

FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies
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Regulatory Reform

FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need For Procedural Safeguards to Reduce "Transparency" Policy Harms in the Post-9/11 Regulatory Environment

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VOLUME 64 NUMBER 3 2009

FDA's Expanding Postmarket Authority to Monitor and Publicize Food and Consumer Health Product Risks: The Need For Procedural Safeguards to Reduce "Transparency" Policy Harms in the Post-9/11 Regulatory Environment

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INTRODUCTION

The legitimacy of the government's interest in protecting the public's health is rarely questioned by Americans. In fact, protecting "public health" is such a widely treasured value, rational persons are not ordinarily prepared to oppose it. Because of the close relationship between "[a] safe and healthy population" and the strength of a country's "government structures, social organizations, cultural endowment, economic security and national defense," some public health law scholars have argued that protecting public health is of such supreme importance that it must transcend all other values when it comes to weighing disparate and competing legal interests.¹

A leading constitutional law scholar, Jonathan Turley, has cautioned that in times of crisis, there is a tendency to grant the government "extreme discretionary authority" with little foresight or consideration concerning the risks such authority presents to law-abiding citizens. Turley notes, "[i]f history can teach us anything, it is that our greatest injuries in a time of crisis are often self-inflicted. This is because government power operates like a gas in a closed space. As you expand the space, the gas fills it completely and absolutely, and it is often hard to restrict that gas again ... [W]e need to consider not just the dangers we face but those we create in an emergency."²

During the eight-year period that has followed the terrorist attacks of September 11, 2001, (9/11), a host of new laws have been enacted which dramatically expand the government's authority and resources to conduct routine surveillance and data collection with respect to the activities of law-abiding people and organizations. Propelled by appeals to strengthen U.S. preparedness to respond to public health emergencies and bioterrorist attacks, sweeping amendments to the Federal Food Drug and Cosmetic Act (FDCA) have been enacted, which grant the Food and Drug Administration (FDA) expansive authority to access company records, Med-Watch adverse event reports, medical records, and other information deemed to be relevant for purposes of monitoring postmarket safety risks associated with food,

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¹ Gostin, Lawrence O., *Symposium: A Theory and Definition of Public Health Law*, 10 J. HEALTH CARE L. & POL'Y 1, 2 (2007).

² See *Public Health and Private Rights: Communicable Diseases, Panic Attacks, and the Constitution*, CATO POLICY FORUM, Wash., D.C., Cato Institute (May 27, 2003) available at <http://www.cato.org/events/030527pf.html>.

dietary supplements, nonprescription drugs, and other consumer health products. The amendments also grant FDA broad discretionary authority to make postmarket product safety determinations and to issue warnings to the public concerning potential product safety risks. The “emergency preparedness” concerns that have shaped FDCA policy developments in the post-9/11 period may help to explain why such dramatic expansions to FDA authority have been allowed to progress so rapidly during the past eight years without any significant public scrutiny concerning the need for procedural safeguards to ensure that FDA can exercise its expanded authority in a manner that complies with constitutional and administrative law standards, and protects the public and regulated companies from unintended and undue harm.

This article provides a summary of the expansion in FDA’s discretionary authority in the post-9/11 period, particularly with respect to FDA’s postmarket authority to monitor and publicize potential health risks linked to food, dietary supplements, nonprescription drugs, and other consumer health products. In addition, this article evaluates the need for FDA to establish procedural safeguards to reduce the significant risks of unintended and undue harm to people and regulated companies that can result from adverse publicity in the more “transparent” post-9/11 FDA regulatory environment. Specifically, Part I summarizes the amendments to the FDCA enacted during the post-9/11 period that have expanded FDA’s postmarket authority to, monitor, evaluate, and publicize potential health risks linked to food, dietary supplements, nonprescription drugs, and other consumer health products marketed in the United States, in conjunction with FDA’s Sentinel Initiative, Reportable Food Registry, and other adverse event reporting requirements.

Part II discusses the convergence of FDA’s expanded postmarket authority to publicize product-related risks with President Obama’s Transparency Initiative aimed at fostering “open government” through increased public access to government information. In addition, Part II considers the nature of the procedural safeguards needed in the post-9/11 FDA regulatory environment, in view of FDA’s historical record and illustrative cases that help expose how adverse “transparency” surrounding FDA warning letters, recalls and safety alerts concerning products in the marketplace can have undue and unintended prejudicial and harmful effects for the people and companies that are legally responsible for such products. Finally, based on these analyses, this article concludes with some observations concerning the nature of the procedural safeguards needed to reduce the significant risks of “transparency” in the post-9/11 regulatory environment.

PART I: THE EXPANSION OF FDCA POSTMARKET SURVEILLANCE AND ADVERSE EVENT REPORTING REQUIREMENTS

A. Historical Pre-Market Safety Focus of FDCA Standards

Under the legal framework of the FDCA, the principal regulatory strategy for protecting the public from product-related harms has been to impose on manufacturers the legal responsibility for establishing the safety of product formulations under the intended conditions of use, as well as the accuracy of marketing claims, *before* a product can be marketed. Historically, manufacturers of food, dietary supplements, cosmetics, and nonprescription drugs had no explicit obligation under the FDCA to engage in systematic postmarket monitoring of product-related harms to consumers or to report such harms (i.e., “adverse events”) to FDA. Instead, the well-established legal obligations of manufacturers to monitor and respond to

postmarket product risks to safeguard consumers historically have been governed principally by the elaborate body of product liability and consumer protection laws which have been adopted in all 50 states.³

In addition, under the FDCA, FDA historically has had no explicit legal mandate to engage in systematic postmarket surveillance, data collection or reporting with respect to safety risks that may be presented by food, dietary supplements, cosmetics, or nonprescription drug products. As a general policy matter, there has been a clear boundary separating the public health regulatory and enforcement functions of FDA from the broader public health and disease risk reporting surveillance functions of other federal agencies. For example, the disease surveillance functions have principally been reserved for FDA's non-regulatory sister agency in the U.S. Public Health Service—The Centers for Disease Control and Prevention (CDC). During the period since 9/11, there has been a rapid expansion of both the responsibilities of product manufacturers and FDA to engage in postmarket surveillance and reporting activities under the FDCA, and an expansion of FDA's discretionary authority to encompass not only increased enforcement authority, but also increased access to product-safety related information through its new public health surveillance and data collection responsibilities.

B. *Expanding FDCA Recordkeeping, Postmarket Surveillance and Adverse Event Reporting Requirements in the Post-9/11 Period*

Since 2001, several amendments to the FDCA have been enacted which dramatically expand FDA's access to postmarket product safety related information through the imposition of records maintenance and postmarket reporting obligations on product manufacturers, suppliers, and distributors.⁴ These amendments also have expanded FDA authority to access product-related data from publicly-owned databases containing public health and medical data. In addition, under pending legislation, FDA's discretionary authority to monitor product safety-related information and publicize potential risks to public health would be further expanded.⁵

1. *Bioterrorism Act Amendments*

In 2002, in direct response to the events of 9/11, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bio-

³ See Rosati, Kristen, et al., *An Analysis of Legal Issues Related to the Use of Electronic Health Information in Pharmacovigilance Programs*, eHI Connecting Communities for Drug Safety Collaboration, (Apr. 15, 2008), at 7, 45-47, available at http://www.ehealthinitiative.org/assets/Documents/eHI_Drug_Safety_Collaboration_Legal_Guidance_Developed_by_Coppersmith_Gordon_04.01.08.pdf.

⁴ For example, products currently covered by FDA's MedWatch reporting system include prescription and nonprescription drugs, dietary supplements, biologics, and human cell and tissue products. See FDA, MedWatch, at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>. Although cosmetics currently are not subject to mandatory reporting requirements, FDA postmarket surveillance programs under the Sentinel Initiative are planned to encompass all FDA-regulated products, including cosmetics. See discussion at page 9 *infra*.

