RPTR FORADORI

EDTR ROSEN

SAFETY OF THE U.S. FOOD SUPPLY: CONTINUING CONCERNS OVER THE FOOD AND DRUG ADMINISTRATION'S FOOD-RECALL PROCESS

FRIDAY, JANUARY 19, 2018

House of Representatives,

Subcommittee on Oversight

and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:00 a.m., in Room 2123, Rayburn House Office Building, Hon. Gregg Harper [chairman of the subcommittee] presiding.

Present: Representatives Harper, Griffith, Brooks, Collins, Walberg, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, Peters, and Pallone (ex officio).

Staff Present: Jennifer Barblan, Chief Counsel, Oversight & Investigations; Ray Baum, Staff Director; Jordan Davis, Director of

Policy and External Affairs; Ali Fulling Legislative Clerk, Oversight & Investigations, Digital Commerce and Consumer Protection; Brittany Havens, Professional Staff, Oversight & Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight & Investigations; Jacquelyn Bolen, Minority Professional Staff Member; Evan Gilbert, Minority Press Assistant; Chris Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Tim Robinson, Minority Chief Counsel; and Andrew Souvall, Minority Director of Communications, Outreach and Member Services.

Mr. Harper. The subcommittee convenes this hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process." Disease outbreaks from tainted food are an ongoing public health challenge. The Centers for Disease Control estimates that each year, one in six Americans, 48 million people, get sick from foodborne illnesses; 128,000 are hospitalized; and 3,000 die.

The number of multistate food illness outbreaks is increasing, affecting greater numbers of Americans. And the number of vulnerable people, older and immune-compromised individuals is growing. The threat of foodborne illness persists even though we have gotten better at detecting and investigating outbreaks. And through the implementation of the hazard and analysis and critical control point rules over the last two decades, CDC trend data indicates major reductions in the incidents of foodborne disease. Yet, the problem remains significant.

When contaminated food reaches store shelves, the FDA is a public's last line of defense. The FDA needs to be able to quickly and effectively help remove dangerous foods from commerce and protect consumers. In 2010, Congress gave FDA more power to recall tainted food. The FDA Food Safety Modernization Act, FSMA, was enacted to provide FDA with the authority to mandate a food recall.

In addition to this law, previous audits by both the HHS, Office of Inspector General, and the Government Accountability Office, made recommendations to FDA to improve its food recall program. How has

FDA performed with food recalls in recent years with the new law and these recommendations? Over the last 2 years, the HHS OIG looked at this question, and last month, released a report that contains findings and recommendations for FDA.

The OIG report looked at 30 voluntary food recalls overseen by FDA between October of 2012 and May of 2015. The FDA has used its mandatory recall authority only two times since the enactment of FSMA, and not all over -- and not at all over the last 4 years. In some cases, the FDA was slow to evaluate health hazards. It took FDA an average of 47 days to complete an evaluation after learning of a planned or in-progress food recall.

The OIG found that FDA was woefully slow in starting recalls. The average length before a recall began, once FDA knew of the safety issue, was 57 days. The report also raises questions about the FDA's ability to cope with uncooperative companies.

In one case involving a dietary supplement company, it took 10 months after FDA issued a warning letter about unlisted ingredients before the firm finally pulled the product. In another case, a recall of nut butter began more than 5 months after the FDA had traced the Salmonella outbreak to the source facility. There were 14 illnesses in 11 States during that time.

A series of recalls of cheese products contaminated with Listeria took 81 days to complete, nine people got sick, including one infant who died, and two fetal loses linked to illness. During that time, the firm owner lied to the FDA, saying that the firm would suspend the

manufacturing and distribution of cheese. However, the owner, despite knowing that the product tested positive for Listeria, continued to allow the product to be distributed. The owner later pleaded guilty to FDA crimes and went to prison. Justice was done, but FDA needed to find a way to detect such deception sooner.

The OIG also found that FDA did not have a reliable system for accessing the recall initiation date, or the date FDA became aware of potentially hazardous food products. More than a third of the recalls reviewed had the wrong initiation date entered into FDA's electronic data system, called the Recall Enterprise System.

The electronic data system also did not include when FDA first found out about the suspect food products. Worse, FDA does not collect sufficient or accurate data so that the agency can measure its performance to tell whether their food recall performance is improving.

In addition to the OIG findings, the FDA told committee staff in a briefing that there are concerns about the turn-around time it takes to get test results from FDA labs that are used to make an evaluation of the seriousness of the food hazard.

To ensure the FDA labs are performing properly, FDA needs to provide independent funding and permanent staff to its Office of Laboratory Science and Safety. This office has not been fully stood up and has been unable to inspect FDA labs. FDA should follow the example of the CDC. The CDC's Office of Lab Science and Safety has detected funding -- has dedicated funding and permanent staff to oversee CDC's own labs.

The enactment of FSMA provided FDA mandatory recall authority and imposed more legal obligations on food manufacturers and distributors. FDA has the tools, but the OIG's findings and FDA's own assessments, show that the FDA needs to reform itself to get this right. I'm heartened that the FDA commissioner has recognized that even just a handful of problematic recalls are too many, because lives are at stake.

I'm also glad that the Commissioner has announced that FDA is looking at ways to improve the timeliness and scope of information provided to the public about FDA-regulated food recalls.

I welcome and thank the witnesses and look forward to their testimony. I'll now recognize the ranking member, Ms. DeGette, for the purpose of her opening statement.

