players is relatively small, agencies can afford to do the individualized inspections that provide the kind of supportive compliance counseling envisioned by the GMA's Dooley. Agencies need substantial funding to field enough inspectors to visit plants frequently, making recommendations to improve compliance and following up to determine that those suggestions are implemented. Unless compliance counseling is carried out in this intensive manner, it is highly unlikely to work, especially with respect to companies like the peanut producer PCA that provide ingredients for finished products and therefore do not risk priceless reputational damage at the retail level. Superficial counseling efforts, such as sponsoring training conferences for small and mid-size company employees, are unlikely to promote the profound changes in corporate culture required to jump start a full-fledged compliance program.

The days of a simple industry structure and ample inspection staff are over for the FDA, if they ever existed. The sheer size and complexity of the food industry, which extends not only from farm to table but from one side of the world to the other, defeat any realistic hope of reverting to that kind of cooperative approach. The GMA is right that the government needs producers to cooperate with its effort to prevent food-borne illness. It is just as certainly wrong that cooperation by even the largest, well-meaning companies can fill the yawning gaps left by the absence of deterrence-based enforcement.

The concern that an aggressive criminal prosecution program will drive the worst actors underground would be more credible in an industry comprised primarily of small and mid-sized,

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independent producers who marketed directly to consumers. In contrast, as the PCA saga demonstrates, large companies like Kellogg and Nestlé are deeply concerned about the purity of the peanut ingredients they purchased from PCA. The first multinational, Kellogg, may well have made serious errors in setting up its program for requiring third party audits, allowing PCA to hire and therefore control the firm providing the inspectors, the American Institute of Baking.<sup>97</sup> The result was that Kellogg continued to do business with PCA at its peril. In contrast, Nestlé's inspectors discovered the grievous conditions at the PCA plant and cut the company out of its supply chain.<sup>98</sup> These episodes show that well-run, third party audits supervised by large producers could work to protect the public if their quality was strong enough to result in the economic isolation of companies like PCA.

#### **PROSPECTS FOR REFORM**

The gist of the debate between Professor Lazarus and former Assistant Attorney General Schiffer regarding the fairness of criminal prosecution under the federal environmental laws boiled down to a fundamental clash over the reliability of prosecutorial discretion as the palliative that makes charging individual responsible corporate executives fair or unfair. In that context, the courts have held that under the responsible corporate officer doctrine, prosecutors need not prove that a defendant actually knew that certain conduct violated a specific law. Rather, the prosecution's burden was to prove that defendant, no matter how high up in the corporate hierarchy, was aware of the offensive conduct—for example, burying discarded chemicals in an unlined pit in the ground.<sup>99</sup> Lazarus argued that because the laws and their implementing regulations are extraordinarily complex, the responsible corporate officer doctrine

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<sup>97</sup> See *supra* notes 13, 51-52 and accompanying text.

<sup>98</sup> See *supra* note 14 and accompanying text.

<sup>99</sup> See *United States v. Dee*, 921 F.2d 741 (4th Cir. 1990).

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permits prosecution of individual conduct that might not reflect sufficient culpability because noncompliance could so easily arise from honest mistake or confusion. Therefore, Congress should consider amending the law to circumscribe the doctrine. Schiffer responded that several external norms, especially the need to prove one’s case to federal judges and juries, gave prosecutors adequate incentives to avoid overreaching and that Lazarus’s proposals were both unnecessary and unwise. Reviving these arguments during a period when the FDA is not developing cases against many people, even for egregious conduct, may seem peculiarly academic, an unflattering characterization that the author takes quite seriously. But on the chance that more explicit language restricting abuse of the doctrine could overcome the objections of a sufficient number of senators to obtain the conversion of a misdemeanor into a felony penalty, this article takes a stab at walking the middle line between the Lazarus/Schiffer debate.

In 1990, the British Parliament enacted the Food Safety Act, which imposes criminal penalties for “offences” of up to two years in jail, a £20,000 fine, and cancellation of a firm’s license or registration.<sup>100</sup> “Offence” is defined, *inter alia*, as “render[ing] any food injurious to health by means of . . . adding any article or substance to the food.”<sup>101</sup> The definition also includes the sale of food that is “injurious to health” or “unfit for human consumption.”<sup>102</sup> The Act also applies a version of the responsible corporate officer doctrine: a “director, manager, secretary, or other similar officer,” or “any person . . . purporting to act in any such capacity,” is

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<sup>100</sup> Food Safety Act, 1990, c. 16 (U.K.).

<sup>101</sup> *Id.* § 7.

<sup>102</sup> *Id.* § 8(2).