⁵ See, e.g., FDA Globalization Act of 2009, H.R. 2749, 111th Cong. § 106(a) (2009); FDA Food Safety Modernization Act, S. 510, 111th Cong. §101(a) (2009). Section 106(a) of the FDA Globalization Act would expand FDA's discretionary authority to access and copy company records not only when it has a "reasonable belief" that an article of food presents a threat of serious adverse health consequences or death, but also when an article of food is "misbranded, or otherwise in violation of the Act." In addition, under section 101(a)(1), whenever FDA has a reasonable belief that an article of food presents a threat of serious adverse health consequences or death, the agency would have the discretionary authority to access and copy records not only with respect to that article of food, but also "any other article of food likely to be affected in a similar manner."

terrorism Act),⁶ amending the FDCA to add section 414 establishing expanded requirements regarding the maintenance of company records subject to FDA inspection. Under the Bioterrorism Act amendments, the expansion in FDA's discretionary authority to access and copy company records is triggered when FDA has a "reasonable belief" that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

In December 2004, FDA issued final regulations regarding the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold or import food.⁷ The regulations clarified that the definition of "food" is the same as that in section 201 of the FDCA, meaning human food and dietary supplements, animal feed, pet food, chewing gum, and articles used for components of any such article. The records companies are required to maintain under the regulation include those necessary to identify the immediately preceding sources and subsequent recipients of food in the supply chain. While these recordkeeping and related requirements were developed in contemplation of both conventional product-related risks and a desire to equip FDA with the information and legal authorities needed to respond to emergencies such as intentional tampering or terrorism, they have been invoked in numerous FDA investigations of foodborne illness, including in the FDA investigation of tainted wheat gluten from China discovered in pet food which ultimately resulted in the criminal prosecution of certain persons.⁸

2. 2006 Amendments Establishing Postmarket Adverse Event Reporting Requirements for Dietary Supplements and Nonprescription Drug Products

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) amended the FDCA to establish mandatory reporting requirements for "serious adverse events" associated with use of dietary supplements and nonprescription drugs.⁹ Under the DSNDCPA a "responsible person"—meaning a manufacturer, packer, or distributor whose name appears on the label of a dietary supplement or nonprescription drug marketed in the United States¹⁰—is required to report to FDA "any report received of a serious adverse event associated with [a dietary supplement or nonprescription drug] when used in the United States, accompanied by a copy of the label on or within the retail packaging of such [dietary supplement or nonprescription drug]."¹¹ Under the DSNDCPA, a

⁶ See Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594. Notably, anti-tampering measures had already been in place since 1983. That year, Congress passed the Federal Anti-Tampering Act after several people died from consuming tampered-with Tylenol. Generally the law granted the federal government criminal authority over tampering with foods, drugs, cosmetics, and other consumer products. Pub. L. No. 98-127, 97 Stat. 831 (1983).

⁷ Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,561 (Dec. 9, 2004).

⁸ Press Release, U.S. Dep't. of Justice, *Business Owners Plead Guilty to Distributing Tainted Ingredient Used in Pet Food* (June 16, 2009) available at <http://www.usdoj.gov/usao/mow/news2009/miller.ple.htm>.

⁹ See Pub. L. No. 109-462, 120 Stat. 3469 (2006). Adverse event reporting and recordkeeping requirements already were already in effect for prescription drugs. See Postmarketing reporting of adverse drug experiences, 21 C.F.R. § 314.80.

¹⁰ See 21 U.S.C. §§ 379aa(b)(1), 379aa-1(b)(1) (FDCA §§ 760(b)(1), 761(b)(1)). If a retailer's name appears on the label, the retailer may, via agreement, authorize the manufacturer to submit the required reports, provided that the retailer directs to the manufacturer all reported adverse events related to the product.

¹¹ *Id.*

“serious adverse event” is one that results in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, a congenital anomaly or birth defect, or requires, based on reasonable medical judgment, a medical or surgical intervention to prevent such an outcome.¹² Serious adverse event reports must be made within 15 days of learning of the event¹³ and must be submitted, along with a copy of the product label, on a MedWatch form through the agency’s electronic MedWatch “Portal.” A serious adverse event report must include five minimum pieces of information prior to being submitted to FDA:

- An identifiable injured person;
- An identifiable initial reporter;
- The identity and contact information for the responsible person;
- Identification of the suspect dietary supplement or nonprescription drug; and
- A description of the serious adverse event or fatal outcome.¹⁴

While the above requirements are mandatory for manufacturers, packers, and distributors, voluntary adverse event reports regarding nonprescription drugs or dietary supplements may be submitted by consumers, health care providers, or any other entity not subject to mandatory reporting. Manufacturers, packers, and distributors also may submit voluntary reports of adverse events that do not qualify as “serious adverse events.” A responsible person is required to maintain records related to each report of all adverse events for six years.¹⁵ Under the DSNDPCA, FDA has broad discretionary authority to make product safety determinations based on the information it receives from MedWatch reports and other sources, and to issue warnings to the public based on its findings with respect to potential product-related safety risks.

3. 2007 FDAAA Amendments Establishing the “Reportable Food Registry” for Human and Animal Food Products

The Food and Drug Administration Amendments Act of 2007 (FDAAA) further expanded postmarket surveillance and reporting requirements concerning product-related safety.¹⁶ For example, the FDAAA established a “Reportable Food Registry,” an FDA-managed database designed to document food adulteration

¹² See *id.* §§ 379aa(a)(3), (b)(1), 379aa-1(a)(3), (b)(1) (FDCA §§ 760(a)(3), (b)(1), 761(a)(3), (b)(1)).

¹³ The responsible person must report serious adverse events received via the address or phone number on the label of the dietary supplement [or nonprescription drug] within 15 days of receipt of the report, if all five data elements are present. FDA also has stated in its guidance that serious adverse events received via other means also should be reported within 15 days. In addition, a responsible person must submit follow-up information relating to a serious adverse event report within 15 days if received within 1 year of the initial report. See, e.g., FDA, *Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act* (2009), available at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm171383.htm> [hereinafter *Dietary Supplement Guidance*].

¹⁴ See *Dietary Supplement Guidance*, *supra* note 13. In addition, while not required, FDA also recommends including hospital discharge summaries, autopsy reports, relevant laboratory data, and other critical clinical data.

¹⁵ See 21 U.S.C. §§ 379aa(e)(1), 379aa-1(e)(1) (FDCA §§ 760(e)(1), 761(e)(1)).

¹⁶ Although this article focuses on legislative and other requirements applicable to food and over-the-counter consumer health and personal care products only, the authors note that the FDAAA also expanded postmarket surveillance and reporting requirements for prescription drugs and other medical products.

incident reports for conventional food and beverage products intended for human consumption in ways that are comparable, but broader than the DSNDCPA requirements.¹⁷ Just as with the “adverse event” reporting requirements for dietary supplements and nonprescription drugs, food adulteration incident reports must be submitted through FDA’s MedWatch Plus Portal, the agency’s new electronic system for aggregating, processing and storing product safety related incident reports for all FDA-regulated products.¹⁸

In June 2009, FDA announced the availability of its draft document, “Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007.”¹⁹ As explained in the draft guidance, the Reportable Food Registry requirements provide that a “responsible party” must use the electronic portal to submit a report to FDA when it determines that an article of food is a “reportable food.” A “reportable food” is an article of food, other than infant formula or a dietary supplement product, for which there is a “reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals.”²⁰ This definition is generally consistent with the standards that would trigger a Class I recall under current FDA policies,²¹ as well as the expanded FDA authority to access and copy company records under the Bioterrorism Act, and would include, for example, foods containing an undeclared allergen. The definition also is comparable to the standard defining “serious adverse events” that triggers mandatory reporting obligations for manufacturers, packers, and distributors of dietary supplements and nonprescription drug products described above. A “responsible party” is defined as a person required to submit a food facility registration under section 415 of the FDCA—i.e., the owner, operator or agent in charge of a domestic or foreign facility that manufactures, processes, packs, or holds food for consumption in the United States—but not a retailer or a restaurant. A responsible party must submit a report to FDA as soon as practicable, but in no case later than 24 hours after determining that an article of food is reportable.

Upon receiving a report, FDA may require the responsible party to submit an amended report to provide contact information for the immediate previous sources and immediate subsequent recipients of the article of food, or to notify such parties of certain facts surrounding the report. In addition, FDA may require a recipient of a notification (if the recipient is itself a responsible party) to submit a report to FDA, investigate the cause of the adulteration (if it may have originated with that party), and provide further notification to the recipient’s immediate previous sources and immediate subsequent recipients of the reportable food.²² All responsible parties must maintain records related to each report received, notification made, and report submitted to FDA for two years.²³

¹⁷ See *supra*, part I.B.2. of this article.

¹⁸ Although the Reportable Food Registry was originally scheduled to launch on Sept. 27, 2008 (one year after the enactment of the FDAAA) and was thereafter delayed until Spring, 2009, FDA subsequently announced that the program would become operational on Sept. 8, 2009. See 74 Fed. Reg. 27803 (June 11, 2009).

