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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY and CENTER FOR ENVIRONMENTAL HEALTH, *Plaintiffs*, v. ALEX M. AZAR II, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; NORMAN E. SHARPLESS, COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Defendants*.	Case No.: 19-5168 **COMPLAINT FOR DECLARATORY AND EQUITABLE RELIEF** Administrative Procedure Act Case

INTRODUCTION

1. This is an action for declaratory and equitable relief regarding the failure by the Defendant Food and Drug Administration (FDA or the agency) to promulgate final regulations and complete actions by mandatory deadlines set by Congress in the Food Safety Modernization Act of 2011 (FSMA).[1]

2. FSMA is the first major overhaul of our country's food safety laws since 1938, and was intended to be a needed sea-change in how we regulate our food system and protect the public health.[2] It was passed by Congress in bipartisan fashion, because foodborne illness is an epidemic in the United States. The Centers for Disease Control and Prevention (CDC) estimates that every year, as a result of foodborne diseases, 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die.[3] Serious long-term health effects associated with several common types of food poisoning include kidney failure, chronic arthritis, and brain and nerve damage.[4] During the years leading up to FSMA's passage, continuous high profile outbreaks related to various foods, ranging from spinach to peanut products to eggs, underscored the dire and urgent need for oversight improvements.[5]

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[1] Food Safety Modernization Act of 2011, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 21 U.S.C. § 301 *et seq.*).

[2] Congress passed the Federal Food, Drug and Cosmetic Act on June 25, 1938. 21 U.S.C. § 301 *et seq.* (1938).

[3] Ctrs. for Disease Control & Prevention, *Food Safety: Foodborne Illnesses and Germs*, https://www.cdc.gov/foodsafety/foodborne-germs.html (last updated Feb. 16, 2018).

[4] FoodSafety.gov, *Food Poisoning*, http://www.foodsafety.gov/poisoning/index.html (last accessed Aug. 19, 2019).

[5] Gardiner Harris and William Neuman, *Senate Passes Sweeping Law on Food Safety*, N.Y. Times, Nov. 30, 2010, https://www.nytimes.com/2010/12/01/health/policy/01food.html (last accessed Aug. 19, 2019).

3. FSMA enables FDA to better protect public health by strengthening its ability to regulate and granting the agency enhanced preventative authority.[6] The law also required FDA to establish a program for the testing of food by accredited laboratories and to develop model standards that a laboratory must meet in order to be accredited by a recognized accreditation body. It was Congress's intent that the implementation of these measures by FDA would result in lives being saved, illnesses prevented, and spare even more people from being infected in the first place, by shoring up and dramatically improving the way we regulate our food system.

4. However, the positive public health outcomes that were the original intent behind FSMA can only be realized if the FDA complies with the law, by promulgating regulations, completing required actions, and enforcing provisions mandated by Congress. A statute without its implementing regulations is an empty vessel. FDA's failure to so implement FSMA leaves all Americans vulnerable to foodborne illness.

5. By 2012, FDA missed at least seven statutory Congressional deadlines for promulgating FSMA's implementing food safety regulations. Because of this failure to comply with Congress's express mandates, the Plaintiffs brought suit to compel FDA to promulgate the required regulations. *See Ctr. For Food Safety v. Hamburg*, 954 F.Supp.2d 965 (N.D. Cal. 2013) (hereafter *FSMA I*).

6. The Court held that the FDA's failure to promulgate the mandated regulations by their statutory deadlines constituted a failure to act under the Administrative Procedure Act (APA) and unlawful withholding of the regulations in violation of FSMA and the APA. *Id.* The Court then granted injunctive relief, establishing a timeline for FDA to promulgate final regulations. *FSMA I*, 2013 WL 1282144 (June 21, 2013); 2013 WL 4396563 (August 13, 2013). After FDA's motion for a stay pending appeal was denied, 2013 WL 5718339 (October 21, 2013), the parties settled and established deadlines for the completion of the rulemakings in a consent decree approved by the Court, which retained jurisdiction to oversee and enforce it. *See*

[6] U.S. Food & Drug Admin., *Background on the FDA Food Safety and Modernization Act (FSMA)*, https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma (last updated Jan. 30, 2018).

id. Dkt. No. 87. FDA met each deadline in timely fashion and promulgated the rules, the last of which was issued in May 27, 2016.

7. Throughout the course of the *FSMA I* litigation, while much of the statute's provisions were neither implemented nor enforced, the foodborne illness epidemic continued. In 2018, high-profile foodborne illness outbreaks garnered significant media coverage and highlighted the problem of tracing an outbreak back to its source in a rapid and efficient manner. FSMA requires FDA to address the traceability problem by designating foods are at an increased potential of being the source of a foodborne illness outbreak as "high-risk" and establishing recordkeeping requirements for those foods so that, in the event of an outbreak, FDA can rapidly and effectively identify the recipients of food to mitigate the outbreak. Unfortunately, FDA failed to meet the deadlines for designating "high-risk" foods and establishing recordkeeping requirements.[7] Because of the failure to comply with these traceability requirements, the Plaintiffs brought suit to compel FDA to designate "high-risk" foods and establish recordkeeping requirements. The parties settled and established deadlines for completing these actions in a consent decree approved by the Court, which retained jurisdiction to oversee and enforce it. *See Ctr. for Food Safety v. Azar*, No.18-cv-06299-YGR (N.D. Cal., June 11, 2019), ECF No. 34 (consent decree establishing compliance deadlines) (hereafter *FSMA II*).

8. Another provision of FSMA requires that, no later than January 4, 2013, FDA "shall . . . establish" a "program for the testing of food by accredited laboratories" and "a publicly available registry of accreditation bodies and laboratories accredited by a recognized accreditation body[.]" 21 U.S.C. § 350k(a)(1). Congress also required FDA to "work with the laboratory accreditation bodies . . . to increase the number of qualified laboratories that are eligible to perform testing under [21 U.S.C. § 350k(b)][.]" *Id.* § 350k(a)(3). FDA is also required to "develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology and included in the

[7] FSMA required FDA to designate "high-risk" foods by January 4, 2012 and to propose recordkeeping requirements for those foods by January 4, 2013. *See* 21 U.S.C. §§ 2223(d)(1)-(2).

publicly available registry." *Id.* § 350k(a)(6). The model standards must ensure that: (i) appropriate sampling, analytical procedures (including rapid analytical procedures), and commercially available techniques are followed and reports of analyses are true and accurate; (ii) internal quality systems are established and maintained; (iii) procedures exist to evaluate and respond promptly to complaints regarding analyses and other activities for which the laboratory is accredited; and (iv) individuals who conduct the sampling and analyses are qualified by training and experience to do so. *Id.* Finally, Congress required that the aforementioned system shall be in place no later than July 4, 2013 and utilized whenever testing is required: (i) in support of an admission of a food import; (ii) under an Import Alert; (iii) in response to a specific testing requirement under this chapter or implementing regulations, when applied to address an identified or suspected food safety problem; and (iv) whenever FDA deems appropriate to address an identified or suspected food safety problem. *See* 21 U.S.C. § 350k(b)(1).