[The prepared statement of Mr. Harper follows:]

******** COMMITTEE INSERT ********

Ms. DeGette. Thank you so much, Mr. Chairman. As you know, food safety is not a new issue for this committee. Many of the challenges that we're going to hear about today are the same issues that we've dealt with over the past decade. All of those examples you mentioned were brought up in hearings in front of this committee.

For example, we held a hearing in 2008 on a major Salmonella outbreak that infected over 1300 people in 43 States. As that case illustrated, we lacked basic controls over food recalls, including traceability. FDA and CDC originally identified tomatoes as the likely cause of the outbreak, but later on, they found out it was because of jalapenos.

Now, this was frustrating to all of us because lives were at stake. The Federal response was slow and inefficient; and yet, that case demonstrated that the response is not as simple as just pulling off all the suspected products from the shelves, because entire industry should be devastated.

When we had these hearings where we thought it was the tomatoes, the tomato industry was absolutely devastated at that time, and it turned out that the problem wasn't even tomatoes, but jalapenos. So it was clear then, as it is now, that the FDA needs the ability to respond to a multitude of different situations that pose risks to the public health.

As you noted, Mr. Chairman, in response to incidents like that, we passed the FDA Food Safety Modernization Act in 2011, and many of the members on this committee worked in a bipartisan way on that bill.

It gave the FDA more tools to prevent and to respond to outbreaks, including, critically, new authority to issue mandatory recall orders and requirements for manufacturing firms to have recall plans in place.

But now, 7 years after we pass the law, the Office of Inspector General has a new report that points to some of the same issues that we've been worrying about in this committee for years. Despite the progress that we've made, here we find ourselves.

OIG found that despite more power to oversee manufacturing firms that produce potentially hazardous food, FDA is not doing enough to monitor firms during a recall. Sometimes there have been long delays in getting firms to recall all of their affected product, or even to provide the FDA with basic information.

In addition to insufficient oversight of firms, FDA has also weaknesses in its own recall responses. For example, it's critical for the public to understand the risk that a food product may present. But OIG found that FDA was sometimes slow to evaluate the health hazard posed by a contaminated product.

This is not to say that these cases are easy and the answer's always crystal year. The FDA is dealing with many recalls every year, each which presents its own challenges and complexities. That being said, I do think there's more the FDA can do to improve the food safety system.

OIG's report presents multiple recommendations for FDA, such as improving its policies and procedures for managing recalls and monitoring firms. However, I'd like to hear more from OIG about what

specific meaningful steps it thinks FDA should take. A few more procedure documents and guidance manuals are not enough, we need to know what actually needs to change to help better protect the American public.

As FDA continues to implement provisions of FSMA, the committee needs to hear how the law is working, what more the FDA needs to do, and how Congress can help. I'd like to take a moment of personal privilege, if I may, I just saw the former chairman of the committee walk into the room, Bart Stupak, and Congressman Stupak was one of the key players in enactment of this food safety legislation. Welcome. We're glad to have here you. I'm sorry that we're still talking about this 7 years later.

With that, Mr. Chairman, I yield back.

[The prepared statement of Ms. DeGette follows:]

******** COMMITTEE INSERT ********

Mr. Harper. The gentlelady yields back. And I would also like to welcome Mr. Stupak for his attendance today, it's great to see you back and wish you the best. Now, the chair would recognize the chairman of full committee, Mr. Walden for the purposes of an opening statement.

The Chairman. Thank you, Mr. Chairman. And, Bart, good to see you again. I enjoyed serving with you when we did all that oversight work, and it's good to see you here.

You know, I take this issue very personally. In February of 2009, this subcommittee held hearings on nationwide outbreaks of Salmonella-related illnesses linked to products from the Peanut Corporation of America. One of the witnesses at that hearing was Peter Hurley from Wilsonville, Oregon.

When Peter's then 3-year-old son, Jake, became sick, doctors recommended they give him his favorite food just to encourage him to eat. Well, Jake's favorite food was Austin brand peanut butter crackers. Tragically, that turned out to be the very thing that was poisoning him. When Oregon State officials tested the crackers, three of the six packages contained peanut butter contaminated by Salmonella.

Jake became ill because Stewart Parnell, the CEO of PCA, knew that the peanut products were contaminated with Salmonella when he told the plant manufacturer to, quote, "turn them loose." At that same hearing, I confronted Mr. Parnell with this container, and I asked him whether he was willing to take the lid off and eat any of these products now, since he was so cavalier about turning it loose on little kids like Jake to eat. He refused, of course, citing his 5th Amendment rights.

Thankfully, Jake overcame his illness, and it was great to see him last year. He's now a young teenager. He and his dad came back to visit us. More than 600 people in 44 States were sickened. And unlike Jake, nine people died. As a result, Mr. Parnell is currently serving a 28-year sentence in prison for his actions.

Now, while this case of PCA is the exception and not the rule, fortunately, foodborne illnesses remain a major concern. Chairman Harper just ran through those numbers. Each year, 48 million people are sick, and 3,000 die from foodborne illnesses. Federal oversight of food safety has been on the Government Accountability Office's high risk list since 2007.

And just in the past few months, dozens of people in the United States and Canada were infected and two have died from what appears to be an E.coli contamination related to leafy greens. So we're here to today to check in on the Food and Drug Administration and their work to protect the Nation's food supply chain and ensure health and safety for all Americans.

