U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

January 17, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, January 19, 2018, at 9:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

This hearing will examine a December 2017 report by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG). The report identified a number of deficiencies in the U.S. Food and Drug Administration's (FDA) food recall process, including that FDA could not always ensure that firms initiated recalls promptly and that FDA did not always evaluate health hazards in a timely manner; issue audit check assignments at the appropriate level; complete audit checks in accordance with its procedures; collect timely and complete status reports from firms that have issued recalls; track key recall data in their electronic system; and maintain accurate recall data in the electronic data system. The purpose of the hearing is to determine the reasons for the identified deficiencies, to what extent the FDA Food Safety Modernization Act (FSMA) has improved FDA's oversight of food recalls since its passage in 2011, and what actions the FDA is taking to implement the report's recommendations or to address the deficiencies.

I. WITNESSES

- Gloria Jarmon, Deputy Inspector General for Audit Services, HHS Office of Inspector General; and,

- Douglas Stearn, Office of Regulatory Affairs, Director, Office of Enforcement and Import Operations, Food and Drug Administration.

II. BACKGROUND

A. Estimates of health and economic impact from foodborne illness

In this decade, the Centers for Disease Control and Prevention (CDC) estimates that each year roughly one in six Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne illness.[1] CDC data also show that the number of reported multistate

[1] CDC, Estimates of Foodborne Illness in the U.S., *available at* https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html.

foodborne illness outbreaks is increasing over the past decade.[2] According to the Government Accountability Office (GAO), this is notable because although multistate outbreaks make up a small proportion of total outbreaks, they affect greater numbers of people.[3]

Most who get sick from a foodborne illness will recover without any lasting effects; however, some individuals may suffer long-term health effects, such as kidney failure, chronic arthritis, or nerve damage.[4] According to a May 2015 estimate from the U.S. Department of Agriculture's (USDA) Economic Research Service, the 15 most common foodborne pathogens together impose an economic burden related to foodborne illnesses, hospitalizations, and deaths in the United States of over $15.5 billion annually.[5] In 2015, FDA researchers estimated that health costs associated with foodborne illness are approximately $36 billion annually.[6]

In addition to the human health toll, foodborne illness outbreaks can impose high costs to industry from food recalls.[7] A study published by the Grocery Manufacturers Association (GMA), surveying 36 GMA member companies, found that more than half had been affected by a product recall in the prior five years.[8] Based on the survey results, the four largest costs that companies face as a result of a recall are business interruption or lost profits; recall execution costs such as destroying and replacing recalled products; liability risk; and company or brand reputation damage.

B. FDA authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was passed by Congress in 1938 and gives authority to the FDA to oversee the safety, of food, drugs, and cosmetics. The FD&C Act "requires FDA to safeguard the Nation's food supply, including dietary supplements, and ensure that all ingredients are safe."[9] The FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the FDA's Office of Regulatory Affairs (ORA) work together to oversee food recalls. The ORA district offices are responsible for overseeing recalls for any companies or

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[2] CDC List of Selected Multistate Foodborne Outbreak Investigations, *available at* https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html.
[3] U.S. GAO – High Risk: Improving Federal Oversight of Food Safety, (2017), *available at* https://www.gao.gov/highrisk/improving_federal_oversight_food_safety/why_did_study.
[4] *Id.*
[5] U.S. Department of Agriculture, Economic Research Service, Economic Information Bulletin Number 140, Economic Burden of Foodborne Illnesses Acquired in the United States, (May 2015), *available at* https://www.ers.usda.gov/webdocs/publications/43984/52807_eib140.pdf.
[6] Travis Minor, et al., The Per Case and Total Annual Costs of Foodborne Illness in the United States, 35 Risk Analysis 1125 (June 2015), *available at* http://onlinelibrary.wiley.com/doi/10.1111/risa.12316/abstract;jsessionid=BB1C19DE0558F076C9D49E994F582A30.f01t01.
[7] *Id.*
[8] GMA, Covington & Burling, and Ernst & Young, Capturing Recall Costs: Measuring and Recovering the Losses, (2011), *available at* http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf.
[9] Department of Health and Human Services Office of Inspector General, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply,* (Dec. 2017), *available at* https://oig.hhs.gov/oas/reports/region1/11601502.pdf.