9. The FSMA laboratory accreditation provisions are inextricably linked to and required for effective implementation of other statutory provisions. *See e.g.*, 21 U.S.C. § 2204(a)(1)(E) (integration of laboratory networks "to rapidly detect and respond to foodborne illness outbreaks"); 21 U.S.C. § 2204(c) (discussing need to "increase capacity to undertake analyses of food samples after collection, to identify new and rapid analytical techniques . . . and to provide for well-equipped and staffed facilities and progress toward laboratory accreditation under section 350k of this title[.]"[8]

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[8] *See also*, Nicholas Obolensky, *The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad*, 17 Roger Williams U. L. Rev. 887, 893 (Summer 2012), https://docs.rwu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1498&context=rwu_LR (explaining how laboratory accreditation provisions are necessary to "ensure compliance with the preventative control standards established to improve food safety and to enable FDA to respond effectively to food safety problems that may arise[.]") (last accessed Aug. 19, 2019); Kristin Eads and Jennifer Zwagerman, *In Focus: Examining the New FDA Food Safety Modernization Act*, 33 Hamline J. Pub. L. & Pol'y 123, 142-43 (Fall 2011), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2989709 (describing interrelatedness of laboratory accreditation provisions with requirement for increased number of food company inspections) (last accessed Aug. 19, 2019); Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety*, 52 Harv. J. on Legis. 125, 140 (2015), https://pdfs.semanticscholar.org/ce09/8d957088a42fbbf89834aac87c8b23ab3a59.pdf (identifying laboratory accreditation provisions as one of many "layers of assurances and

10. As FDA itself has acknowledged, testing "plays a very important role in ensuring the safety of food." Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646, 3667 (proposed Jan. 16, 2013). "An important purpose of testing is to verify that control measures, including those related to suppliers and those verified through environmental monitoring, are controlling the hazard[.]" *Id.* (citation omitted). Despite the importance of food testing, "there's currently little known about the state of food labs, and standards are largely voluntary."[9] "There is not an exact tally of the number of food laboratories that exist, nor is there an accounting of the skills and training of the food lab workforce, quality control processes employed, or access to technology."[10] "This information deficiency and lack of standardization means the country may not have the capacity to respond effectively to biological or chemical foodborne threats."[11] "It also makes it more difficult to trace the source of multi-state foodborne outbreaks."[12]

11. Congress intended the FSMA laboratory accreditation provisions to remedy these deficiencies and mandated that FDA quickly establish a new food testing program whereby an increased number of accredited laboratories following model standards developed by the agency would be in place "to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards[.]" 21 U.S.C. §§ 350k; 2204(a)(1)(E). In the years that FDA has failed to

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guarantees" intended "to achieve higher levels of trust" for products) (last accessed Aug. 19, 2019); Karen Appold, *Industry Urges FDA to Release FSMA Lab Proposed Rule*, Food Quality & Safety, Aug. 9, 2019, https://www.foodqualityandsafety.com/article/industry-urges-fda-to-release-fsma-lab-proposed-rule/ ("[a]lthough [FSMA] mentions 'laboratories' and 'laboratory test' nearly 100 times, a proposed rule addressing the quality and accuracy of that testing remains outstanding.") (last accessed Aug. 19, 2019).

[9] Robin E. Stombler, *Moving Toward Laboratory Standards*, Food Quality & Safety, Oct. 22, 2014, https://www.foodqualityandsafety.com/article/moving-toward-laboratory-standards/?singlepage=1.

[10] *Id.*

[11] *Id.*

[12] *Id.*

complete these requirements, devastating foodborne illness outbreaks have continued and spread across the country, killing hundreds and hospitalizing thousands of Americans; as Congress intended, these foodborne illness outbreaks may have been prevented or lessened if these FSMA measures were in place.

12. FDA's failure to implement FSMA's laboratory accreditation provisions by their statutory deadlines is an abdication of the agency's fundamental responsibilities. Moreover, the agency's unlawful withholding and unreasonable delay is putting millions of lives at continued risk from contracting foodborne illnesses, contrary to Congress's commands. This lawsuit therefore seeks to require FDA to complete the laboratory accreditation actions FSMA requires by Court-established deadlines.

JURISDICTION

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (United States as Defendant).

14. Plaintiffs have a right to bring this action pursuant to the Administrative Procedure Act (APA). 5 U.S.C. § 702.

15. The relief requested is specifically authorized pursuant to 5 U.S.C. § 706(1) and 28 U.S.C. § 1651 (writs).

VENUE

16. Venue properly lies in this Court pursuant to 28 U.S.C. § 1391(e) because one or more of the Plaintiffs reside in this District.

PARTIES

17. Plaintiff CENTER FOR FOOD SAFETY (CFS) brings this action on behalf of itself and its members. CFS is a public interest, nonprofit membership organization that has offices in San Francisco, CA; Portland, OR; and Washington, DC. CFS represents over 950,000 consumer and farmer members, from every state across the country. FDA's continued failure to adhere to mandatory deadlines established by FSMA has adversely affected CFS and its members.

18. Since the organization's founding in 1997, CFS's overarching mission has been to protect our food, farms, and the environment. For twenty years, CFS has been at the forefront of organizing a powerful food movement, fighting the industrial model of food production and instead promoting organic, ecological, and sustainable alternatives. Industrial food production systems have led to an increase in the prevalence of foodborne illness, perhaps first among the many health and environmental problems they have caused. For example, one major cause of food contamination is overcrowded, unsanitary conditions on confined animal feeding operations, or factory farms, where animals get sick and pass diseases on to other animals, or where food is contaminated through contact with animal waste. Another factor is our industrial food distribution system, through which contaminated food is transported across the nation. In addition, our increased reliance on imported foods (e.g., sixty percent of our seafood is imported) with unknown safety standards puts the U.S. food supply at risk. Adding to this perfect storm of risk is government deregulation and inadequate funding for inspections and oversight. CFS seeks to redress and prevent these harms through promoting sustainable, healthful forms of agriculture and food production, as well as proper government oversight and regulation of industrial paradigms.

19. CFS combines multiple tools and strategies in pursuing its goals, including public and policymaker education, outreach, campaigning and, when necessary, public interest litigation. With regard to education, CFS disseminates to government agencies, members of Congress, and the general public a wide array of informational materials addressing foodborne illnesses and food supply. These materials include news articles, policy reports, legal briefs, press releases, action alerts, and fact sheets.