I was glad to see the FDA Commissioner, Scott Gottlieb, showed his commitment to improving food safety in our Nation with yesterday's announcement that the FDA will accelerate the release of information about problematic products before they may officially be classified as recall items. We look forward to hearing from the FDA today about what plans and benchmarks it's developed to fully implement the law and address the recommendations from the OIG.

We also look forward to the FDA implementing the other expert

recommendations to provide proper funding and permanent staff to the FDA office that oversees the FDA labs, which do play a critical role in food recalls.

I thank the HHS OIG for testifying today, and commend its work with both the recent report in December as well as the Early Alert it issued to FDA in June of 2016. This recent work builds on the past work done by the OIG, most notably, two reports related to food recalls that were released in 2009 and 2011.

While the reports from 2009 and 2011 were issued prior to the Food Safety Modernization Act, many of the recommendations in the recent December report are similar, if not the same as they were in 2009 and 2011.

Further, the GAO raised concerns about FDA's food recall process in 2012. And while FDA says that it's addressed many of the findings of the recent OIG report, it is troubling that many of the recommendations from almost a decade ago stand today, despite the additional authority, given to the FDA through FSMA in 2010.

Today's hearing will give us a good opportunity for FDA to share specific plans to address the recommendations made by the OIG, including the timeframe in which we can expect these changes to be implemented. I don't see Dr. Burgess, I know he was looking for some time. If anyone else would like the remainder of my time -- if not, I will yield back to the chairman so we can proceed with the hearing.

And I also have another hearing I have to go to, so I'll be in and out of this one. Thank you again for the good work you do. I know

we're on the same team to try to and make sure Americans can trust their food is safe to eat. With that, I yield back.

[The prepared statement of Mr. Walden follows:]

******** COMMITTEE INSERT ********

Mr. Harper. Thank you, Mr. Chairman. Now the chair will recognize the ranking member of the subcommittee -- the full committee, Mr. Pallone, for purposes of an opening statement.

Mr. Pallone. Thank you, Mr. Chairman. This committee has a long history of overseeing food safety. Over the last decade, we've had multiple hearings examining the Food and Drug Administration's oversight of food recalls, and the agency's authority to protect the Nation's food supply.

FDA plays a critical role. In fiscal year 2017 alone, FDA oversaw more than 3,600 recalls, and this is no small task, but we have seen cases that exposed weaknesses in FDA's ability to respond to these threats. For example, as I already mentioned, in 2007, a committee investigation into a Salmonella outbreak identifies serious flaws in our food safety network.

In 2010, the committee found that FDA had limited authority to ensure compliance and did not always take swift action when needed. Witnesses repeatedly told this committed that FDA lacked sufficient authority to address weaknesses in our food safety system, and that's why Congress passed the Food Safety Modernization Act, or FSMA, in 2011, and FSMA significantly reformed FDA's overall approach to food safety and gave FDA new authorities to strengthen the food recall process.

For instance, FDA now has the ability to mandate recall when a product poses a serious adverse health consequence. This is a significant tool because we've seen cases of manufacturing firms reluctant to cooperate with the FDA. And thanks to FSMA, firms are

also required to have recall plans in place to help prepare before contamination occurs.

FSMA provided these new tools, but it's up to FDA to make sure they are being put to good use, and that's why this hearing is so important. We need to hear about how FDA is implementing FSMA, and whether things have improved since we passed the law. A recent Office of Inspector General report shed some light on that question and suggests that FDA still may not always adequately oversee food recalls.

The Inspector General reported that FDA did not always effectively monitor firms during a recall, such as ensuring that firms initiate the recalls promptly. And some of the cases highlighted in the report are particularly troubling. For example, between 2012 and 2014, as was mentioned, nut butter contaminated with Salmonella sickened 14 people in 11 States. FDA identified the source of the outbreak in March of 2014, but the products were not fully recalled until August of that year, 165 days later.

The Inspector General also cited a series of recalls of cheese products that were contaminated with Listeria and lead to one infant's death and two lost pregnancies. And I know everyone on this committee will argue that even one fatality is far too many. So while we should recognize that these issues are complex and every recall poses a unique challenge, these findings demonstrate that FDA must exercise judicious, yet forceful oversight when the public's health is at risk.

And so I look forward to hearing how FDA is implementing FSMA and what challenges remain to protect our Nation's food supply. I don't

think anyone -- anyone else wants my time, so I'll yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

******** COMMITTEE INSERT ********

Mr. Harper. The gentleman yields back. I ask unanimous consent that the members' written opening statements be made part of the record. And, without objection, they will be entered into the record.

I'd now like to introduce our panel of witnesses for today's hearing. Today we have Ms. Gloria Jarmon, who is the Deputy Inspector General of Audit Services for the Office of Inspector General at HHS. We welcome you today. And Mr. Douglas Stearn, the Director of the Office of Enforcement and Import Operations in the Office of Regulatory Affairs at the FDA. Welcome to you both, and thank you for being here today to help and to provide testimony. And we look forward to the opportunity to discuss the FDA's food recall process.

You are aware that the committee is holding an investigative hearing, and when so doing, it has the practice of taking testimony under oath. Do you have any objection to testifying under oath?

Mr. Stearn. No, sir.

Ms. Jarmon. [No verbal response.]

Mr. Harper. Both witnesses have indicated no. The chair then advises you that under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Mr. Stearn. No, sir.

Ms. Jarmon. [No verbal response.]

Mr. Harper. Both witnesses have indicated no. In that case, if you would, please rise and raise your right hand and I will swear you in.

Do you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth?

Mr. Stearn. I do.