"firms" where a recalling firm is located and therefore are responsible for providing guidance to the recalling firms and monitoring day-to-day activities related to the recalls.

In January 2011, FSMA was signed into law. This law gives the Secretary of HHS authority to conduct mandatory recalls and assess and collect fees related to food facility re-inspections and food recall orders. FSMA "aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it."[10] In order for FDA to use its mandatory recall authority, FDA must determine that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals. To date, FDA has initiated the process to use its mandatory recall authority twice; once in February 2013 and once in November 2013.[11]

"A recall is a firm's removal or correction of a marketed product that FDA considers to be in violation of the FD&C Act and against which FDA would initiate a legal action (e.g., seizure)."[12] Corrections may include repair, modification, adjustment, relabeling, destruction, or inspection of a product without its physical removal to some other location.[13] Food recalls are the most effective means of protecting public health when a widely consumed food product is either defective or potentially harmful.[14]

FDA completes a health hazard evaluation (HHE) for each recall, which is used to classify the recall and assess the firm's recall strategy. A recall may be classified as Class I, II, or III. In Class I recalls, there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.[15] In Class II recalls, the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences or death is remote.[16] In Class III recalls, the use of or exposure to a violative product is not likely to cause adverse health consequences.[17]

C. Recent audits before the 2017 OIG Report

Prior to the 2017 report and the enactment of FSMA, OIG had issued two audits related to FDA food recalls. In 2009, the OIG reviewed the FDA's monitoring of pet food recalls.[18] Among the deficiencies noted, the OIG found: FDA did not always follow its procedures in

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[10] U.S. Food & Drug Administration, FDA Food Safety Modernization Act (FSMA), *available at* https://www.fda.gov/Food/GuidanceRegulation/FSMA/.
[11] OIG report, *supra* note 9.
[12] *Id*. at 2.
[13] GAO, Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening, GAO-12-859, (July 2012), *available at* https://www.gao.gov/assets/600/593031.pdf.
[14] OIG report, *supra* note 9 at 1.
[15] 21 CFR § 7.3.
[16] *Id.*
[17] *Id.*
[18] Department of Health and Human Services Office of Inspector General, *The Food and Drug Administration's Monitoring of Pet Food Recalls*, A-01-07-01503, (Aug. 2009), *available at* https://oig.hhs.gov/oas/reports/region1/10701503.pdf.

overseeing three of the five recalls reviewed; FDA's procedures were not always adequate for monitoring large recalls; occasional lax adherence by FDA to its recall guidance and internal procedures and the inadequacy of some of those procedures; and limited FDA ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

In 2011, the OIG reviewed the FDA's monitoring of imported food recalls.[19] The OIG's review found that FDA's guidance for developing and implementing food recalls was not adequate to ensure the safety of the Nation's food supply because it was not enforceable. In addition, FDA did not always follow its own procedures for ensuring that the recall process operated efficiently and effectively. Among its observations, the OIG found that FDA did not always conduct timely and complete audit checks of consignees, or did not review recall strategies and promptly issue notification letters to firms conveying the review results and other essential instructions.

The GAO also raised concerns about FDA's food recall process in 2012, noting that FDA faced a number of communication challenges when advising the public about food recalls or outbreaks of foodborne illness.[20] In addition, in 2017, the GAO continued to include federal oversight of food safety on the high-risk list.[21] Improving federal oversight of food safety has been on GAO's high-risk list since 2007.[22]

D. HHS OIG Early Alert

The HHS OIG started its review of FDA's food-recall process in early 2015, with field work starting in April 2015.[23] In June 2016, HHS OIG issued an Early Alert memorandum to FDA on a preliminary finding from its ongoing audit. The early alert raised concerns that FDA did not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary recalls."[24] Two months earlier, the FDA established a team of senior leaders to make decisions in the most challenging food recall cases.[25] The team is called SCORE (Strategic Coordinated Oversight of Recall Execution).[26] FDA's hearing witness, Douglas Stearn, is a co-leader of SCORE. According to FDA, SCORE has reviewed and directed a large number of operations in the most difficult cases that FDA faced during the April 2016 – October 2017 time period.[27] The agency believes SCORE has made a difference in