¹⁹ See Draft Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007, Availability, Announcement of Further Delay in Implementation of the Food and Drug Administration Amendments Act of 2007, 74 Fed. Reg. 27,803 (June 11, 2009) [hereinafter Reportable Food Guidance].

²⁰ *Id.*

²¹ See 21 C.F.R. 7.41; see also, *Guidance for Industry: Product Recalls, Including Removals and Corrections*, available at, <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>.

²² See Reportable Food Guidance.

²³ *Id.*

“Data elements” that must be included in an initial report to the agency concerning a “reportable food,” include:

- A description of the article of food that the responsible party has determined to be a reportable food, including the quantity or amount;
- The extent and nature of the adulteration of the article of reportable food;
- When known, the results of any investigation of the cause of adulteration, if it may have originated with the responsible party; and
- When known, the disposition of the article of food.²⁴

Federal, state, and local public health officials may submit instances of reportable food through the portal as well.²⁵

Dietary supplements are excluded from the Reportable Food Registry requirements but are covered by similar adverse event reporting requirements under the DSNDCPA described above. In addition, the Reportable Food Registry provides a very narrow exemption for instances of food adulteration discovered and corrected before the article of food is transferred to any other party. More specifically, the Reportable Food Registry reporting requirements do *not* apply to a person otherwise qualifying as a “responsible party” if 1) the adulteration originated with the responsible party; 2) the responsible party detected the adulteration prior to any transfer of the article of food to another person; *and* 3) the responsible party has corrected the adulteration or destroyed the article of food.²⁶ Notably, the second prong of the exemption states broadly that the article of food must not have been transferred to “another person,” rather than specifying that the article of food must not have been transferred to *consumers*.

Like the DSNDCPA, the FDAAA grants FDA broad discretionary authority to make food safety determinations based on the information it receives from MedWatch reports submitted to the Reportable Food Registry and other sources, and to issue warnings to the public based on its findings with respect to potential food safety risks.

²⁴ *Id.* The data elements also must include the food facility registration number of the responsible party making the report; the date on which the article of food was determined by the responsible party to be a reportable food; and the product information typically found on packaging to identify the article of food (e.g., product codes, use-by dates, names of manufacturers, packers, distributors).

²⁵ In addition, although not an FDCA amendment, the Obama administration has recently demonstrated its support for a broader, related food safety reporting initiative that likely will affect FDA's implementation of the Reportable Food Registry and further increase its impact. On July 7, 2009, President Obama's Food Safety Working Group announced its key findings and recommendations regarding a public health-focused approach to food safety based on prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery. One of the working group's key findings and recommendations was the creation and implementation—within three months—of a government-wide “Unified Incident Command System,” designed to address outbreaks of food borne illness and to link all relevant federal agencies and state and local governments to facilitate more effective communication and decision-making in an emergency. Press Release, The White House, *Obama Administration Delivers on Commitment to Upgrade U.S. Food Safety System* (July 7, 2009) available at http://www.whitehouse.gov/the_press_office/Obama-Administration-Delivers-on-Commitment-to-Upgrade-US-Food-Safety-System.

²⁶ FDCA § 417(d)(2). In addition, we note that currently-pending food safety legislation could, if passed, expand the application and requirements of the Reportable Food Registry in several respects, including by expanding the reporting requirements to farms, restaurants, and retail food establishments and by requiring responsible parties to submit any analytical results from testing along with their reports. Further, the legislation would specifically authorize the public disclosure of information otherwise exempt under FOIA if the Secretary of Health and Human Services determines such disclosure is necessary to protect public health. See Food Safety Enhancement Act, H.R. 2749, 111th Cong. section 112 (2009).

4. 2007 FDAAA Amendments Establishing the “Sentinel Initiative” Postmarket Risk Monitoring System

The FDAAA further expanded FDA authority to access postmarket product safety-related information from electronic health records maintained by governmental and private organizations, through a program known as the “Sentinel Initiative.” The FDAAA amendments established FDCA section 505(k)(3), which requires FDA to create a “post-market risk identification and analyses system” linking product safety data from multiple sources, including not only adverse event reports submitted to FDA under the DSNDCPA and Reportable Food Registry requirements discussed above, but also healthcare and public health surveillance data (Sentinel data), which will eventually be used to monitor all FDA-regulated products in the market.²⁷

More specifically, in relevant part, the FDAAA provides:

The Secretary shall, not later than 2 years after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, in collaboration with public, academic, and private entities—

(i) develop methods to *obtain access* to disparate data sources ... ;

(ii) develop *validated methods* for the establishment of a postmarket risk identification and analysis system *to link and analyze safety data* from multiple sources ... ; and

(iii) convene a *committee of experts*, including individuals who are recognized in the field of protecting data privacy and security, to make recommendations to the Secretary on the development of tools and methods for the ethical and scientific uses for, and communication of, postmarketing data ... including recommendations on the development of effective research methods for the study of drug safety questions.²⁸

FDA formally launched the “Sentinel Initiative” in May 2008, but has not yet fully implemented the program. Once the Sentinel Initiative is fully implemented, FDA intends to rely on Sentinel data to monitor the safety of all FDA-regulated products intended for use in humans or animals, *including all food and dietary supplements products, cosmetics, nonprescription drugs and other consumer health care products, as well as medical products for human and veterinary use.*²⁹ In addition, FDA intends

²⁷ FDAAA § 905, amending § 505 of the FDCA. The information that will be made available through the Sentinel System is being developed primarily as a result of a series of contracts awarded by FDA. At least eight contracts already have been awarded to entities charged with exploring a variety of topics to inform the development of the new system. In addition, several pilot projects already are underway, designed to answer some of the many technical and policy-related questions and challenges posed by the system. In June 2009, FDA announced the availability of grant funds to support an independent entity’s work to organize conferences and meetings with stakeholders and experts to explore the methodological, data development, technical, and communication issues related to active medical product surveillance. The grant recipient is expected to synthesize, summarize, and communicate findings from the meetings to a broad range of individuals who will use the information to further develop the surveillance systems.

²⁸ *Id.* (emphasis added).

²⁹ See FDA, *FDA’s Sentinel Initiative: Background*, available at <http://www.fda.gov/Safety/FDAs-SentinelInitiative/ucm149340.htm>.

to monitor, collect, and evaluate Sentinel data in “real time,” including through such activities as conducting electronic searches of medical and public health records maintained and controlled by governmental agencies and private companies, including healthcare services and insurance providers.³⁰ Under the Sentinel Initiative, FDA plans to have access to medical and public health data maintained and controlled by the Veterans Health Administration, Department of Defense, National Institutes of Health, and Medicare, and coordinate its data collection and evaluation programs with these and other federal and state governmental agencies.³¹

The FDAAA grants FDA broad discretionary authority to make postmarket product safety determinations based on its evaluation of Sentinel data. FDA has indicated that the agency intends to publicize “confirmed findings” that are made through its evaluation of Sentinel data. The agency has not yet issued regulations or policies establishing the specific scientific and regulatory standards that will govern the agency’s exercise of discretion with respect to its evaluation of Sentinel data, confirmation of findings concerning product safety risks, or the conditions under which FDA intends to make its findings public through warnings or other publicity.³²

FDA has acknowledged that the Sentinel Initiative presents sensitive medical privacy issues and recognized the agency’s legal obligations to protect the privacy interests of product consumers. For example, FDA briefing papers indicate that the agency does not intend to collect or maintain copies of patient medical records or other personal health information pertaining to particular identifiable persons. However, FDA has not yet codified this commitment in regulations or policies that can be readily understood and enforced by the people or companies that are affected.³³ In addition, FDA has not yet acknowledged the broader implications the Sentinel Initiative presents in the context of constitutional and administrative law standards generally, nor fully addressed its obligations with respect to the people and companies whose legal interests may be prejudiced or harmed by the actions FDA chooses to take based on its evaluation of Sentinel data.³⁴

In view of the expanding breadth and sensitivity of the information that the Sentinel Initiative is bringing within FDA’s control, there is a critical need to establish procedural safeguards so that the agency can exercise its expanding discretionary authority in accordance with constitutional and administrative law standards and reduce the risks of undue and unintended harms to the people and companies that have legal responsibility for the FDA-regulated products in the marketplace.

³⁰ See FDA, *The Sentinel Initiative: Fact Sheet*, available at <http://www.fda.gov/Safety/FDAs-SentinelInitiative/ucm089489.htm>.