20. CFS also sends action alerts to its membership. These action alerts generate public involvement, education, and engagement with governmental officials on issues related to fighting the health and environmental impacts of industrial agriculture and promoting a more sustainable, healthier food system. Collectively, the dissemination of this material has made CFS an information clearinghouse for public involvement and governmental oversight of food safety issues.

21. As *FSMA I* and *FSMA II* illustrate, CFS is one of the leading public interest organizations working to protect food safety through FSMA's direly-needed improvements.

22. Plaintiff CENTER FOR ENVIRONMENTAL HEALTH (CEH) also brings this action on behalf of itself and its members. CEH is located in Oakland, CA. Founded in 1996, CEH is a nonprofit organization dedicated to protecting the public from environmental and public health hazards. CEH is committed to environmental justice, promoting a safe and sustainable food supply, supporting communities in their quest for a safer environment, and fostering corporate accountability. CEH promotes safer food and farming to provide families the right to know what they are feeding their families. CEH works in support of safer, sustainable food production that serves to regenerate natural resources, support healthier food for consumers, and create healthier environments for farmers, farm workers, and rural communities. CEH's scientific investigations, food safety testing, legal advocacy and litigation, and work with state and national food advocacy coalitions all converge around the goals of ending unsafe, unsustainable food production practices and supporting ecological, organic alternatives that promote healthier farming and a healthier food supply. As part of its work in this area, CEH was also a plaintiff in *FSMA I* and *FSMA II.* CEH and its members are being, and will be, adversely affected by FDA's failure to adhere to FSMA's mandatory deadlines.

23. Defendant ALEX M. AZAR II is sued in his official capacity as the Secretary of the Department of Health and Human Services (HHS). As Secretary, Mr. Azar has ultimate responsibility for HHS's activities and policies and for the implementation of FSMA.

24. Defendant NORMAN E. SHARPLESS is sued in his official capacity as Commissioner of the FDA, an agency of the United States Department of Health and Human Services. FDA administers programs at HHS related to food safety. As Commissioner, Mr. Sharpless has ultimate responsibility for FDA's activities and policies, including the implementation of FSMA.

25. Defendant UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES is a federal agency of the U.S., which is charged with enhancing and protecting the

health and well-being of all Americans. HHS, including FDA, is the Agency responsible for the implementation of FSMA.

LEGAL BACKGROUND

Administrative Procedure Act

26. Pursuant to the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . is entitled to judicial review thereof." 5 U.S.C. § 702.

27. The APA's definition of "agency action" includes an agency's "failure to act." *Id.* § 551(13).

28. Pursuant to the APA, a reviewing court "shall compel agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

Food Safety Modernization Act

29. Pursuant to FSMA, FDA "shall . . . establish a program for the testing of food by accredited laboratories" no later than January 4, 2013. *See* 21 U.S.C. § 350k(a)(1)(A).

30. Pursuant to FSMA, FDA "shall . . . establish a publicly available registry of accreditation bodies recognized by the Secretary and laboratories accredited by a recognized accreditation body" no later than January 4, 2013. *See* 21 U.S.C. § 350k(a)(1)(B).

31. Pursuant to FSMA, FDA "shall develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing method and included in the registry[.]" *See* 21 U.S.C. 350k(a)(6). The model standards shall include, at a minimum, methods to ensure appropriate sampling and analytical procedures are followed, internal quality systems are established and maintained, and employees have the necessary qualifications to conduct sampling and analyses. *Id.* § 350k(a)(6)(A).

STATEMENT OF FACTS

The Food Safety Modernization Act (FSMA)

32. Foodborne illness is a significant public health epidemic in the U.S. The greater tragedy is that it is a largely preventable one.[13] CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.[14] More specifically, the U.S. Centers for Disease Control and Prevention estimates that thirty-one of the most important known agents of foodborne disease found in foods eaten in the U.S. annually cause 9.4 million illnesses, 55,961 hospitalizations, and 1,351 deaths.[15] Other unspecified agents in food consumed in the U.S. cause an additional 38.4 million gastroenteritis illnesses, 71,878 hospitalizations, and 1,686 deaths each year.[16] After combining the estimates for the major known pathogens and the unspecified agents, the overall annual estimate of the total burden of disease due to contaminated food consumed in the U.S. is 47.8 million illnesses, 127,839 hospitalizations, and 3,037 deaths.[17] Serious long-term health effects associated with several common types of food poisoning include kidney failure, chronic arthritis, and brain and nerve damage.[18] In financial terms, the annual costs to the U.S. economy due to foodborne illness have been estimated to top $93 billion a year, and that figure does not include all costs.[19]

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[13] U.S. Food & Drug Admin., *FDA Food Safety Modernization Act (FSMA)*, https://www.fda.gov/food/guidanceregulation/fsma/ (last updated Apr. 26, 2019).

[14] Ctrs. for Disease Control & Prevention, *Estimates of Foodborne Illness in the United States*, https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html (last updated Nov. 5, 2018).

[15] *Id*.

[16] *Id.*

[17] *Id.*

[18] FoodSafety.gov, *Food Poisoning*, http://www.foodsafety.gov/poisoning/index.html (last accessed Aug. 19, 2019).

[19] Robert Scharff, *State Estimates for the Annual Cost of Foodborne Illness*, 78 J. Food Prot. 1064 (2015).

33. On January 4, 2011, President Obama signed FSMA into law. FSMA enables FDA to better protect public health by strengthening the food safety system. FSMA's major elements can be divided into five key areas: preventive controls, inspection and compliance, response, imported food safety, and enhanced partnerships.[20] Preventive controls and response to foodborne illness outbreaks are only effective to the extent they are followed; therefore, FSMA grants FDA inspection and enforcement powers to ensure compliance as well as the power to create additional recordkeeping requirements for certain facilities and mandate recalls. The laboratory accreditation provisions are critical component to the successful implementation of FSMA as they are central to the agency's mandate to "increase the number of qualified laboratories" to "rapidly detect and respond to foodborne illness outbreaks and other food-related hazards[.]"[21]

34. Due to the ongoing current public health epidemic, Congress established specific implementation deadlines for FDA in FSMA. These deadlines require FDA to complete various FSMA implementation tasks by dates certain including *inter alia*: the promulgation of regulations; completion of industry guidance documents and reports; enhanced tracking mechanisms for food products to help identify possible contamination incidents; and a consumer-friendly website for recall information and foodborne illness outbreaks. FDA failed to meet many of these deadlines.

Center for Food Safety v. Hamburg (FSMA I)

35. On August 29, 2012, CFS sued FDA because of its failure to promulgate seven major FSMA food safety rules, including: (i) preventive controls for human food; (ii) preventive controls for animal food; (iii) a foreign supplier verification program; (iv) produce safety standards; (v) accreditation of third-party auditors; (vi) sanitary transport of food and feed; and

[20] U.S. Food & Drug Admin., *Background on the FDA Food Safety Modernization Act (FSMA)*, https://www.fda.gov/food/guidanceregulation/fsma/ucm239907.htm (last updated Jan. 30, 2018).