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[19] U.S. Department of Health and Human Services, Office of Inspector General, *Review of The Food and Drug Administration's Monitoring of Imported Food Recalls,* A-01-07-01503, (Aug. 2009), *available at* https://oig.hhs.gov/oas/reports/region1/10701503.pdf.
[20] U.S. Government Accountability Office, Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening, GAO-12-589, (July 2012), *available at* https://www.gao.gov/assets/600/593031.pdf
[21] U.S. Government Accountability Office, High Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others, GAO-17-317, (Feb. 2017), *available at* https://www.gao.gov/assets/690/682765.pdf.
[22] GAO, *High-Risk Series: An Update*, GAO-07-310, (Jan. 2007), *available at* https://www.gao.gov/assets/260/255951.pdf.
[23] OIG Report, Appendix C: Audit Scope and Methodology, *supra* note 9 at 32.
[24] OIG report, *supra* note 9.
[25] FDA Comments (Oct. 6, 2017), Appendix J to HHS OIG Dec. 2017 report.
[26] *Id.*
[27] *Id.*

ensuring that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market.[28] FDA also has recently initiated a new quality systems audit process and a plan to provide earlier notice to the public and more guidance to staff.[29] HHS OIG acknowledged that the Early Alert memorandum and its review spurred major changes in FDA's oversight of the process, but maintained the recommendations in the Early Alert memorandum in the report.[30]

E. HHS OIG December 2017 Report

The HHS OIG audit covered 30 voluntary food recalls (23 Class I and seven Class II) "judgmentally" selected by the OIG from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. The OIG focused on FDA's (1) oversight of firms' initiation of food recalls, (2) monitoring of firm-initiation of food recalls, and (3) maintenance of food-recall data in the electronic recall data system. The OIG report found deficiencies in each of these areas.

The OIG found:[31]

- *FDA could not always ensure that firms initiated recalls promptly.* The 30 voluntary recalls reviewed had a median of 29 days to initiate, with an average of 57 days. Initiation of these recalls ranged from nine days before to 303 days after FDA learned that the product was potentially hazardous. The timeliness of recalls depended on how quickly firms chose to respond to safety information, whether FDA and the firm disputed the lawfulness of a product, or whether the firm lied to FDA about suspending manufacture and distribution of a product. Recalls were not always initiated promptly because FDA did not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary recalls.

- *FDA did not always evaluate health hazards in a timely manner.* For the 14 recalls that the OIG could evaluate for timeliness, the median working days to complete the HHE after learning of a planned or in-progress recall was 27 working days, with an average of 47 days. There were three reasons for FDA not completing some HHEs in a timely manner: (1) FDA did not always follow the 24-hour timeframe in its procedures for submitting the recall alert to an electronic data system called the Recall Enterprise System (RES) after learning of a firm's decision to recall; (2) FDA sometimes had difficulties obtaining necessary information for decisions about the seriousness of the health hazard because the firm's lack of responsiveness or the firm's own difficulties obtaining information; and (3) FDA's interim mandatory recall procedures did not include factors to consider when determining the existence of a reasonable probability that a food would cause serious adverse health consequences or death.

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[28] *Id.*
[29] *Id.*
[30] OIG report, *supra* note 9, at 4.
[31] OIG report, *supra* note 9.

- *FDA did not always issue audit check assignments consistent with the level of the proposed audit program.* A recall "audit check" is a visit, telephone call, or letter from FDA staff to a consignee to verify that the consignee has been notified of the recall, and has taken appropriate action.[32] For 19 of the 27 recalls, the FDA monitoring district office issued audit check assignments at the level of the proposed audit program. For the remaining eight recalls, fewer audit checks were issued than what was required for the level in the proposed program. FDA did not always issue audit checks at assigned levels or based on accurate distribution information because FDA recall coordinators (1) had insufficient oversight to ensure that the assignment was at the appropriate level or (2) obtained incomplete or inaccurate information from the firm.