³¹ See FDA, *The Sentinel Initiative: Monitoring Medical Product Safety*, at 8, 18 (May 2008) available at <http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf>.

³² See FDA, *The Sentinel Initiative: Questions and Answers*, available at <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm089481.htm>.

³³ See Rosati, Kristen, *An Analysis of Legal Issues Related to Structuring FDA Sentinel Initiative Activities*, eHI Health Initiative Foundation, (Mar. 31, 2009), available at <http://www.regulations.gov/search/Regs/contentStreamer?objectId=090000648098bad2&disposition=attachment&contentType=pdf>. “The creation of a distributed data network that leaves individually identifiable data at the data source, versus creating a centralized database for analysis, alleviates many of the privacy concerns that might otherwise surround the transmission of individually identifiable data to FDA or its partners.” *Id.* at 2.

³⁴ *Id.* Notably, this report, dedicated to exploring all the legal issues surrounding participation in pharmacovigilance programs (such as the Sentinel Initiative), includes no discussion of the increased risk of disseminating inaccurate adverse information in a manner that negatively impacts patients or regulated-companies. See also, Rosati, Kristen, *An Analysis of Legal Issues Related to the Use of Electronic Health Information in Pharmacovigilance*, eHI Health Initiative Foundation, (Apr. 15, 2008), available at http://www.ehealthinitiative.org/assets/Documents/eHI_Drug_Safety_Collaboration_Legal_Guidance_Developed_by_Coppersmith_Gordon_04.01.08.pdf.

In order to develop procedural safeguards that provide adequate protection to the legal rights and interests of the affected parties, it is essential that these rights and interests be fully characterized along with the procedural safeguards that have already been established to protect these interests under existing constitutional and administrative law standards.³⁵ In addition, the legal rights of the people and companies held legally responsible for product compliance with FDCA standards merit careful scrutiny in the development of procedural safeguards that are adequate to address the distinctive risks presented in the post-9/11 legal and social environment.³⁶ Notably, while the Sentinel Initiative has been characterized principally as a postmarket surveillance and public warning program, procedural safeguards are needed which fully account for the fact that, once under FDA's control, sensitive and potentially prejudicial Sentinel data may be used by FDA and other governmental agencies to pursue administrative, civil, or criminal enforcement actions against the people and/or companies implicated by FDA's findings concerning alleged product safety risks. In addition, should FDA make sensitive product safety data or related FDA findings available to the public, whether or not FDA findings prove to be valid, the people and companies who are held legally and economically responsible for the implicated product are likely to become the targets of costly and burdensome attacks on manufacturer goodwill and related consumer and commercial law suits, as illustrated by cases discussed in Part II below.

There also is a need for procedural safeguards that fully account for the increased liability risks that FDA's Sentinel Initiative presents for the people and companies that are legally responsible for the products in the marketplace. In addition, procedural safeguards must account for the unintended, but nonetheless foreseeable capacity for even well intended but unfounded actions taken by FDA to trigger a cascade of litigation under state laws, resulting in unjustified increases in legal liability and other harms to the people and companies that are implicated.

Because of the substantial liability risks and potential prejudice to the legal rights and interests of the people and companies responsible for ensuring that the products they market are safe and otherwise comply with FDCA requirements, procedural safeguards are needed to prevent and mitigate the risks presented by "false alarms" issued by FDA based on Sentinel data to the fullest extent possible. In this regard, procedural safeguards are needed which ensure that the specific scientific methodologies FDA relies on to evaluate Sentinel data and to draw conclusions which implicate the safety of products in the marketplace meet rigorous standards to ensure the scientific integrity of the agency's findings as well as the quality of the data upon which FDA findings rely. In addition, procedural safeguards are needed to prevent the release of preliminary and unsubstantiated findings that implicate the safety and FDCA compliance of a product in the marketplace, which not only may inflict undue injury on responsible people and companies, but also may compromise public confidence and FDA credibility. Official government warnings and other adverse publicity implicating the safety of particular products can inspire misplaced and exaggerated public anxiety that extract huge social and economic costs, as Professor Cass Sunstein has observed.

[W]idespread fear helps produce an array of additional problems. It may, for example, make people reluctant to engage in certain activities, such as

³⁵ See, e.g., Funk, William, *Federal Administrative Procedure Sourcebook* (ABA 4th ed. 2008).

³⁶ Gidiere, P. Stephen, *The Federal Information Manual: How the Government Collects, Manages, and Discloses Information Under FOIA and Other Statutes*, pp. 349-53 (ABA 2006).

... eating certain foods. The resulting costs can be extremely high; the mad cow disease scare is an example, producing millions of dollars of losses. ... The reduction of even baseless fear is a social good, not least because of the potentially enormous "ripple effects" associated with it.³⁷

PART II: PRESIDENT OBAMA'S TRANSPARENCY INITIATIVE: AN OPPORTUNITY TO ESTABLISH NEEDED PROCEDURAL SAFEGUARDS

A. The President's Transparency Initiative

Immediately upon assuming office on January 21, 2009, President Barack Obama issued a memorandum entitled "Transparency and Open Government," announcing his commitment "to creat[e] an unprecedented level of openness in Government" and directing the White House "Chief Technology Officer, in coordination with the Director of the Office of Management and Budget (OMB) and the Administrator of General Services, to coordinate the development by appropriate executive departments and agencies ... of recommendations for an "Open Government Directive" to be issued by the Director of OMB, that instructs executive departments and agencies to take specific actions implementing the principles set forth in this memorandum," within 120 days³⁸ The President's memorandum further stated,

My Administration is committed to creating an unprecedented level of openness in Government. We will work together to ensure the public trust and establish a system of transparency, public participation, and collaboration. Openness will strengthen our democracy and promote efficiency and effectiveness in Government.

Government should be transparent. Transparency promotes accountability and provides information for citizens about what their Government is doing. Information maintained by the Federal Government is a national asset. My Administration will take appropriate action, consistent with law and policy, to disclose information rapidly in forms that the public can readily find and use. Executive departments and agencies should harness new technologies to put information about their operations and decisions online and readily available to the public. Executive departments and agencies should also solicit public feedback to identify information of greatest use to the public.³⁹

On the same day, President Obama issued a second memorandum directing the Attorney General to develop new Freedom of Information Act (FOIA) guidelines reaffirming the commitment to both accountability and transparency.⁴⁰ In addition,

³⁷ Sunstein, Cass. R., *The Laws of Fear: Beyond the Precautionary Principle* (Cambridge Univ. Press (2005)) at 127, citing Pidgeon, Nick, *The Social Amplification of Risk* (Cambridge Univ. Press, (2003)).

³⁸ Press Release, The White House, *Memorandum for the Heads of Executive Departments and Agencies: Transparency and Open Government* (Jan. 21, 2009) available at http://www.whitehouse.gov/the_press_office/Transparency_and_Open_Government/.

³⁹ *Id.*

⁴⁰ Press Release, The White House, *Memorandum for the Heads of Executive Departments and Agencies: Freedom of Information Act* (Jan. 21, 2009) available at http://www.whitehouse.gov/the_press_office/Freedom_of_Information_Act/.

the President's memorandum emphasized that the purpose of the "transparency" initiative is to enable the government to be held accountable for its actions. "A democracy requires accountability, and accountability requires transparency. As Justice Louis Brandeis wrote, 'sunlight is said to be the best of disinfectants.' In our democracy, [FOIA], which encourages accountability through transparency, is the most prominent expression of a profound national commitment to ensuring an open Government. At the heart of that commitment is the idea that *accountability* is in the interest of the Government and citizenry alike."⁴¹ In addition, the memorandum directed the Director of the Office of Management and Budget to update its guidance to increase and improve information dissemination to the public, including through the use of new technologies, and "to publish such guidance in the *Federal Register*."⁴²

The President's announcement has come as a welcome relief for those who have been concerned that the post-9/11 growth of government surveillance programs designed to look for suspicious conduct in the day-to-day activities of innocent people and companies has occurred behind a veil of too much secrecy. As one legal scholar observed, "[i]t is perhaps the greatest danger that can face a free society: a government cloaked in secrecy with total information on its citizens."⁴³ Since the President's announcement, federal agencies have begun to implement a host of concrete actions to expand the scope of government information that is readily available to the public through agency websites and social networking services (e.g., Twitter and Facebook). For example, according to a recent report of the General Accountability Office (GAO), more than 50 federal agencies, including FDA, currently use Twitter to distribute information to the public.⁴⁴ In addition, under current FDA transparency policies,⁴⁵ a wide range of information is available through the FDA website, including FDA warning letters, product recalls, and safety alerts based on FDA's postmarket findings with respect to products in the marketplace.