[21] 21 U.S.C. §§ 350k(a)(3); 2204(a)(1)(E).

(vii) protection against intentional contamination.[22] In April 2013, this Court granted Plaintiffs' motion for summary judgment, holding that FDA violated FSMA and the APA by failing to promulgate these regulations by their statutory deadlines.[23] The Court then granted injunctive relief and established a timeline for the FDA to promulgate final regulations. *FSMA I*, 2013 WL 1282144 (June 21, 2013); 2013 WL 4396563 (August 13, 2013). After FDA's motion for a stay pending appeal was denied, 2013 WL 5718339 (October 21, 2013), the parties settled and established deadlines for the completion of the rulemakings in a consent decree approved by the Court, which retained jurisdiction to oversee and enforce it. *See id.* Dkt. No. 87.[24] FDA met each deadline in timely fashion and promulgated the rules.[25]

Center for Food Safety v. Azar (FSMA II)

36. On October 15, 2018, the Plaintiffs sued FDA for its failure to: (i) designate those foods that have an increased risk of being the source of a foodborne illness outbreak as "high risk;" (ii) propose additional recordkeeping requirements for facilities that manufacture, process, pack, or hold "high-risk" foods; and (iii) publish a final recordkeeping rule.[26] In June 2019, the parties settled and established deadlines for the completion of the required designations and rulemaking in a consent decree approved by the Court, which retained jurisdiction to oversee and enforce it.[27]

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[22] *See Ctr. for Food Safety v. Hamburg*, 954 F.Supp.2d 965, 966-67 (N.D. Cal. 2013).

[23] *Id.* at 970-71.

[24] Consent Decree, Ctr. for Food Safety v. Hamburg, No. 12-cv-04529-PJH (N.D. Cal. Feb. 24, 2014), ECF No. 85-1.

[25] *See* U.S. Food & Drug Admin., *FSMA Rules & Guidance for Industry*, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry (last updated June 3, 2019).

[26] Complaint, Ctr. for Food Safety v. Azar, No.18-cv-06299-YGR (N.D. Cal., Oct. 15, 2018), ECF No. 1.

[27] Consent Decree, Ctr. for Food Safety v. Azar, No.18-cv-06299-YGR (N.D. Cal., June 11, 2019), ECF No. 34.

The Continuing Epidemic of Foodborne Illness

37. During and after the time it took FDA to finalize the regulations at issue in *FSMA I* and during the course of the *FSMA II* litigation, dozens of major foodborne illness outbreaks regrettably occurred, underscoring the continued need for all FSMA regulations to be implemented to effectuate the statute.

38. For example, in March 2013, a *Salmonella* Heidelberg outbreak from chicken reached twenty-nine states and Puerto Rico.[28] The outbreak hospitalized approximately 240 people and sickened 634 people.[29] Also in March 2013, a Hepatitis-A outbreak linked to pomegranates spread to 10 states, sickened 165 people, and hospitalized 71 people.[30] There were nine other outbreaks reported by the CDC in 2013.[31]

39. In May 2014, a *Salmonella* Newport outbreak from cucumbers reached twenty-nine states and the District of Columbia.[32] The outbreak resulted in 275 reports of illness, with at least 48 people hospitalized and one death.[33] The same month there was a *Cyclospora* outbreak

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[28] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Multidrug-Resistant Salmonella Heidelberg Infections Linked to Foster Farms Brand Chicken (Final Update)*, https://www.cdc.gov/salmonella/heidelberg-10-13/index.html (last updated July 31, 2014).

[29] *Id*.

[30] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Hepatitis A Virus Infections Linked to Pomegranate Seeds from Turkey (Final Update)*, https://www.cdc.gov/hepatitis/Outbreaks/2013/A1b-03-31/index.html (last updated Sept. 15, 2014).

[31] Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (under "List of Selected Outbreak Investigations, by Year," select "2013") (last updated July 29, 2019).

[32] Ctrs. for Disease Control & Prevention, *Outbreak of Salmonella Newport Infections Linked to Cucumbers — United States, 2014*, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6406a3.htm (last updated Feb. 20, 2015).

[33] *Id*.

from cilantro that sickened 304 people in 19 states, with 7 individuals hospitalized.[34] There were eleven other outbreaks reported by the CDC in 2014.[35]

40. In early 2015, the CDC investigated an outbreak of *Listeriosis* from prepackaged caramel apples that spanned twelve states from North Carolina to Washington State in February.[36] The outbreak killed 7 people, hospitalized 34 people, and infected 35 people.[37] *Listeriosis* also contaminated Blue Bell ice cream in 2015.[38] This outbreak killed three people and hospitalized all ten people it affected.[39] Between June-October 2015, *Listeriosis* also contaminated soft cheeses and the outbreak spread across Washington, California, Colorado, Illinois, Michigan, Ohio, Tennessee, Virginia, New York, and Massachusetts, killing three

[34] Ctrs. for Disease Control & Prevention, *Cyclosporiasis Outbreak Investigations — United States, 2014*, https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/2014/index.html (last updated June 14, 2018).

[35] Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (under "List of Selected Outbreak Investigations, by Year," select "2014") (last updated July 29, 2019).

[36] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Commercially Produced, Prepackaged Caramel Apples Made from Bidart Bros. Apples (Final Update)*, https://www.cdc.gov/listeria/outbreaks/caramel-apples-12-14/index.html (last updated Feb. 12, 2015).

[37] *Id*.

[38] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update)* https://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html (last updated June 10, 2015).

[39] *Id*.

people, and infecting thirty people.[40] These are just three of the eleven outbreaks the CDC recorded for 2015.[41]

41. In January 2016, CDC announced an outbreak of *Listeriosis* that contaminated packaged salads in nine states.[42] The outbreak killed one person and hospitalized all nineteen people affected.[43] A few months later, CDC announced an outbreak of *Listeriosis* that contaminated frozen vegetables in Washington, California, Maryland, and Connecticut, killing three people, and hospitalizing all nine people affected.[44] In March 2016, another *Listeriosis* outbreak occurred in California and Florida, sickening two and killing one.[45] The CDC reported eleven other outbreaks during 2016.[46]

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[40] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Soft Cheeses Distributed by Karoun Dairies, Inc. (Final Update)* https://www.cdc.gov/listeria/outbreaks/soft-cheeses-09-15/index.html (last updated Oct. 23, 2015).

[41] Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (under "List of Selected Outbreak Investigations, by Year," select "2015") (last updated July 29, 2019).