- *FDA did not always complete audit checks in accordance with procedures*. For 21 of the 25 audit checks that were conducted in the OIG sample, FDA did not complete the last audit check within 20 days of issuance of the firm's recall communication. For these 21 recalls, the median days for FDA to finish the audit check after the firm issued its recall communication was 69 days, with an average of 118 days. The OIG noted that FDA did not retain a third-party contractor to assist with audit checks despite limited staff resources. The OIG also observed that the FDA staff did not always provide regular updates to the recall coordinator and that the recall coordinators did not always follow up with district offices to ensure that audit checks were completed in a timely manner. None of the FDA data systems could be used to assist staff with tracking results of audit checks.

- *FDA did not always collect timely and complete status reports from recalling firms.* For 11 of the 30 recalls, FDA either did not request or collect status reports. For the remaining 19 recalls, the median days for FDA to collect the first status report was 122 days, with an average of 143 days. In addition, for the 19 recalls in which at least one status report was provided, five did not contain complete effectiveness check information. FDA's procedure for collecting timely and complete status reports was inadequate because the procedures did not require staff to request status reports at the time the recall was initiated. FDA also did not always include the request for status reports in the recall notification letter or follow up with firms when the status reports were not provided, provided late, or were incomplete.

- *FDA did not track key recall data in the electronic recall enterprise system.* FDA did not have established performance measures and indicators to track key milestones of the food-recall process, in accordance with federal internal control standards. In addition, the FDA RES data system did not track all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls. For example, FDA could not use the RES to calculate that it took 151 days to initiate the recall of hazelnuts contaminated with *Salmonella*.

[32] FDA 2017 Investigations Operations Manual, chapter 7.3.2.1, *available at* https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123513.pdf.

- *FDA did not always maintain accurate recall data in the recall enterprise system.* For 11 of the 30 recalls (37 percent), the RES contained an inaccurate recall initiation date, which was off by a median of four days and an average of 16 days. FDA's RES User Manual did not clearly define the term "recall initiation" date, and therefore, FDA staff input other dates into the RES. Finally, FDA did not have a data quality assurance process to help ensure that RES data was accurate and complete.

As a result of these findings, the OIG issued 14 recommendations to FDA. The OIG recommended that FDA:

- Establish set timeframes, through its SCORE initiative, for FDA to (1) discuss the possibility of a voluntary recall with a firm and (2) initiate its use of its mandatory recall authority;

- Include in its recall audit plan a step to monitor when the recall alert was submitted to the RES, and if appropriate, take steps to encourage submission of the recall audit plan to the RES as soon as possible;

- Finalize its interim mandatory recall procedures and consider issuing guidance for FDA staff on factors that should be considered in determining a reasonable probability that a food could cause a serious adverse health consequence or death;

- Ensure, through its recall audit plan, that audit checks are issued at the level specified in the FDA audit program;

- Develop procedures to ensure FDA uses complete and accurate distribution lists when assigning audit checks;

- Increase the use of third-party audits through its recall strategic plan;

- Ensure through its recall audit plan that FDA audit checks follow procedures;

- Improve audit check tracking and monitoring using the RES or another FDA system;

- Implement procedures to request status reports at the initiation of the recall and ensure follow-up with firms that do not provide timely or complete status reports;

- Develop a policy for defining and a procedure for identifying retrospectively the date that FDA learns of a potentially hazardous product;

- Establish performance measures for the length of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall;

- Clarify the definition of "recall initiation date" in its policies and procedures;

- Develop and implement a data quality assurance process to ensure that the RES contains accurate information; and

- Consider the results of the OIG review when implementing recent SCORE initiatives.