Ms. Jarmon. I do.

Mr. Harper. Thank you. And you may both be seated. You're now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute summary of your written testimony. And we will recognize Ms. Jarmon first for your testimony.

TESTIMONIES OF GLORIA JARMON, DEPUTY INSPECTOR GENERAL OF AUDIT SERVICES, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND DOUGLAS STEARN, DIRECTOR, OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS, OFFICE OF REGULATORY AFFAIRS, U.S. FOOD AND DRUG ADMINISTRATION

TESTIMONY OF GLORIA JARMON

Ms. Jarmon. Good morning, Chairman Harper, Ranking Member DeGette, and other members of the subcommittee. I am Gloria Jarmon, Deputy Inspector General, Audit Services, Office of Inspector General, U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you today.

Conducting audits, evaluations, and inspections aimed at food safety is a priority for OIG, and remains key to our mission of protecting the health and safety of the American people. I'm here today to discuss our recently published audit report on the food recall process at the Food and Drug Administration, and our recommendations for improving that process.

This audit reviewed documentation for 30 recalls, which were judgmentally selected from the 1,557 food recalls reported to FDA between October 2012 and May 4, 2015. For the 30 recalls we reviewed, we found that FDA's food recall process was not always effective and efficient in ensuring the Nation's food supply. Specifically, we

identified deficiencies in FDA's oversight of recall initiation, FDA's monitoring of recalls, and the recall information captured and maintained in the FDA's recall data system.

My testimony today focuses on key aspects of these three findings, and OIG's recommendations to FDA for improving its food recall process. First, our review of FDA's oversight of firm initiator recalls determined that FDA cannot always ensure that firms initiated recalls promptly, and did not always evaluate health hazards in a timely manner.

To improve FDA's oversight of recall initiation, we recommended that FDA establish set internal timeframes for discussing the possibility of a voluntary recall with a firm, and initiating the use of its mandatory recall authority. In addition, we recommended that FDA take several specific actions aimed at ensuring that health hazard evaluations are completed in a timely manner.

Second, our audit also identifies several deficiencies in FDA's monitoring of firm initiator recalls. Specifically, we found that FDA did not always issue audit checks at the appropriate level. Complete audit checks, as assigned, and collect timely and complete status reports from recalling firms. To improve FDA's monitoring of recalls, we recommended that FDA take steps to ensure that audit checks are assigned at the level specified in the audit program, and that product distribution lists are complete and accurate.

It takes specific actions to help ensure that audit checks are completed in a timely manner and implement procedures for requesting status reports of initiation of a recall and follow up with firms that

do not provide timely or complete status reports.

Third, our review of FDA's recall data system determined that FDA did not always track key recall data and maintained accurate recall data. To help ensure the completeness and accuracy of data in the data systems and give FDA staff involved in managing recalls access to information about key events, we recommended, among other things, that FDA consider adding to its recall data system, or another FDA system, a field for the date FDA learns of a potentially hazardous product, and clarify the definition of recall initiation date in its policies and procedures, and ensure a consistent understanding of recall initiation date among recall personnel.

In FDA's comments on our report, it agreed with our conclusion that it needs to help ensure that recalls are initiated promptly in all circumstances. FDA said it will continue to consider the results of our audit as it moves forward to operate its SCORE team, which stands for Strategic Coordinated Oversight of Recall Execution. This SCORE initiative was developed to establish set timeframes, expedite decision making to recall cases forward, and improve electronic recall data.

We appreciate the steps that FDA has taken, as well as the steps it plans to take, to address the vulnerabilities we identified during our audit. OIG work has demonstrated ways for FDA to improve its oversight of the food recall process, and we will continue to work with the FDA and Congress to help ensure the safety of the Nation's food supply.

Again, thank you for the opportunity to testify this morning, and I'm happy to answer your questions.

[The prepared statement of Ms. Jarmon follows:]

******** INSERT 1-1 ********

Mr. Harper. Thank you, Ms. Jarmon. The chair will now recognize Mr. Stearn for 5 minutes for the purposes of a summary of his written testimony. Thank you and welcome.

TESTIMONY OF DOUGLAS STEARN

Mr. Stearn. Thank you, sir. Good morning, Chairman Harper, Ranking Member DeGette, and members of the subcommittee. I am Douglas Stearn, Director of Enforcement and Import Operations in the Office of Regulatory Affairs, and the Acting Deputy Director for Regulatory Affairs for the Center for Food Safety and Applied Nutrition.

We appreciate the opportunity to provide you with information -- oh, I'm sorry. Is that better? We appreciate the opportunity to provide you with information about how we oversee recalls of FDA-regulated products. FDA is committed to continuously improving our practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to best protect consumers.

In this regard, we appreciate the Office of Inspector General's focus on this subject. I would like to thank the committee for the opportunity to report on major changes FDA has made in response to OIG's investigation. When we learn about a food in the marketplace that may be unsafe, we must act quickly to keep people from getting sick or being harmed.

FDA has authority to act in a variety of ways, but often, the

fastest and most efficient way to ensure unsafe foods are recalled quickly is to work directly with the involved companies while simultaneously providing the public with timely, accurate information that they can act on, making sure FDA has effective recall practices in place, and we take immediate action to address unsafe foods are high priorities for the agency.

FDA has wide-ranging oversight responsibilities. In the foods areas, FDA is responsible for oversight and regulation of more than 300,000 registered food facilities, and more than 12 million lines of imported food products per year. FDA is also responsible for overseeing industry recalls of food products. In the most recent fiscal year, FDA oversaw more than 3,600 food product recalls.