[42] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Packaged Salads Produced at Springfield, Ohio Dole Processing Facility (Final Update)* https://www.cdc.gov/listeria/outbreaks/bagged-salads-01-16/index.html (last updated Mar. 31, 2016).

[43] *Id*.

[44] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Frozen Vegetables (Final Update)*, https://www.cdc.gov/listeria/outbreaks/frozen-vegetables-05-16/index.html (last updated July 15, 2016).

[45] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Raw Milk Produced by Miller's Organic Farm in Pennsylvania* (Final Update), https://www.cdc.gov/listeria/outbreaks/raw-milk-03-16/index.html (last updated Dec. 14, 2016).

[46] Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (under "List of Selected Outbreak Investigations, by Year," select "2016") (last updated July 29, 2019).

42. In March 2017, CDC announced an outbreak of *Listeriosis* linked to soft raw milk cheese, which killed two people and infected eight people in Connecticut, Florida, Vermont, and New York.[47] In May 2017, a *Cyclospora* outbreak caused 597 people in thirty-six states to get sick.[48] Also in 2017, four different outbreaks of *Salmonella*, all from papaya, caused 2 deaths, 79 hospitalizations, and 251 sicknesses.[49]

43. In January of 2018, chicken salad contaminated with *Salmonella* Typhimurium killed one person, hospitalized 94, and sickened 265 people in Minnesota, Wisconsin, South Dakota, Nebraska, Iowa, Illinois, Indiana, and Mississippi.[50] In April 2018, an outbreak of *E. coli* in romaine lettuce sickened at least 210 people, with 96 hospitalized and 5 deaths.[51]

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[47] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Listeriosis Linked to Soft Raw Milk Cheese Made by Vulto Creamery (Final Update)*, https://www.cdc.gov/listeria/outbreaks/soft-cheese-03-17/index.html (last updated May 3, 2017).

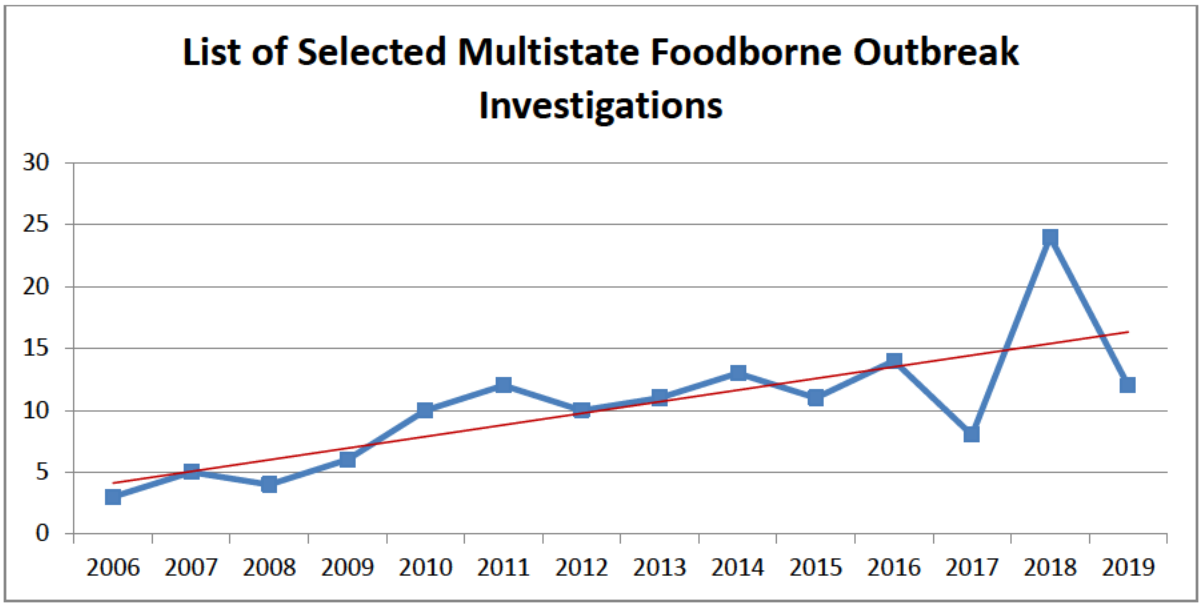
[48] Ctrs. for Disease Control & Prevention, *Cyclosporiasis Outbreak Investigations – United States*, 2017, https://www.cdc.gov/parasites/cyclosporiasis/outbreaks/2017/index.html (last updated Oct. 6, 2017).

[49] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Salmonella Urbana Linked to Imported Maradol Papayas (Final Update)* https://www.cdc.gov/salmonella/urbana-09-17/index.html (last updated Nov. 3, 2017); *Multistate Outbreak of Salmonella Newport and Salmonella Infantis Infections Linked to Imported Maradol Papayas (Final Update*) https://www.cdc.gov/salmonella/newport-09-17/index.html (last updated Nov. 3, 2017); *Multistate Outbreak of Salmonella Anatum Infections Linked to Imported Maradol Papayas (Final Update)*, https://www.cdc.gov/salmonella/anatum-9-17/index.html (last updated Nov. 3, 2017); *Multistate Outbreak of Salmonella Infections Linked to Imported Maradol Papayas (Final Update)*, https://www.cdc.gov/salmonella/kiambu-07-17/index.html (last updated Nov. 3, 2017).

[50] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of Salmonella Typhimurium Linked to Chicken Salad (Final Update)*, https://www.cdc.gov/salmonella/typhimurium-02-18/index.html (last updated Apr. 6, 2018).

[51] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157:H7 Infections Linked to Romaine Lettuce (Final Update)*, https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html (last updated June 28, 2018).

44. In May 2019, CDC announced an outbreak of *Salmonella* Carrau in pre-cut melons, which sickened 137 people and hospitalized 38 in ten states.[52] At the time this complaint was written, there have already been twelve multistate foodborne illness outbreaks *just in 2019*, which is already more than the total number of such outbreaks in 2017.[53]



Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (last updated Aug. 5, 2019).

45. The above examples are merely illustrative and not in any way comprehensive. Between 2013 and the present, there have been foodborne illness outbreaks that reached all fifty states, Washington D.C., and Puerto Rico. These are almost certainly conservative figures as they indicate only those investigations involving "multistate" foodborne illness investigations in which "CDC was the lead public health agency."[54] Moreover, "CDC data suggests there is under-reporting of foodborne illness by consumers."[55]

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[52] Ctrs. for Disease Control & Prevention, *Outbreak of Salmonella Infections Linked to Pre-Cut Melons (Final Update)*, https://www.cdc.gov/salmonella/carrau-04-19/index.html (last updated May 24, 2019).

[53] Ctrs. for Disease Control & Prevention, *List of Selected Multistate Foodborne Outbreak Investigations*, https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html (under "List of Selected Outbreak Investigations, by Year," select and compare "2017" and "2019") (last updated July 29, 2019).