In response to President Obama's directive to federal agencies, on June 3, 2009, FDA announced the formation of a new FDA Transparency Task Force, chaired by Principal Deputy Commissioner Dr. Joshua M. Sharfstein and including agency-wide representation by the Center directors, Associate Commissioner for Regulatory Affairs, Chief Counsel and Chief Scientist, to develop recommendations for enhancing the transparency of agency activities.⁴⁶ FDA held its first public meeting to discuss the Task Force only three weeks later and intends to issue its report and recommendations by the end of the year.

The convergence of FDA's transparency initiative in response to the President's "Transparency and Open Government" agenda and the post 9/11 expansion in FDA's postmarket authority to monitor and publicize potential product safety risks has the potential to substantially amplify the risks of unintended and undue harms to people and companies that have legal responsibility for FDA-regulated products

⁴¹ *Id.* (emphasis added).

⁴² *Id.*

⁴³ Turley, Jonathan, *Big Brother Bush and Connecting the Data Dots*, LOS ANGELES TIMES (June 24, 2006).

⁴⁴ Press Release, GAO, *GAO Enlists New Technologies to Report Its Findings* (July 7, 2009) available at http://www.gao.gov/press/gao_enlists_new_technologies2009jul07.pdf. GAO has "established a presence on YouTube and Twitter to help users of such sites stay informed about GAO's work" including two Twitter feeds, one for reports and testimony and another for its legal products. See e.g., *U.S. FDA (FDA Recalls) on Twitter*, available at <http://twitter.com/FDARecalls>.

⁴⁵ See 21 C.F.R. Parts 20 and 21.

⁴⁶ See FDA Transparency Task Force; Public Meeting, 74 Fed. Reg. 26,712 (June 3, 2009).

in the marketplace. At the same time, given the priority the President has given to implementing constitutional and administrative law standards in the context of the "Transparency and Open Government" agenda, and the transcendent purpose of the President's agenda to enable the government to be held more "accountable" for its actions, the door may be open to establish the procedural safeguards needed to foster greater accountability. In the context of existing transparency policies in particular, FDA's Transparency Task Force could provide the first genuine opportunity for FDA to review its basic administrative procedures and establish procedural safeguards that account for the post-9/11 expansion in the agency's authority and the substantially increased risks of undue prejudice and harm presented in the context of the Sentinel Initiative and the related FDA programs.

B. *FDA's Historical Efforts to Strengthen Procedural Safeguards to Counter Harmful FDA Transparency*

FDA has established procedural safeguards that implement FOIA exemptions⁴⁷ and are intended to prohibit the public release of information by FDA that would "harm an interest" protected under FOIA (e.g., trade secret and confidential business information). However, in light of the broad discretion these policies grant the agency to release adverse product-related information to the public which can have prejudicial and harmful effects with respect to the interests of the people and companies that are held legally responsible for such products, the sufficiency of FDA's FOIA policies to supply the procedural safeguards needed in the post-9/11 environment must be explored. Concerns regarding the impact of FDA disclosure policies are well recognized in the context of FDA's historical "publicity" policies under FDCA section 705.⁴⁸ Under FDCA section 705, FDA is authorized to issue "report[s] summarizing decrees and court orders which have been rendered under the Act, including the nature of the charge and the disposition thereof."⁴⁹ Section 705 also authorizes FDA to "disseminate information" regarding specific products in situations involving "imminent danger to health, or gross deception of the consumer."⁵⁰

The FDA record establishes that, two decades before the post-9/11 expansion in FDA's postmarket authority to monitor and publicize potential product safety risks, the agency recognized the need for procedural safeguards to mitigate harms from adverse FDA transparency under FDCA section 705. In response to the recommendations of the Administrative Conference of the United States (ACUS),⁵¹ FDA proposed regulations to establish procedural safeguards in the form of a new "Publicity Policy." In the preamble to the proposed regulations, FDA recognized that,

despite the[] positive objectives of publicity, there are occasions when publicity can have a negative or adverse effect[s]. For example, an excess of negative information could make the public indifferent or insensitive

⁴⁷ See 21 C.F.R. Part 20.

⁴⁸ 21 U.S.C. § 375.

⁴⁹ *Id.* § 375(a).

⁵⁰ *Id.* § 375(b).

⁵¹ See *Recommendation 73-1: Adverse Agency Publicity*, 38 Fed. Reg. 16839 (June 27, 1973), available at <http://www.law.fsu.edu/library/admin/acus/acustoc.html>. ACUS was an independent agency and advisory committee created in 1968 that studied U.S. administrative processes with an eye to recommending improvements to Congress and agencies. From 1968 to 1995, ACUS issued approximately 200 recommendations, most of which have been at least partially implemented. Congressional funding for ACUS was terminated in 1995.

to important warnings about a potentially dangerous product. Adverse publicity may prejudice a defendant's right to a fair trial in a criminal prosecution, or might improperly influence civil litigation. Under certain circumstances, the issuance of publicity could create a greater hazard than that posed by a particular violation by causing a panic-type reaction. Adverse publicity can cause economic harm to both individuals and firms.⁵²

While the FDA proposal recognized that, in some cases, it may be necessary for the agency to issue potentially harmful adverse publicity, notably, the proposal affirmed FDA's commitment to "guard[] against injury from unwarranted publicity about agency charges of law violations prior to the completion of administrative proceedings to resolve disputes related to the validity of the charges," and other potential harms.⁵³ In addition, FDA's proposed regulations establishing the new FDA Publicity Policy were designed to comply with key ACUS recommendations. The ACUS recommended that agencies provide affected parties with advance notice of adverse agency publicity whenever "practicable and consistent with the nature of the proceeding."⁵⁴ The ACUS also recommended that agencies issue a "retraction or correction of adverse publicity where it is shown to be erroneous or misleading, and when a person named in publicity requests a retraction or corrections."⁵⁵ Despite FDA's commitment to strengthening procedural safeguards in the context of the agency's proposed Publicity Policy, ultimately the agency was required to abandon the proposal, citing resource constraints and competing agency public health priorities.⁵⁶

While FDA's proposed Publicity Policy was never implemented, the Department of Health and Human Services (HHS) regulations establish a similar policy, which was adopted in 1976 and governs the release of "adverse information to news media."⁵⁷ For purposes of the HHS policy, "adverse information released by an agency" encompasses "any statement or release by the Department or any principal operating component made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein."⁵⁸ Notably, while the HHS policy restricts the release of "adverse information," including information "relating to regulatory investigations of specifically identified persons or organizations or to pending agency trial-type proceedings,"⁵⁹ the policy imposes no restrictions with respect to "any disclosure of records to the public in response to requests made under [FOIA],"⁶⁰ which authorizes government agencies to release information to the public that otherwise would qualify as "adverse information" under the HHS policy. The HHS policy has not been updated since it was promulgated in 1976, and, in view of the expansive exclusion provided for "adverse information" subject to release under FOIA through electronic communications, is an inadequate model for the development of the required FDA procedural safeguards.

⁵² Administrative Practices and Procedures: Publicity Policy, 42 Fed. Reg. 12436 (Mar. 4, 1977).

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ See 56 Fed. Reg. 67,440 (Dec. 30, 1991).

⁵⁷ 45 C.F.R. Part 17. See also 41 Fed. Reg. 3 (Jan. 2, 1976); 5 U.S.C. 301.

⁵⁸ 45 C.F.R. Part 17.1.

⁵⁹ *Id.* Part 17.4. See also 45 C.F.R. Part 17.6-17.7 (requiring HHS to provide "advance notice" to respondents and prospective respondents in an agency proceeding of information to be released about the proceeding "if practicable and consistent with the nature of the proceeding" and requiring HHS to retract or correct misleading or factually incorrect statements released by HHS).

⁶⁰ 45 C.F.R. Part 17; 45 C.F.R. Part 5 (HHS regulations implementing FOIA). See also 21 C.F.R. Part 20 (FDA regulations implementing FOIA).

C. *The Need for Procedural Safeguards: Lessons from Historical Cases*

In addition to the issues articulated by FDA in its own proposed Publicity Policy, historical cases emphasize the need for procedural safeguards to accompany the impending increase in data potentially eligible for dissemination by FDA through expanded postmarket reporting and surveillance and the agency's transparency initiative. As discussed below, historical cases illustrate a range of serious risks posed by FDA's current publicity practices and enforcement policies, including with respect to FDA warning letters, recalls, safety alerts, and other matters.