The recent OIG review of a selected group of 30 food recalls initiated between 2012 and 2015 found some unacceptable delays in the removal of food from the market. This group included a number of challenges, including criminal behavior from a firm that hid critical information; new technology used to link clinical samples to their source; and key questions about how broad a recall should be.

One of the most significant steps FDA has taken was in April 2016. FDA established a team of senior leaders charged with reviewing complex or unusual food safety situations and determining the proper action to address the problem. SCORE, the Strategic Coordinated Oversight of Recall Execution, meets at least weekly and makes decisions about what actions to take.

SCORE has made a difference in addressing complicated,

challenging, and unusual incidents. The team has been involved in cases that range from lead contamination of a dietary supplement, Salmonella contamination of powdered milk, E.coli 0157:H7 in soy nut butter, to Listeria in hummus, soft cheese, and smoked fish.

In addition to facilitating recalls and import alerts for the detention of products entering the U.S., SCORE helped expedite the registration suspension of two food facilities, actions that prohibit food distribution after recall. In addition to SCORE, FDA has put in place several additional procedural changes. Last year, after a comprehensive review of our recall process, we developed a new strategic plan to improve recall management. The plan helps to standardize how FDA assesses a company's recall efforts, establishes monitoring of recall activities, provides additional training and guidance to our staff to monitor and assess recall effectiveness, and increases the timeliness and amount of recall information provided to the public.

The procedural changes FDA has completed since the OIG investigation establish a monthly monitoring system and regular audits, improve recall recommendations and recall audit check assignments, expand third party recall audit checks, improve the pathway for foreign suppliers to provide information about recalls to FDA, and create a set of best practices for our State partners.

FDA will continue to implement additional changes that will continue to improve how we protect the public through the recall process and through consumer messages. FDA has improved its recall

classification process, and now averages 13 to 15 days, down dramatically from a year earlier.

Furthermore, the agency is focused on providing more information to consumers in a number of ways. We now publicize recalls prior to classification. Yesterday, we released a draft guidance to improve public awareness in additional recall areas. And the Commissioner also announced a way to share additional information with consumers during recalls, such as specific stores where recalled food may have been sold.

FDA is also currently pursuing major initiatives that have implications for the oversight of recalls in the future. The Food Safety Modernization Act shifts the focus of the food safety system from responding to contamination to preventing it, and will change how companies prevent and respond to food safety issues.

In addition, FDA field operations have recently undergone a reorganization to meet today's challenges by specializing recall coordinators and other FDA staff.

Thank you for the opportunity to discuss FDA's recall processes. I would be happy to answer any questions you may have.

[The prepared statement of Mr. Stearn follows:]

******** INSERT 1-2 ********

Mr. Harper. Thank you very much, Mr. Stearn, for your summary of your testimony. At this time, the members will each have 5 minutes to ask questions of you, and I'll recognize myself for that purpose. And I'll start with you if I may, Mr. Stearn, to ask you some questions.

The Office of Inspector General and the Government Accountability Office, in previous audit reports dating back to 2009, has raised concerns about the FDA's monitoring of food recalls, such as verifying to make sure that retail grocery stores know about the recalls and the products have been removed from their shelves. Yet, the December 2017 report from OIG finds that monitoring recalls is still a problem for FDA.

Why is this still a problem? And why should the subcommittee believe that the FDA is going to get it right this time?

Mr. Stearn. Thank you for your question, sir. I answer it a number of ways. First, I would say, we do take this issue seriously. I've outlined in my testimony today, and in greater form in my written testimony, a number of actions that we have already taken, and those included that those that I just outlined in terms of establishing a group of senior leaders and audit process and additional procedures.

I would say, too, that the oversight of the food safety system is a large-scale enterprise, and we are actively working on FSMA implementation, which is the overall solution that we think will bend this curve in terms of food safety, and it is something that we have been in great dialogue with with all of the other places in the food safety system.

Mr. Harper. I think it would be safe to say that a goal of FDA, through its implementation of FSMA, is to reduce the incidents of foodborne illness in the United States. Is that fair to say?

Mr. Stearn. Yes, sir.

Mr. Harper. Is that FDA goal documented somewhere and is there a timeframe?

Mr. Stearn. Well, I think, in terms of the HHS initiatives and agency initiatives, there is language that speaks to that. I can say, as somebody who is involved in FSMA implementation myself, I am on the steering committee, it is something that we are driven to do, we have time frames. At the same time, we think it's really important to get things right. We don't want to have to reverse back if we get a standard that's not correct. And we are actively out implementing a lot of the provisions of FSMA, inspections have started in a number of areas, the rules have been written, and so forth. So we have a lot of actions that have been taken place.

Mr. Harper. Does the FDA view improvements to its food recall process as part of achieving this public health goal?

Mr. Stearn. We do.

Mr. Harper. And are you satisfied that you're putting the metrics in place where we can actually do a quantitative view of what your improvement and process is going to be?

Mr. Stearn. Yes, sir. We've taken a number of things to create more metrics and standards. We have an audit process in the steps that I've outlined which tracks during recalls the steps in between each

of the, sort of, critical control points, each of the steps that take place, and we do think that that's important. There's always more we can do, and some of these issues can be complicated, but we do think that that's important.

Mr. Harper. I know that the public expects, you know, not to maybe do it that day, but the timeframe that you've got to shrink that. Do you believe that you're in the process to do that? To reduce greatly the number of days that it takes to complete this process when there is a recall?