[54] *Id.*

FDA's Failure to Act With Regards to Laboratory Accreditation

46. As explained above, one of the critical purposes of FSMA is to "establish a program for the testing of food by accredited laboratories" and to "develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology[.]" 21 U.S.C. § 350k(a)(1); (6). In addition, FDA is required to "increase the number of qualified laboratories" and "establish a publicly available registry of accreditation bodies . . . and laboratories." 21 U.S.C. § 350k(a)(1); (3). These provisions are intended to strengthen FDA's ability to "rapidly detect and respond to foodborne illness outbreaks and other food-related hazards[.]" 21 U.S.C. § 2204(a)(1)(E). Congress repeatedly invoked the imperative nature of FSMA.[56]

47. As such, Congress required FDA to complete the laboratory accreditation provisions in relatively short order. Congress mandated that the program for the testing of food by accredited laboratories be established no later than January 4, 2013.[57] Congress required the public registry of accreditation bodies and laboratories be made available by that same date.[58]

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[55] Susan Arendt et al., *Reporting of Foodborne Illness by U.S. Consumers and Healthcare Professionals*, 10 Int. J. Environ. Res. Pub. Health 3684, 3686 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3774464/pdf/ijerph-10-03684.pdf (last accessed Aug. 19, 2019).

[56] *See, e.g.*, 156 Cong. Rec. H8861, H8885 (daily ed. Dec. 21, 2010) (statement of Rep. Waxman) ("There is no time for any further delay."); *id.* (statement of Rep. Pallone) ("The modernization of our food safety system is desperately needed."); *id.* at H8889 (statement of Rep. Dingell) ("We will bring to a halt a shameful situation where 48 million Americans are sickened by bad food, 128,000—yes 128,000 Americans—hospitalized and 3,000 people killed by bad food."); *id.* (statement of Rep. Jackson Lee) ("The safety and sanitation of food produced and distributed throughout the United States is of utmost importance. The health and well being of every person in this country hinges on the quality and effectiveness of the food inspection process.").

[57] 21 U.S.C. § 350k(a)(1)(A).

[58] *Id.* § 350k(a)(1)(B).

Congress also intended the model laboratory standards to be developed within the same timeframe; in order to have a "program for the testing of food by accredited laboratories," FDA must first "develop [the] model standards that a laboratory shall meet to be accredited[.]"[59] Moreover, Congress intended food testing to begin at accredited laboratories no later than July 4, 2013, something that can only occur if the aforementioned provisions are implemented.[60]

48. FDA has failed to meet any of these deadlines and/or take the Congressionally-required actions. The FSMA laboratory accreditation provisions are inextricably linked to and required for effective implementation of other statutory provisions.[61] In March 2016, "[a] common refrain [was] that the agency [was] developing a proposed rule to implement laboratory

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[59] 21 U.S.C. §§ 350k(a)(1); (6).

[60] 21 U.S.C. § 350k(b)(1).

[61] *See e.g.*, 21 U.S.C. § 2204(a)(1)(E) (integration of laboratory networks "to rapidly detect and respond to foodborne illness outbreaks"); 21 U.S.C. § 2204(c) (discussing need to "increase capacity to undertake analyses of food samples after collection, to identify new and rapid analytical techniques . . . and to provide for well-equipped and staffed facilities and progress toward laboratory accreditation under section 350k of this title[.]"; *see also*, Nicholas Obolensky, *The Food Safety Modernization Act of 2011: Too Little, Too Broad, Too Bad*, 17 Roger Williams U. L. Rev. 887, 893 (Summer 2012), https://docs.rwu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1498&context=rwu_LR (explaining how laboratory accreditation provisions are necessary to "ensure compliance with the preventative control standards established to improve food safety and to enable FDA to respond effectively to food safety problems that may arise[.]") (last accessed Aug. 19, 2019); Kristin Eads and Jennifer Zwagerman, *In Focus: Examining the New FDA Food Safety Modernization Act*, 33 Hamline J. Pub. L. & Pol'y 123, 142-43 (Fall 2011), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2989709 (describing interrelatedness of laboratory accreditation provisions with requirement for increased number of food company inspections) (last accessed Aug. 19, 2019); Alexia Brunet Marks, *The Risks We Are Willing to Eat: Food Imports and Safety*, 52 Harv. J. on Legis. 125, 140 (2015), https://pdfs.semanticscholar.org/ce09/8d957088a42fbbf89834aac87c8b23ab3a59.pdf (identifying laboratory accreditation provisions as one of many "layers of assurances and guarantees" intended "to achieve higher levels of trust" for products) (last accessed Aug. 19, 2019); Karen Appold, *Industry Urges FDA to Release FSMA Lab Proposed Rule*, Food Quality & Safety, Aug. 9, 2019, https://www.foodqualityandsafety.com/article/industry-urges-fda-to-release-fsma-lab-proposed-rule/ ("[a]lthough [FSMA] mentions 'laboratories' and 'laboratory test' nearly 100 times, a proposed rule addressing the quality and accuracy of that testing remains outstanding.") (last accessed Aug. 19, 2019).

accreditation and model laboratory standards as outlined in the law" but it had "not yet been promulgated."[62] More than three years later (and six years after the deadlines), FDA has not even proposed establishing a program for the testing of food by accredited laboratories or established a publicly available registry of accreditation bodies and laboratories. Nor has FDA developed model laboratory standards.

49. In July 2019, a coalition of organizations submitted a letter to FDA urging the agency to issue a proposed rule "address[ing] laboratory accreditation and model laboratory standards."[63] As these groups noted, "[l]aboratory testing is a component of most all of the FSMA final rules issued to date" and is important "to measure accurately for the presence or absence of harmful pathogens, allergens, spoilage organisms and chemical contaminants in food and food products."[64] Even though "laboratory test results have a significant impact on the health of the public . . . there is currently no required accountability for food laboratories or the accuracy of their test results."[65] Nor is there an "accounting for the number of food laboratories in the United States."[66]

50. In sum, FDA has failed to comply with the Congressional mandates of the FSMA laboratory accreditation provisions. FDA has failed to establish a program for the testing of food by accredited laboratories as required by Section 202(a)(1)(A).[67] FDA has also failed to establish a publicly available registry of accreditation bodies recognized by the Secretary and laboratories

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[62] Robin E. Stombler, *Preparing Your Laboratory for FDA's Proposed Rule*, Food Quality & Safety, Mar. 10, 2016, https://www.foodqualityandsafety.com/article/preparing-your-laboratory-for-fdas-proposed-rule/?singlepage=1 (last accessed Aug. 19, 2019).

[63] Letter from Food Laboratory Alliance et al. to Frank Yiannas, FDA Deputy Commissioner for Food Policy & Response (July 23, 2019) (Ex. 1).