1. *FDA Warning Letters*

Under established FDA policies, despite the substantial risk of undue prejudice and harms that can result from adverse publicity surrounding FDA's administrative enforcement actions, companies have little opportunity to resolve matters before FDA, much less seek judicial review of the agency's allegations, before the matter is made public. A review of past class action lawsuits brought against companies under state laws based on violations of FDCA requirements alleged in FDA warning letters shows that transparency surrounding FDA warning letters can result in substantial liability for affected companies, even when the legal basis for the FDA allegations is suspect and the subject of a pending challenge by the affected company. For example, although Carbolite Foods, Inc. (Carbolite) challenged a June 20, 2001 warning letter in which FDA alleged that the company's brand name was effectively banned under the FDCA,⁶¹ the warning letter was immediately posted on the FDA website, where it still remains. Notably, an FDA warning letter does not constitute a final agency action,⁶² and companies cannot readily obtain judicial review of the allegations stated therein. In addition, FDA has no procedural safeguards that preserve the confidentiality of the allegations until the affected company has the opportunity either to resolve the matter before FDA or seek judicial review. Nonetheless, once an FDA warning letter becomes public, the alleged FDCA violations stated in the letter can readily become the basis for lawsuits filed against the company by consumers, customers, and/or competitors alleging related

⁶¹ See Petition for Reconsideration and Stay of Action at 4, Carbolite Foods, Inc., FDA Docket 02P-0462 (FDA Feb. 13, 2003) ("FDA's decision denying the Carbolite brand name petition is unsupported by the applicable First Amendment, Administrative Procedure Act, and [FDCA] law. Accordingly, Carbolite petitions the agency to stay any enforcement action under that Decision, including any enforcement action under the June 2001 warning letter with respect to the use of the Carbolite brand name, pending reconsideration of the Carbolite brand name petition in accordance with governing law."). After receiving the Carbolite submissions, FDA took no further action against the company and announced plans to develop policies authorizing claims for low-carbohydrate weight loss diet foods, of the kind produced by Carbolite. See FDA, *CFSAN 2006 Program Priorities* (May 3, 2006), available at <http://www.fda.gov/AboutFDA/CentersOffices/CFSAN/ReportsBudgets/ucm112690.htm>.

⁶² See *Summit Tech., Inc. v. High-Line Med. Instruments, Co.*, 933 F. Supp. 918, 934, fn 9 (C.D. Cal. (1996)) ("warning letters do not constitute final agency action"); *Professionals and Patients for Customized Care v. Shalala*, 847 F. Supp. 1359, 1365 (S.D. Tex. (1994)). See also FDA, *Compliance and Enforcement* ("A Warning Letter is an informal advisory to a firm communicating the agency's position on a matter but does not commit FDA to taking enforcement action. The agency's policy is that a Warning Letter should be issued for violations which are of regulatory significance in that failure to adequately and promptly take corrections may be expected to result in enforcement action should the violation(s) continue.") available at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplianceEnforcement/default.htm>.

violations of state law.⁶³ In the Carbolite matter, while the company's challenge of the FDA allegations still was pending, a consumer class action lawsuit was filed against the company which relied on the FDA warning letter in asserting claims that the company had violated state law on related grounds.⁶⁴ The company ultimately settled the lawsuit at an estimated cost to the company of over \$1,000,000.⁶⁵

In contrast to FDA's policy to make warning letters available to the public immediately through the agency's website, under Federal Trade Commission (FTC) procedures, violations of the FTC Act alleged by FTC staff in access letters, including allegations of false advertising pertaining to food, dietary supplements, nonprescription drugs, and other consumer health products, remain confidential while the FTC investigation is pending.⁶⁶ Also in contrast to FDA practices, in the case that a company responds to the allegations in a manner that successfully establishes the company's compliance with FTC Act requirements, the allegations remain confidential, and FTC issues a public "closing letter" documenting that the agency has concluded that an enforcement action is not merited in the particular case.⁶⁷ In the case that FTC instead chooses to pursue an enforcement action, the FTC complaint and record in the case are then made publicly available.⁶⁸ The FTC procedures protecting the confidentiality of pending investigations of alleged legal violations are instructive for the development of procedural safeguards in the context of FDA warning letters and similar regulatory actions (e.g., untitled letters) alleging that products in the marketplace violate FDCA requirements.

2. "False Alarms"

Historical cases also illustrate the need for procedural safeguards to reduce the risk of substantial harm that can result when FDA issues warnings to the public concerning health risks presented by products in the marketplace that are well-in-

⁶³ For example, in 2009, a number of consumer class action and other lawsuits were filed within days after FDA issued a June 16, 2009 warning letter to Matrixx International, Inc. under state laws alleging that the company's product, Zicam, was being marketed in violation of FDCA requirements. *See, e.g.*, Complaint, *Hammett v. Matrixx Initiatives, Inc.*, No. 3:09cv00391 (S.D. Miss. (July 6, 2009)); Complaint, *Tassi v. Matrixx Initiatives, Inc.*, No. 09cv1450 (S.D. Cal. (July 2, 2009)); Complaint, *Echols v. Matrixx Initiatives, Inc.*, No. 2:09cv213 (E.D. Tex. (July 10, 2009)); and Complaint, *Coleman v. Matrixx Initiatives, Inc.*, No. 02:09cv2838 (E.D.N.Y. (July 2, 2009)). FDA warnings can cause stocks to plummet as well. *See, e.g.*, *Zicam Cold Remedy Gets FDA Warning; Matrixx Dives*, available at <http://www.bloomberg.com/apps/news?pid=20601087&sid=aiertOwjkuM8>.

⁶⁴ *See* Complaint, *Hughes v. Carbolite Foods, Inc.*, No. 22P01-0401-PL-26 (Super. Ct. Floyd County, Ind. (Jan. 21, 2004)).

⁶⁵ Final Order at 6, *Hughes v. Carbolite Foods, Inc.*, No. 22D01-0401-PL-26, (Super. Ct. Floyd County, Ind. (Mar. 15, 2006)) (recognizing that, at the time of plaintiffs' purchase of Carbolite products, the labeling disclosed the "sugar alcohols in the total carbohydrate count in the Nutrition Facts panel, and added a separate 'Carbohydrate Facts' box which itemized the different types of carbohydrates in the product," and the "Carbolite brand name" was presented on the front of the label "with the federally required phrase 'Manufactured For Carbolite Foods, Inc.'"); *id.*, at 8 (stating, "[t]here are important weaknesses in plaintiff's theories of liability. ... In this case, the labels at issue accurately stated the amount of total carbohydrates in two separate places. This would make an allegation of fraud ... [or the warranty claims] ... difficult to prove as a matter of law.").

⁶⁶ *See* 15 U.S.C. § 57b-2(f)(1) (FTC Act § 21(f)).

⁶⁷ *See* FTC, Commission Closing Letters, <http://www.ftc.gov/os/closings/commclosing.shtm>. A typical FTC closing letter states that "[u]pon further review of this matter, it now appears that no further action by the Commission is warranted at this time. Accordingly, the investigation has been closed. This action is not to be construed as a determination that a violation may not have occurred, just as the pendency of an investigation should not be construed as a determination that a violation has occurred. The Commission reserves the right to take such further action as the public interest may require."

⁶⁸ *See* 15 U.S.C. § 57b-2(d)(2).

tended, but nonetheless constitute harmful “false alarms.” The FDA warnings issued in 2008 concerning the potential health risks of *Salmonella St. Paul* contamination associated with fresh tomatoes help illustrate the range of harms that can result from “false alarms,” which not only can impose substantial costs and legal liability on the companies implicated by the warning, but also can trigger protracted avoidance of beneficial products among product consumers.