Mr. Stearn. We do.

Mr. Harper. Okay. Ms. Jarmon, if I can ask you a few questions. What deficiency identified in the report does the HHS OIG view is the most serious and why?

Ms. Jarmon. As you know, there were several deficiencies identified, but we feel like it's so important that there's better control over the oversight of firm's initiation of food recalls, and that the health hazard evaluations are done sooner. We have several examples in our report where Health Hazard Evaluations weren't done until, you know, in some cases over 100 days. I think on average, 57 days. And it's so important that that's done so that there's better information that FDA would have about what the harm is of the products. We think that's the most important.

Mr. Harper. The OIG report stated that this review was conducted to determine whether FDA is fulfilling its responsibility and safeguarding the Nation's food supply now, now that it has the authority

to conduct mandatory recalls.

Does the OIG see any evidence that the mandatory recall authority has been helpful to FDA's ability to carry out its mission to protect the U.S. food supply?

Ms. Jarmon. We are encouraged by the progress that FDA has made. We see that there has been progress, but definitely more needs to be done, and maybe more time because a lot of the things, like Mr. Stearn mentioned, have been recently done, and we haven't had an opportunity to go back and assess the progress. But the fact that the team was set up of senior executives, the SCORE team, is a positive step. The fact that there is a strategic plan now for recalls is positive. And the fact that they have the audit plan, as Mr. Stearn mentioned, is also positive, and that yesterday they issued draft guidance for improving the recall process. And all of those things could possibly be related to this legislation, so we see it as steps in the right direction.

Mr. Harper. That's right. Thank you very much for your testimony there. The chair will now recognize Ranking Member DeGette for 5 minutes.

Ms. DeGette. Thank you, Mr. Chairman. Ms. Jarmon, I'm encouraged to hear you say that -- and Mr. Stearn, I also believe it's true that the FDA is making efforts to improve their systems. The OIG's recommendations largely relate to the FDA improving its policies, procedures, and guidance. Do you agree with that?

Ms. Jarmon. Yes. Many of them do relate to improving their

policies and procedures and guidance, and initiating the processes sooner. We mentioned long delays.

Ms. DeGette. Okay. So I'm wondering, what more actionable steps do you think FDA should take to improve its recalls between just -- in addition to just improving the policies and procedures? You mentioned initiating the guidance sooner. What -- can you expand on that?

Ms. Jarmon. Yes. I mentioned doing the Health Hazard Evaluations sooner, because in our report, one of the examples that the chairman mentioned earlier about the issue that we mentioned in our Early Alert from June 2016, one related to a cheese product and one related to nut butter for the period of time from the time that FDA became aware of the hazardous product in a time that the firm initiated the recall, and that's just the initiation, more has to happen after that to get the products off the shelf.

Ms. DeGette. Right.

Ms. Jarmon. For the nut better, that was 165 days. For the cheese, it was 81 days. In that period of time, while we aren't specifically saying in our recommendations what the period of time should be, we believe it's reasonable to expect less time than that.

Ms. DeGette. The reason is, because if the food is contaminated, more people could be consuming it during that time. That is what Chairman Walden was talking about.

Ms. Jarmon. Yes. And more illnesses and possible deaths.

Ms. DeGette. Yes. Mr. Stearn, what's the agency's response to

this?

Mr. Stearn. Well, I would say a couple of things first, as I've outlined, we've changed a number of our procedures and policies. I will say, one of the issues underneath here is to make sure that a problem is understood and that a recall actually is solving the problem.

The cheese recall that was mentioned, there was actually four different recall actions that took place during the course of that. So, you know, part of the question that gets to, you know, what action is taken, is that sufficient? One of the reasons that we put SCORE in place, and we feel that that's really critical; and also, the specialization of the field staff, which has been going on for years, is that it's important for people to have the technical expertise to make those judgments, and sometimes to order additional investigation because --

Ms. DeGette. Are you having difficulty getting people with the appropriate expertise?

Mr. Stearn. Well, we've got to make sure that they're at the table, and it gets more complicated. I mean, one of the things that happened during this period of time -- in the nut butter recall, we started, for the first time, doing an entirely new technology, which is whole genome sequencing. We need people to understand that.

We need people to understand, you know, the rules that have been mentioned in FSMA. And so the level of specialization and the level of understanding of the supply chain needs to be high.

Ms. DeGette. I get it.

Mr. Stearn. Yeah.

Ms. DeGette. Are you having difficulty attracting those people?

Mr. Stearn. Well --

Ms. DeGette. Yes or no will work.

Mr. Stearn. We have a number of great people in the agency, we're always looking for more.

Ms. DeGette. Would having a stable budget help in that situation?

Mr. Stearn. A stable budget is helpful.

Ms. DeGette. Okay. So one issue that, as I recall -- we really talked a lot about before we passed the Act -- was this issue of mandatory versus voluntary recall. And I'm wondering if you're finding, because the agency has the ability to implement mandatory recall, if that's helping expedite the voluntary recall process more?

Mr. Stearn. We believe it is helpful for certain categories because there's a certain point where we reach with a firm in our discussions, and the firm knowing that that power is there, does affect the result.

Ms. DeGette. And have you noticed, since the Act passed, the number of mandatory recalls have gone up?