[64] *Id*.

[65] *Id*.

[66] *Id*.

[67] 21 U.S.C. § 350k(a)(1)(A).

accredited by a recognized accreditation body as required by Section 202(a)(1)(B).[68] FDA has also failed to develop model laboratory standards as required by Section 202(a)(6).[69] Finally, because none of these provisions have been implemented, food testing by Federal and non-Federal accredited laboratories has not begun as required by the July 4, 2013 deadline in Section 202(b)(1).[70]

Harm to Plaintiffs

51. The interests of Plaintiffs, organizationally and through their hundreds of thousands of members, are being and will be adversely affected by Defendants' continued failure to: (1) establish a program for the testing of food by accredited laboratories; (2) establish a publicly available registry of accreditation bodies and accredited laboratories; (3) develop model laboratory standards for accredited laboratories; and (4) begin testing food in Federal laboratories and non-Federal accredited laboratories.

52. In particular, Defendant's unlawful withholding and unreasonable delay of FSMA implementing actions pursuant to 21 U.S.C. § 350k, regarding laboratory accreditation and analyses for food, injures Plaintiff organizations by putting their members' health and safety in increased jeopardy, through the risk of contracting foodborne illnesses. Without the increased network of accredited laboratories that are required to handle the increased number of food inspections FSMA calls for, Congress's will is thwarted and Plaintiffs' members are put at a greater risk of contracting a foodborne illness. Foodborne illness affects their health, well-being, and finances.

53. For example, Plaintiffs' members and their families have fallen ill as a result of foodborne illness outbreaks in, among other foods, mangoes, imported melons, and raw foods. The effects of these illnesses included severe vomiting and diarrhea, weight loss, and

[68] *Id.* § 350k(a)(1)(B).

[69] *Id.* § 350k(a)(6).

[70] 21 U.S.C. § 350k(b)(1).

hospitalization. Plaintiffs' members also pay a price premium to make food from scratch and to buy organic produce and products to reduce the risk of contracting a foodborne illness.

54. In addition, Defendants' unlawful withholding and unreasonable delay injures Plaintiff organizations by frustrating their food safety missions, and forcing the organizations to divert organizational resources to address FDA's delay and food safety risks, resources that would otherwise be used in other organizational program areas. Plaintiff organizations are forced to fill the gap for their members and consumers generally, taking policy, outreach, and campaign actions to identify foodborne illness outbreaks.

55. CDC estimates that each year 48 million people (or 1 in 6 Americans) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases, including Plaintiffs' members.[71] While some will recover, many will die or have serious long-term health effects that can be devastating to both the victims and their families. Serious long-term health effects associated with several common types of food poisoning include kidney failure, chronic arthritis, and brain and nerve damage.[72] The laboratory accreditation measures that Congress required to be carried out by FDA are a key component of FSMA's goal to dramatically reduce the number of illnesses caused by foodborne pathogens in the U.S., as well as reduce the economic healthcare burden of treating these problems. The laboratory accreditation requirements would enhance FDA's ability "to increase the number of qualified laboratories" to "rapidly detect and respond to foodborne illness outbreaks and other food-related hazards."[73] In an era of seeking ways to lower healthcare costs, prevention of foodborne illnesses and outbreaks should be paramount.

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[71] Ctrs. for Disease Control & Prevention, *Food Safety: Foodborne Illness and Germs*, https://www.cdc.gov/foodsafety/foodborne-germs.html (last updated Feb. 16, 2018).

[72] FoodSafety.gov, *Food Poisoning*, http://www.foodsafety.gov/poisoning/index.html (last accessed Aug. 19, 2019).

[73] 21 U.S.C. §§ 350k(a)(3); 2204(a)(1)(E); *see also* 156 Cong. Rec. H8861, H8887 (daily ed. Dec. 21, 2010) (statement of Rep. DeLauro) ("[a]ll of these tools will help improve the FDA's ability to respond to food-borne illness outbreaks and to hold industrial food production facilities to higher standards.").

56. Since Congress passed FSMA, FDA's implementation of the law has been extensively delayed, requiring litigation to enforce mandatory deadlines. During this time, while the law largely went unimplemented, numerous outbreaks have unfortunately continued to occur. In just the last year or so, there have been devastating outbreaks, putting peoples' health and lives at risk. In May 2018, for example, an *E. coli* O157 outbreak from romaine lettuce killed 5 people, hospitalized 96 people, and caused 210 to get sick. The outbreak reached thirty-six states.[74]

57. FSMA is a substantial overhaul and modernization of federal food safety oversight and evinces Congress's express and clear intent that FDA act without delay in implementing regulations and enforcing this crucial new law and its preventive food safety measures. Congress required FDA to establish a program for the testing of food by accredited laboratories by January 4, 2013. Congress further required FDA to establish a publicly available registry of recognized accreditation bodies and laboratories accredited by a recognized accreditation bodies by January 4, 2013. Congress also required FDA to develop model standards that a laboratory shall meet to be accredited by a recognized accreditation body for a specified sampling or analytical testing methodology. Finally, Congress intended food testing to begin at accredited laboratories no later than July 4, 2013. Years later, however, FDA has still failed to meet these deadlines and to take other required actions.

58. These statutory mandates are critical for FDA to better enable "[s]urveillance systems and laboratory networks to rapidly detect and respond to foodborne illness outbreaks and other food-related hazards[.]"[75] FDA's failures to meet the statutory deadlines to establish a program for the testing of food, establish a publicly available registry of recognized accreditation bodies and laboratories, develop model laboratory accreditation standards, and begin food testing

[74] Ctrs. for Disease Control & Prevention, *Multistate Outbreak of E. coli O157:H7 Infections Linked to Romaine Lettuce (Final Update)*, https://www.cdc.gov/ecoli/2018/o157h7-04-18/index.html (last updated June 28, 2018).

[75] 21 U.S.C. § 2204(a)(1)(E).

injures Plaintiff organizations by putting their members' health and safety in jeopardy, through the risk of contracting foodborne illnesses.

59. The requested relief will redress this harm by compelling FDA to promulgate regulations and enforce self-executing provisions as required by law for the safety of all Americans, and Plaintiffs' members in particular.

CAUSE OF ACTION

[Violation of the FDA Food Safety Modernization Act and the Administrative Procedure Act – Against FDA]
[By Plaintiffs]

60. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 59 *supra*.

61. FSMA requires FDA to establish a program for the testing of food by accredited laboratories and to establish a publicly available registry of accreditation bodies and laboratories accredited by a recognized accreditation body no later than January 4, 2013. FSMA also requires FDA to develop model standards that accredited laboratories must meet for specified sampling and testing methodologies. Finally, Congress intended food testing to begin at accredited laboratories no later than July 4, 2013. FDA's failure to take any of these actions constitutes unlawfully withheld and unreasonably delayed agency action within the meaning of the APA, 5 U.S.C. § 555(b), and FSMA.