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liable to the same extent as the corporation if the violation is committed with the “consent or connivance” of the individual.<sup>103</sup>

To modulate the application of strict liability and give food processors an incentive to self-regulate, the British law creates a “due diligence” defense allowing the accused to prove that she “took all reasonable precautions and exercised all due diligence to avoid the commission of the offence.”<sup>104</sup> Consistent with responsible corporate officer enforcement, these efforts must cover any person under the control of the defendant.<sup>105</sup> The law suggests that to prove diligence, a person could show that commission of the offense was due to an “act or default” either of a person “not under his control” or done in “reliance on information supplied by such a person.”<sup>106</sup> This provision could be read to exempt manufacturers such as Kellogg from acts or omissions of its suppliers, such as PCA. However, it is joined by the word “and” with two additional provisos.

- The accused carried out all “checks of the food in question as were reasonable” or that “it was reasonable” for the accused “to rely on checks carried out by the person who supplied the food to him;” and
- The accused “did not know and had no reason to suspect” that the “act or omission would amount to an offence.”<sup>107</sup>

A detailed examination of how the due diligence defense could or should be implemented is beyond the scope of this article. Four reference points that flesh out the proposal to adopt it in the United States should assist readers to make a threshold assessment of its desirability.

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<sup>103</sup> *Id.* § 36.

<sup>104</sup> *Id.* § 21(1).

<sup>105</sup> *Id.* § 21(3).

<sup>106</sup> *Id.* § 21(3)(a).

<sup>107</sup> *Id.* § 21(3)(b),(c).

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First and foremost, the defense should not be applicable to the conduct exemplified by the PCA peanut scandal because that company’s executives failed to make reasonable efforts to ensure the safety of the food they processed. Ironically, one of the strongest arguments in potential defendants’ favor should the PCA criminal case ever go to trial is that Georgia state inspectors did not cite the company for its own mistakes. Yet those mistakes were anything but subtle or hidden. This anomaly suggests that the due diligence defense should be conditioned on federal “overfilling” authority: that is, favorable state inspections should not foreclose initiation of a federal prosecution. This approach would forestall collusion between underfunded and incompetent state inspectors and bad corporate actors.

Both the House and Senate FDA reform bills strengthen the requirement in existing law that food processing facilities register, by adding requirements that they register annually or biennially, and that they update their registration within thirty days after any change in critical information.<sup>108</sup> Foreign facilities providing food for American consumers are also required to register.<sup>109</sup> Failing to register should constitute a rebuttable presumption that the facility’s owner, operator, or agent cannot meet the burden of proof under the due diligence defense, with only cases involving legitimate disputes at the borderline of the new law’s definition of what constitutes a covered facility creating justification for overturning the presumption. This scheme could be set forth in legislative history.

Third, the bills also require the preparation and implementation of “hazard analysis and risk-based preventive controls” plans and “food safety plans” by owners, operators, or agents of

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<sup>108</sup> Compare H.R. 2749, 111th Cong. § 101(b) (2009) (annual registration); S. 510, 111th Cong. § 102 (2009) (requiring biennial registration); with 21 U.S.C. § 350d (2006) (requiring initial registration only).

<sup>109</sup> H.R. 2749, 111th Cong. § 204-205 (2009) (registration for commercial importers of food and customs brokers); S. 510, 111th Cong. §§ 301-309 (2009) (foreign supplier verification program).

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covered facilities.<sup>110</sup> Enforcing criminal penalties against companies that prepare plans that are inadequate or that prepare adequate plans but do not implement them effectively will involve more complex deliberations among prosecutors, regulators, and defense attorneys. Congress should require the Department of Justice, in consultation with the FDA, to prepare detailed guidelines on how it will exercise its prosecutorial discretion. In general, a company that makes a good faith effort to comply with planning requirements, and that establishes a robust system for conducting internal self audits of its plan's procedures, should be exempt from criminal prosecution.

Fourth, and arguably most important, the Department of Justice should make it a priority to prosecute violations of safety requirements by importers of food products. The abandonment of any effort to mandate that the FDA employ a FSIS approach to certifying the efficacy of exporting nations' regulatory systems should come with the recognition that the only way to protect public health in this country is to place a far heavier burden on importers to ensure that they verify minimal safety practices at the food facilities where their products originate.

### CONCLUSION

In an era when Congress must move quickly and with determination to reclaim the efficacy of the FDA's regulatory programs for food safety, but is unwilling to increase the agency's funding to the point that traditional inspection programs can coax food producers into compliance, deterrence-based enforcement is the best alternative for reform. Criminal penalties must be an integral component of that approach. Industry fears of the unfair exercise of prosecutorial discretion are outweighed by the urgent need resuscitate a safer marketplace.

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<sup>110</sup> H.R. 2749, 111th Cong. § 102; S. 510, 111th Cong. § 103. Both bills leave existing Hazard Analysis Critical Control Point (HACCP) plan regulations in place.

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Adopting a due diligence defense modeled on England's food safety law is a promising way to balance these concerns and imperatives.