In May 2008, the CDC informed FDA of a possible “significant statistical association” between consumption of certain types of tomatoes and a multi-state outbreak of *Salmonella St. Paul*. FDA had difficulty locating the source of the salmonella because of the various ways raw tomatoes are washed, packaged, repackaged and sold. Consequently, throughout the FDA investigation, the CDC alerted consumers to various types of tomatoes that could possibly be contaminated, including red round, red plum, and red roma tomatoes. In July 2008, FDA expanded its investigation to include peppers, eventually lifting its warning on the consumption of certain types of raw tomatoes on July 17. After discovering on July 21, 2008 that one of the jalapeno pepper samples originating from Mexico tested positive for *Salmonella St. Paul*, FDA announced that there was no link between domestically-grown tomatoes or peppers and the salmonella outbreak.⁶⁹ Nonetheless, tomato growers experienced a significant and protracted decrease in sales as a result of the “tomato scare” and related consumer avoidance of fresh tomatoes.⁷⁰ California retail sales of the red round and roma tomatoes were down 50 percent in June 2008, and tomato prices for farmers decreased 50 percent as well.⁷¹ California tomato growers experienced a 40-to-50 percent drop in retail sales, translating into a direct loss of \$300,000 to dump untainted products, \$1 million of loss in sales, and up to \$24 million in direct losses resulting from low demand and low prices.⁷²

While FDA-regulated companies are reluctant to complain publicly about the high cost of well-intended, but nonetheless erroneous public warnings and product recalls, the tomato recall of 2008 is not an isolated case. For example, a faulty FDA analytical test proved costly for Sargento Foods Inc. In July 2001, FDA publicly announced that “two varieties of Sargento shredded cheese were contaminated with *Listeria monocytogenes*,” warning that the contamination could cause fatal infections among certain at-risk populations.⁷³ Even though there were no confirmed cases of *Listeria monocytogenes* contamination in any of Sargento’s products, Sargento

⁶⁹ See House Committee on Energy & Commerce, Subcommittee on Oversight and Investigations, *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health* (July 31, 2008) (Statement of David W.K. Acheson, M.D. Assistant Commissioner for Food Protection) available at http://archives.energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108.Acheson-Testimony.pdf.

⁷⁰ See House Committee on Energy & Commerce, Subcommittee on Oversight and Investigations, *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health* (July 31, 2008) (Statement of Mr. Reginald L. Brown, Executive Vice President, Florida Tomato Growers Exchange Florida) available at http://archives.energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108.Brown-Testimony.pdf.

⁷¹ See House Committee on Energy & Commerce, Subcommittee on Oversight and Investigations, *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health* (July 31, 2008) (Statement of Mr. Ed Beckman, President California Tomato Farmers) available at http://archives.energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108.Beckman-Testimony.pdf.

⁷² House Committee on Energy & Commerce, Subcommittee on Oversight and Investigations, *The Recent Salmonella Outbreak: Lessons Learned and Consequences to Industry and Public Health* (July 31, 2008) (Statement of the Honorable A.G. Kawamura, Secretary, State of California Department of Agriculture) available at http://archives.energycommerce.house.gov/cmte_mtgs/110-oi-hrg.073108.Kawamura-testimony.pdf.

⁷³ Daykin, Tom, *Plymouth, Wis.-Based Sargento Foods Tries to Recover from Erroneous Recall*, MILWAUKEE J. SENTINEL (Aug. 31, 2001).

responded to the FDA determination by immediately launching a costly nationwide recall involving more than 100,000 pounds of cheese products.⁷⁴ Several months later, after discovering the error, FDA sent a letter to Sargento apologizing for the “difficulties” caused by the false alarm and noting that the agency was reviewing its procedures to determine how the mistake had occurred,⁷⁵ but FDA issued no public statement to correct the record or bolster public confidence in the safety of the company’s products.

In contrast to the Sargento case, the government voluntarily paid \$10 million for losses suffered by cranberry growers as a result of a warning issued by the Secretary of Health, Education, and Welfare, Arthur Fleming in November, 1959. In a highly-publicized press conference, the Secretary urged the public not to eat certain cranberries because they might contain a “weed killer” found to cause cancer in laboratory rats.⁷⁶ It was later determined that most of the cranberries in the marketplace posed no significant risk to human health, but the Secretary’s false alarm triggered consumer fear and avoidance of cranberries, and the winter holidays passed with 99 percent of the year’s cranberry crop left unsold.⁷⁷

3. Zero Tolerance Compliance Standards

Historical cases also help to illustrate the substantial risk of undue and unintended harms that can result from FDA transparency in the context of “zero tolerance” type regulatory compliance standards that make it difficult or impossible for responsible companies to readily establish and document that products comply with FDCA requirements. In addition, rigid enforcement policies have the capacity to trigger massive product recalls and a cascade of costly litigation by consumers, customers, and competitors that can swamp the people and companies that have legal responsibility for products in the marketplace.

An example is FDA’s announcement in September 2000 that StarLink corn, a genetically-modified variety of corn authorized solely for use in animal feed, had been inadvertently commingled with corn intended for human consumption—a finding that constituted a violation of FDCA requirements.⁷⁸ Even though the potential for any risk to human health (particularly, whether the protein in the StarLink corn was an allergen) was still unresolved, the public announcement and resulting publicity triggered an expansive and costly series of corn and corn-containing product recalls. The volume of corn and other products affected by the StarLink recall was indeed massive, as the variety of corn was grown on approximately 350,000 acres nationwide in 2000 and nearly 300 different kinds of taco shells, tortillas, chips, and tostadas were recalled across the country.⁷⁹ The recalls quickly escalated to an international market scare that threatened the U.S. corn market,

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ See Morey, Richard S., *Publicity as a Regulatory Tool*, 30 FOOD DRUG COSM. L. J. 469, 471-472 (1975); GELLHORN, ERNEST, *ADVERSE PUBLICITY BY ADMINISTRATIVE AGENCIES*, 86 HARV. L. REV. 1380, 1413 (1973).

⁷⁷ *Id.*

⁷⁸ See Beebe, Linda, *In Re StarLink Corn: The Link Between Genetically Damaged Crops and an Inadequate Regulatory Framework for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL’Y REV. 511 (2004).

⁷⁹ Vorman, Julie, *StarLink Recall Climb to 300 Different Items* and Ingwersen, Julie, *Amount of corn mixed with StarLink hard to pin down*, (Nov. 1, 2000), available at <http://www.organicconsumers.org/ge/starlink300.cfm>.

as both domestic and foreign food manufacturers sought alternative international sources of corn.⁸⁰ In addition, the product recalls triggered a wave of class action litigation by consumers and farmers, a seventeen-state attorney general settlement, expansive and costly testing (that often could not prove the presence of the protein at issue), and a request that the Environmental Protection Agency (EPA) cancel the StarLink registration for use in U.S. agriculture.⁸¹ Notably, the company that owned StarLink settled consumer allegations of allergic reactions to the product without any conclusive evidence⁸² that the protein was in fact an allergen or posed any other human health risks.⁸³

The StarLink case illustrates the substantial harms that can result from rigid “zero tolerance” compliance and enforcement standards, which make it difficult or impossible for companies to establish and document that products which can be reasonably established as “safe” also can be marketed in compliance with FDCA requirements. The StarLink case also suggests that consistent, transparent, bright-line compliance “safe harbors” of the kind FDA has considered in the context of food allergens “thresholds”⁸⁴ can provide substantial procedural protection against the undue harms associated with product recalls, plant shutdowns, market declines, and related litigation. Particularly in view of the staggering statistics on U.S. and global hunger,⁸⁵ the StarLink case is a sobering reminder of the need for procedural safeguards to ensure that FDCA enforcement standards do not leave companies with no other “safe” choice under the law than to recall and destroy safe and wholesome food.

4. *Regulatory Policies Vulnerable to Manipulation*

Finally, analyses of security threats to government-housed information and trends in cyber terrorism show that expansions to governmental surveillance and transparency, despite providing many intended benefits to the public, can also create vulnerability to manipulation by unscrupulous third parties. For example, in 2007, the Congressional Research Service (CRS) of The Library of Congress issued a

⁸⁰ See Nelson, Amelia, *Legal Liability in the Wake of StarLink: Who Pays in the End?*, 7 DRAKE J. AGRIC. L. 241 (2002).

⁸¹ *Id.*

⁸² In noting that there was no conclusive evidence that the StarLink® protein was an allergen, the specific nature of the evidentiary standards and procedures that would be needed to mitigate the risk of a reoccurrence of a “StarLink-type” case is beyond the scope of this article.

⁸³ See Uchtman, Donald, *Symposium: Liability Issues: Lessons From StarLink*, 10 RICH. J.L. & TECH. 22 (2003).

⁸⁴ See Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food (2006), available at <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/Guidance-ComplianceRegulatoryInformation/ucm106108.htm> (recognizing that reasonable “thresholds” can be established for regulatory compliance purposes based on the best available current information, and periodically updated as needed based on a) analytical methods; b) safety assessments; c) risk assessments; or d) statutory benchmarks).