62. The APA grants a right of judicial review to "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action." 5 U.S.C. § 702.

63. The definition of "agency action" includes a "failure to act." 5 U.S.C. § 551(13).

64. Plaintiffs and their members are adversely affected by FDA's past and continued failure to complete the actions required by Congress in FSMA. *See id.*

65. The APA states that a reviewing court "shall" interpret statutes and "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1),

66. FDA's failure to promulgate said regulations or complete other required actions constitutes unlawfully withheld and unreasonably delayed agency action that this Court shall compel. *See id.*

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court enter an Order:

1. Declaring that FDA has violated FSMA and the APA by failing to complete FSMA actions by statutory deadlines;

2. Declaring that FDA continues to be in violation of FSMA and the APA by failing to complete FSMA actions by statutory deadlines;

3. Ordering FDA to promulgate all FSMA regulations and complete all actions required under FSMA at issue in this case as soon as reasonably practicable, according to a Court-ordered timeline;

4. Retaining jurisdiction of this action to ensure compliance with its decree;

5. Awarding Plaintiffs attorney's fees and all other reasonable expenses incurred in pursuit of this action; and

6. Granting other such relief as the Court deems just and proper.

Respectfully submitted this 19th day of August, 2019.

/s/Sylvia Shih-Yau Wu
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Emails: swu@centerforfoodsafety.org
rtalbott@centerforfoodsafety.org

Counsel for Plaintiffs

Exhibit 1

July 23, 2019

The Honorable Frank Yiannas
Deputy Commissioner for Food Policy & Response
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Yiannas:

There have been significant accomplishments by the FDA in moving forward with the Food Safety Modernization Act (FSMA). While the focus of the agency has been on promulgating the initial seven FSMA rules, as mandated by court order, we would like to bring your attention to FSMA section 202, which addresses laboratory accreditation and model laboratory standards.

Laboratory testing is a component of most all of the FSMA final rules issued to date. Both the public and food facilities rely on laboratory testing to measure accurately for the presence or absence of harmful pathogens, allergens, spoilage organisms and chemical contaminants in food and food products. Laboratories are also utilized in the testing of finished products, in supplier verification, and environmental monitoring. Overall, laboratory test results have a significant impact on the health of the public, the food industry and the economy.

Despite the significant, foundational role of laboratories in food safety, there is currently no required accountability for food laboratories or the accuracy of their test results. Indeed, there is no accounting for the number of food laboratories in the United States. FSMA section 202 helps to remedy these concerns.

Dates for the promulgation of the proposed rule for FSMA section 202 have steadily slipped from the year 2013 to as recent as May 2019. It is time for the proposed rule to be released for review and public comment.

Thank you for your time and attention to this important matter.

Sincerely,

Food Laboratory Alliance
A2LA
Association of Public Health Laboratories
Cherney Microbiological Services
Consumer Federation of America
Eurofins Scientific Inc.
LGC
Microbiologics
National Environmental Health Association
The Pew Charitable Trusts
STOP Foodborne Illness
Trust for America's Health

CIVIL COVER SHEET

The JS-CAND 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Center for Food Safety, Center for Environmental Health

(b) County of Residence of First Listed Plaintiff
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Center for Food Safety, 303 Sacramento St., Second Floor, San Francisco, CA 94111; Tel. 415-826-2770

DEFENDANTS
Alex M. Azar II, Secretary of U.S. Dept. of Health and Human Services; Norman E. Sharpless, Commissioner of U.S. Food and Drug Administration and U.S. Dept. of Health and Human Services

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)* *(For Diversity Cases Only)*

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment Of Veteran's Benefits
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury -Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury – Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities–Employment
- ☐ 446 Amer. w/Disabilities–Other
- ☐ 448 Education

PRISONER PETITIONS

HABEAS CORPUS
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

OTHER
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee–Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC § 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC § 158
- ☐ 423 Withdrawal 28 USC § 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent—Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS–Third Party 26 USC § 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC § 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation–Transfer ☐ 8 Multidistrict Litigation–Direct File

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. §§ 551 et seq., § 702, § 706(1)
Brief description of cause:
APA unlawful withholding/unreasonable delay for taking actions/promulgating rules required by Food Safety Modernization Act

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, Fed. R. Civ. P.
DEMAND $
CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S), IF ANY *(See instructions):*
JUDGE DOCKET NUMBER

IX. DIVISIONAL ASSIGNMENT (Civil Local Rule 3-2)
(Place an "X" in One Box Only) ☒ **SAN FRANCISCO/OAKLAND** ☐ **SAN JOSE** ☐ **EUREKA-MCKINLEYVILLE**

DATE 08/19/2019 **SIGNATURE OF ATTORNEY OF RECORD** s/Sylvia Shih-Yau Wu

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS-CAND 44

Authority For Civil Cover Sheet. The JS-CAND 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved in its original form by the Judicial Conference of the United States in September 1974, is required for the Clerk of Court to initiate the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)."

II. Jurisdiction. The basis of jurisdiction is set forth under Federal Rule of Civil Procedure 8(a), which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

(1) United States plaintiff. Jurisdiction based on 28 USC §§ 1345 and 1348. Suits by agencies and officers of the United States are included here.

(2) United States defendant. When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

(3) Federal question. This refers to suits under 28 USC § 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

(4) Diversity of citizenship. This refers to suits under 28 USC § 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS-CAND 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerk(s) in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the six boxes.

(1) Original Proceedings. Cases originating in the United States district courts.

(2) Removed from State Court. Proceedings initiated in state courts may be removed to the district courts under Title 28 USC § 1441. When the petition for removal is granted, check this box.

(3) Remanded from Appellate Court. Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

(4) Reinstated or Reopened. Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

(5) Transferred from Another District. For cases transferred under Title 28 USC § 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

(6) Multidistrict Litigation Transfer. Check this box when a multidistrict case is transferred into the district under authority of Title 28 USC § 1407. When this box is checked, do not check (5) above.

(8) Multidistrict Litigation Direct File. Check this box when a multidistrict litigation case is filed in the same district as the Master MDL docket.

Please note that there is no Origin Code 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC § 553. Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Federal Rule of Civil Procedure 23.

Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS-CAND 44 is used to identify related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

IX. Divisional Assignment. If the Nature of Suit is under Property Rights or Prisoner Petitions or the matter is a Securities Class Action, leave this section blank. For all other cases, identify the divisional venue according to Civil Local Rule 3-2: "the county in which a substantial part of the events or omissions which give rise to the claim occurred or in which a substantial part of the property that is the subject of the action is situated."

Date and Attorney Signature. Date and sign the civil cover sheet.