Mr. Stearn. Well, what often happens, more often than not, it reaches this certain point and there is a voluntary recall. And, you know, a lot of the -- so we do think that it has an impact by being there, and it's usually in firms taking a voluntary recall, either because there's a mandatory authority or because they know that there

might be a communication from the agency. You know, those two things are actually drivers in the self-interest.

Ms. DeGette. Nudging them along.

Mr. Stearn. Yes.

Ms. DeGette. So, you know, I really appreciate the OIG's recommendations, and I appreciate the agency's implementing them. If you think that there's more authority this committee needs to give to the agency to bolster that, and if you think there's more resources or stability of resources to do this hiring, let us know, because we -- this is one of these bipartisan issues. We care deeply about the safety of our constituents. Thank you. I yield back.

Mr. Stearn. Thank you.

Mr. Harper. The gentlelady yields back. The chair will now recognize the vice chairman of the subcommittee, Mr. Griffith, for 5 minutes.

Mr. Griffith. Thank you very much, Mr. Chairman. Mr. Stearn, I know you're here doing the best you can and that you're trying to make everything better, but there's some real serious questions that I have related to a number of different things, but I'm going to start with the nut butter situation, because we just touched on a couple of those.

One, you were talking about having the mandatory authority. If you look at the timeframe, which is Attachment A in the OIG report, if you look at the timetable there on their chart, page 30 of what I have, but you may have something different, you all exercised, or let

them know that you might use mandatory on August 15th, and they voluntarily recalled on August 19th. So I think in response to Ms. DeGette's question, it clearly works because you told them you were about to do it, and 4 days later, they were, like, Okay, okay, we'll do it voluntary.

The problem I have is on two things that you said also in that regard, you said that part of the problems was the new technology, the whole genome sequencing. But when you look at the time chart, it raises all kinds of questions for me. So I want you to explain the whole genome in a minute.

Mr. Stearn. All right.

Mr. Griffith. But here is the question that I have. There was enough information that something was going on that you all opened up an investigation in February -- late February, 6 weeks later, you actually, under using the older technology, matched an uncommon strain of Salmonella to that facility. That was on March 24th. And connected it with some of the diseases -- some of the folks who had gotten sick.

Nothing was done, apparently, at that point, there may have been some letters, I don't know. But then, the whole genome sequencing was completed on May 12th. So the discussion that you want to make sure you're doing the right thing and not disrupting, as Ms. DeGette said earlier, an entire industry with a recall that is not justified. You had that confirmation on May 12th. So May 12th, June 12th, July 12th, August 12th, all went by, eventually 3 months and a few days later you

then threatened the mandatory recall.

Mr. Stearn. Right.

Mr. Griffith. So the question is, the American people who are watching this, either live or later when they are having insomnia, are going to ask is, okay, we want to make sure we're doing the right thing. Maybe you can justify, although there's a question mark there between March 24th and May 12th. But once you've got the whole genome sequencing, and there's no distinguishing between the Salmonella in the sick people and in your environmental, and I know I'm not using the scientific terms, but the sick people and in the nut butter, why didn't you act then?

Mr. Stearn. So there's a number of issues that make this complicated, if I can go back a little bit.

Mr. Griffith. Okay.

Mr. Stearn. So there was a link under the PFGE pattern in March of 2014. It's important to understand that a couple of things --

Mr. Griffith. Now, folks back home don't because know because -- what is PFGE --

Mr. Stearn. This is pulsed-field gel electrophoresis. And this was -- it helps link the clinical, that is, from the person to what's happening at the facility.

Mr. Griffith. Right.

Mr. Stearn. It's something that we used -- been relying on for a while. It's not perfect, because it's more limited in the amount of information that -- in terms of comparison of those organisms. And

it shows that there's a strong link between what those organisms actually are, because something like, you know --

Mr. Griffith. And that's what you linked up in March?

Mr. Stearn. That is what we linked up in March. I will tell you that our expert analysis is that was not enough to show causation at that point.

Mr. Griffith. Okay.

Mr. Stearn. There was no link. And it was done differently than we usually do it. Usually there's a food history that links -- where they ask people, what did you eat? And they link that back. Then we look at the PFGE. That didn't happen in this case. People did something new in this case. They went through some of the data bank and they linked that up. They linked it up with PFGE and they linked it up with whole genome sequencing. They're very excited about that when that happened, because it does -- and it actually has been something that we used that is linking up to this database, and it's something that really is very promising. But we -- there were delays in this case, and I should say, first of all, I think we have done better in this case.

I will tell you that when we did the whole genome sequencing, we did it for the environmentals in May. It was not until August that we linked it to the clinicals. And that was a delay in terms of doing that whole genome sequencing link which was the trigger for that, you know, request for mandatory recall and the discussions with the firm that resulted in recall.

There were things that I think could have been done differently in this case, but I do think it's important to understand some of the complexities. This was not an obvious case on day one, and in fact, in a number of these cases, it's not obvious on day one. It's very important that we accelerate our own investigation. It's important that firms have their own investigation and their own preventative models.

But it was less than clear to the people who had that, you know, back in March because there were environmentals which were concerning, but the links to the clinicals were less than crystal clear. Like I said, it wasn't supported at that time by the food histories. And the firm tested all their products, all the products was negative. So, you know, the firm testing was -- the firm was pushing back on us with some of their own testing.

The story's a little bit more complicated, but at the same time, we take the OIG's point in this, and we agree with it. We need to make sure this is -- it's not okay if it takes this long, even if it's complicated, that's why we have this approach in place where we feel we need to make sure that the agency leadership and the staff are prepared to, you know, know what's a red flag and act on it to make sure we get to the right result as soon as possible.