F. FDA comments

FDA agreed with the OIG's conclusion that it needed to help ensure that recalls are initiated promptly in all circumstances and said that it will consider the results of the OIG review as it "continues to operate the SCORE team." FDA also described actions it took in response to the OIG's June 2016 Early Alert. Although FDA has claimed that the OIG's recall sample was an "extreme outlier," FDA Commissioner Scott Gottlieb has stated that "[e]ven just a handful of problematic recalls are too many, because lives are at stake."[33] Dr. Gottlieb also stated that the FDA agreed that in some situations identifying the retail stores not just the food manufacturer and distributor would help, and the agency is looking into the collection and release of this information.[34] In addition to the issues identified by the OIG, the FDA through its SCORE initiative is also identifying approaches for improving the timeliness of its food recall process.

Although there have been only two mandatory recalls since FSMA was enacted, the FDA told bipartisan committee staff that it believed the mandatory recall authority improved FDA's leverage during recall discussions with firms and was helpful to industry response since the law provided a legal foundation for the firm's role in recalls.[35] FDA also told staff that the FDA laboratories, primarily ORA laboratories, provide sample-testing that can be part and a critical component of the HHE.[36] However, FDA acknowledged that there are issues with turnaround time in getting test results from the labs.[37]

Regarding oversight of training, scientific capability, and safety of labs, the FDA, partly in response to the Oversight and Investigations Subcommittee's April 2016 hearing on federal select agents,[38] established the FDA Office of Laboratory Science and Safety (OLSS). In accordance with the recommendations of an external federal working group and the model followed by the CDC, the OLSS is located in the Office of FDA Commissioner with the OLSS Director being a direct report to the Commissioner. However, FDA is not yet completely following the working group recommendation and the CDC model because it has not established

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[33] FDA Commissioner Scott Gottlieb, "FDA: We're working to protect consumers," USA Today (Jan. 2, 2018), *available at* https://www.usatoday.com/story/opinion/2018/01/02/fda-working-protect-consumers-editorials-debates/109104418/.
[34] *Id.*
[35] FDA briefing with bipartisan Committee staff, Jan. 12, 2018. FDA staff also stated that FDA is not requesting additional authority.
[36] *Id.*
[37] *Id.*
[38] How Secure Are U.S. Bioresearch Labs? Preventing the Next Safety Lapse, Hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations (April 20, 2016), *available at* https://energycommerce.house.gov/hearings/how-secure-are-us-bioresearch-labs-preventing-next-safety-lapse/.

a dedicated and independent source of funding for OLSS and a permanent staff for OLSS.[39] Instead, OLSS is being supported by funding from the FDA Centers and relies temporarily on detailees for staffing. FDA is still working to establish the long-term funding for OLSS. As a result, it appears that the FDA OLSS has not conducted any GAO-recommended[40] annual inspections of the FDA labs during the last two years.[41]

III. ISSUES

The following issues may be examined at the hearing:

- What is FDA doing to ensure that recalls are initiated promptly?
- How does FDA plan to improve the audit check process?
- How does FDA plan to better track and maintain accurate recall data in their electronic data system?
- What impact has FSMA had on the FDA food-recall process?
- How does the HHS OIG plan to follow-up in its next audit to determine whether the FDA has implemented the OIG recommendations and is making progress with the food-recall process?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, Brittany Havens, or Jen Barblan of the Committee staff at (202) 225-2927.

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[39] Email from FDA Office of Legislative Affairs to Committee Staff, (Aug. 30, 2017), ("In FY 2017, OLSS recruited 19 individuals through temporary detail assignments and contract support, but did not hire any permanent FTEs. . . . Absent a direct appropriation for OLSS in FY 2018, OLSS will not be funded through a central source, and instead FDA will identify an appropriate method to utilize funding Congress provides the agency to support the lab safety program. One possibility being considered is allocating costs across FDA Centers based on the level of support OLSS will provide to their lab programs.").

[40] U.S. Government Accountability Office, High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety, GAO-16-305, (March 2016), *available at* https://www.gao.gov/assets/680/675925.pdf.

[41] Email from FDA Office of Legislative Affairs to Committee Staff, December 6, 2017 ("Regarding annual inspections, which are currently performed by FDA Centers and ORA, FDA is providing a standardized process to support this work. To further strengthen the process, OLSS intends to conduct audits of the inspection reports being produced by the centers.").