⁸⁵ See Press Release, Feeding America, *Unemployment Reaches Record Levels, Food Banks Struggle to Feed Hungry Americans* (Mar. 6, 2009) available at <http://feedingamerica.org/newsroom/press-release-archive/unemployment-rate.aspx> (noting that “as unemployment rates in the U.S. reach record levels, Feeding America, the nation’s largest domestic hunger-relief organization, today warned that the nation’s food banks could soon be overwhelmed by demand,” and “participation in the SNAP program (the Supplemental Nutrition Assistance Program, formerly known as Food Stamps) has also reached the highest levels ever.”); see also, Press Release, Food and Agriculture Organization of the United Nations, *More People Than Ever Are Victims of Hunger* (June 15, 2009), available at http://www.fao.org/fileadmin/user_upload/newsroom/docs/Press%20release%20june-en.pdf (noting that, “for the first time in human history, more than one billion people are undernourished worldwide”).

report analyzing capabilities for terrorist cyber attacks, noting that during the first half of 2005, criminal-driven computer attacks had increased by 50 percent, with government agencies targeted the most frequently.⁸⁶ The report described the various efforts being undertaken to address cyber security threats across government departments and agencies and noted that the Department of Homeland Security Secretary had created a new position of Assistant Secretary for Cyber and Telecommunications Security, acknowledging “both the efficiencies and vulnerabilities of modern technology.”⁸⁷

Particularly in light of the above, FDA’s surveillance and transparency initiatives should raise concerns regarding the range of unintended and undue harms that could potentially result when information is made available to or received from those with unscrupulous interests. For example, expansive access to database information combined with practices promoting “open government” could result in increased opportunities for cyber-attackers, or allow malicious competitors or even terrorists to intentionally submit inaccurate information about a product in order to harm a particular company or industry or to create a public health scare. Similarly, the dramatic expansion of surveillance, reporting, and transparency of safety-related information may increase the chance that such information ends up in the hands of a person or company that would use it to obtain an unwarranted competitive advantage. Thus, even though the intended public health and policy goals of increased surveillance and transparency may seem uncontroversial at first glance, such changes should not be implemented without careful scrutiny. In establishing appropriate safeguards, the potential benefits of transparency should be weighed against the real dangers that the FDA regulatory systems may be manipulated in ways that are injurious to consumers and manufacturers of FDA-regulated products.

CONCLUSION

The convergence of the post-9/11 expansion in FDA’s postmarket authority to monitor and publicize potential food and consumer health product safety risks, with President Obama’s “Transparency and Open Government” agenda and the related FDA Transparency Task Force initiative, presents both substantial risks and potential opportunities for FDA procedural reforms. On the one hand, the combined effect of FDA’s Sentinel Initiative, related postmarket programs, and increasing FDA transparency empowered by electronic communications with virtually immediate global reach presents substantial risks of undue prejudice and other harms associated with the release of adverse information and publicity that may be amplified and become intolerably virulent for the people and companies that have legal responsibility for products in the marketplace. On the other hand, in light of the policy reform priorities represented by the President’s “Transparency and Open Government” agenda, the FDA Transparency Task Force initiative could provide the agency with the first genuine opportunity to consider the need for procedural safeguards to account for the post-9/11 expansion in FDA’s postmarket authority to monitor and publicize potential health risks associated with food and consumer health products.

⁸⁶ See Congressional Research Service Report, *Terrorist Capabilities for Cyberattack: Overview and Policy Issues* at 17 (Jan. 22, 2007), available at <http://www.fas.org/sgp/crs/terror/RL33123.pdf>.

⁸⁷ *Id.* at 7-9, 23.

In this context, FDA's historical record and illustrative cases expose how adverse transparency with respect to FDA enforcement actions and product safety warnings can result in foreseeable and unduly harmful effects for people and companies legally responsible for the products at issue; however, those cases also suggest ways in which FDA's procedural safeguards can be strengthened. In view of the expanding breath and sensitivity of the postmarket information that the post-9/11 FDCA amendments have brought within FDA's control, there is a critical need for procedural safeguards to guide the agency's exercise of discretionary authority in accordance with constitutional and administrative law standards and to reduce the risks of undue prejudice and other harms to the people and companies responsible for food and consumer health products in the marketplace. In particular, there is a need for procedural safeguards to ensure that the constitutional and other legal rights of those who are legally responsible for FDA-regulated products can be readily enforced. FDA procedures must account for the fact that, once within FDA's control, sensitive and potentially prejudicial postmarket product-related information may be used not only for public health protection, but to pursue enforcement actions, which may include criminal prosecution of the people and companies held legally responsible for unsafe and violative products in the marketplace. In addition, procedural safeguards are needed which account for the undue and unintended increase in liability risks that can result from FDA actions (e.g., letters, safety alerts) for people and companies under state laws by triggering a reactive cascade of costly litigation, even before the responsible parties have the opportunity to resolve matters before FDA or seek judicial review of questionable FDA allegations or findings. In addition, procedural safeguards are needed to prevent "gaming" of FDA product risk monitoring and data collection systems and transparency policies by unscrupulous competitors or others, and to ensure the authenticity and integrity of the information upon which FDA relies in exercising its postmarket discretionary authority with respect to the Sentinel Initiative and related programs.

In this regard, based on FDA's historical record and lessons derived from illustrative cases that help expose the causal relationships between current FDA enforcement and transparency policies and their prejudicial and harmful effects for the people and companies that are legally responsible for products in the marketplace, it appears that FDA could make significant headway toward the establishment of appropriate procedural safeguards to mitigate the risk of such undue harms through systematic policy reforms, including the following:

- Establish clear and transparent policies which protect the confidentiality of pending warning letters, regulatory letters, and related investigations of alleged FDCA violations until such time as the affected parties have the opportunity either to resolve the matter with FDA or a final agency action is taken which is clearly subject to judicial review;
- Establish clear and readily-enforceable administrative procedures governing the confidentiality of FDA investigations of alleged FDCA violations, requiring the agency to issue "closing letters" in the case that the investigation concludes with an FDA finding that no enforcement action is merited in the case, and granting affected parties the option to preserve the confidentiality of the closing letter or to waive the option and permit the letter to be released by FDA;
- Establish clear and readily-enforceable administrative procedures which govern FDA's collection and evaluation of postmarket product safety-related data and

prevent the public release of preliminary findings and unsubstantiated warnings concerning potential product-related risks, except in cases presenting a public health emergency and in accordance with procedures that provide clear and enforceable procedural safeguards to protect the legal interests of the people and companies that are legally responsible for the products at issue;

- Eliminate uncertainty with respect to FDA regulatory compliance standards and enforcement policies to the fullest extent possible. This can be done by eliminating ambiguous “zero tolerance” compliance standards that make it difficult or impossible for people and companies that are legally responsible for products in the marketplace to confirm and document that their products comply with FDCA standards, with certainty. Such ambiguous compliance standards can be replaced with clear and enforceable compliance “safe harbors” that are based on the best-available technical information available at the time, which can be updated, as needed. The general approaches FDA has explored for setting compliance “thresholds” for food allergens and gluten provide useful options. By expediting the implementation of such compliance “safe harbors” and “thresholds” systematically throughout FDA’s regulatory policies concerning food and consumer health products, the agency can substantially reduce the risk of undue harms attributable to overly broad product recalls involving products that are safe and in compliance with FDCA requirements.

In view of the heightened risks of transparency in the post-9/11 period, the FDA Transparency Task Force initiative may provide the agency a prime opportunity to strengthen its procedural safeguards in a manner that is both “open” and “fair.” The crucial role FDA plays in protecting public health could not be more evident at any time than the period since 9/11. The historical FDA record, however, also demonstrates that grievous harms to FDA, the public, and FDA-regulated companies can also be the unintended result of even the most well-intentioned actions taken to protect public health. Thus, while protecting public health is of great, if not supreme, value for Americans, the words of Justice Brandeis are a timely reminder that it is precisely when the purposes of our government are the most beneficent that Americans should be most vigilant in attending to the procedural safeguards needed to protect their liberty:

*Experience should teach us to be most on guard to protect liberty when the government’s purposes are beneficent. Men born to freedom are naturally alert to repel invasion of their liberty by evil-minded rulers. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning but without understanding.*⁸⁸

⁸⁸ *Olmstead v. United States*, 277 U.S. 438, 479 (1928).