Mr. Griffith. I appreciate it and yield back.

Mr. Harper. The gentleman yields back. The chair will now recognize the gentlemen from New York, Mr. Tonko, for 5 minutes.

Mr. Tonko. Thank you, Mr. Chair. This committee has repeatedly

heard that FDA must manage food recalls more effectively. That is why Congress gave FDA new authorities under FSMA in 2011. FDA has told us that it's taking steps to improve that recall process. However, the OIG's report finds that FDA's data on food recall is often incomplete or inaccurate, which makes it difficult, if not impossible, to tell how things have improved since Congress gave the FDA new tools.

For instance, FDA's recall data system does not track key milestones, such as the date that FDA learned that a product was potentially hazardous.

So, Ms. Jarmon, can you offer some insight about why those data are important and how incomplete data make it difficult for FDA to manage food recalls?

Ms. Jarmon. Yes. It's very important that the data in their recall systems is complete and accurate, that way, they can -- that's key to monitoring the food recalls. And like we mentioned in our report, there was no data in there for when FDA became aware that an item was potentially hazardous.

And so in some cases -- so without having that date there, it's not possible for them to determine how long it's taken -- how long it took them to -- from the time they became aware that the product was potentially hazardous until the time that the food recall initiation occurred. And in some cases, some of the longer examples that we have like one, which was a dietary supplement, where it was 303 days from the date that FDA became aware that their product was hazardous, and actually sent a warning letter to the firm, it was 303 days later when,

in that case, the food recall initiation occurred because that date wasn't in the system. If you look at FDA system, it was 10 days based on -- because they had -- the dates in the system were not correct.

Mr. Tonko. Uh-huh.

Ms. Jarmon. So it's very important to make sure that the action is happening faster.

Mr. Tonko. Right. And I thank you for that. And OIG points out that because FDA doesn't record the date when it learns a product is potentially hazardous, FDA couldn't determine, for instance, that it took a firm 151 days to actually initiate a recall of hazelnuts contaminated with Salmonella. FDA claims that it would be time consuming to track this information.

Mr. Stearn, if FDA does not track milestones like this, how can you tell when firms are not moving swiftly enough to remove dangerous foods, and when to take more aggressive action?

Mr. Stearn. Thank you for your question, sir. We do think it's important for the agency to record when there's a critical hazardous step. There are a lot -- a number of issues in terms of our systems and how they interlink. We have different systems for different purposes and what kind of information that can be in there. We take this point, we're looking at trying to make sure that our procedures clarify, and make sure that the records are correct when it has tipped over. And we're going to continue to work on that.

Mr. Tonko. Thank you. In addition to incomplete data, OIG also found that FDA did not always collect timely and complete status reports

from firms during a recall.

Ms. Jarmon, does that hinder FDA's efforts to oversee the recalls, and how so?

Ms. Jarmon. Yes, because it's important when -- after the firm initiates the recall that the FDA is also monitoring what's happening after that period of time, so that, of course, when the initiation first started, the products are still on the shelf. So in many cases, the firm is still testing effectiveness and verifying different things related to the product. And we found, in some cases, the status reports weren't received over 100 days until after this process -- the firm had been communicating their story, the recall.

So it's important that FDA continues to check on this status and monitor the firms when they're in the recall process, and the status report is one way to do that.

Mr. Tonko. Thank you. And, Mr. Stearn, does FDA agree that it needs to improve its collection of these status reports? If so, what steps do you think we should take?

Mr. Stearn. Yeah, it would be -- well, let me say first that we would like to have better status reports. It is entirely a voluntary process, so -- it's right now and historically, and during this time, there's no obligation for a firm to provide us status reports. And we do think that that will be improved through the implementation of the preventative control rule, which requires firms to have recall plans. And so for the first time, FDA -- there will be an obligation in terms of how they conduct their recalls.

Third party audits for recall audit checks we think are critical. We did have an extended discussion with OIG about that. We have expanded that program. That gives us a lot more flexibility, and it turns around our recall audit check process much faster. And we do think consumer notices are appropriate because it sort of jumps over the whole recall system and gets the message to where it needs to be.

Mr. Tonko. Thank you very much. Mr. Chair, I yield back.

Mr. Harper. The gentleman yields back. The chair will now recognize the gentlelady from Indiana, the distinguished chair of the Ethics Committee, Mrs. Brooks, for 5 minutes.

Mrs. Brooks. Thank you, Mr. Chairman. And thank you and the ranking member for holding this important oversight hearing today. As the committee is well-aware, biodefense issues are something that I've been working on. Public health securities is a top priority as we look at how we oversee our food supply. It's a security issue as well as to how it impacts a threat to our food system, that can be devastating. Much of our Nation's corn, soy, and hog supply comes from my State of Indiana. And I know and believe that our Nation needs a stronger system of monitoring animal health, both for the threats to our Nation's food supply, but also for potential outbreaks in the animal population that can mutate and jump to humans.

And should a bad actor seek to affect our food supply, our system I'm not certain is equipped to quickly determine if it's a foodborne illness naturally occurring, or if it is manmade. And in the case of a bioterror attack, obviously, timely response is crucial, but I know

can be difficult.

So with that, Mr. Stearn, I'm interested in FDA's efforts to protect the U.S. food supply from bioterrorism or economically motivated adulteration, and what steps has the working group on economically motivated adulteration taken to improve protection of our food supply? And, more directly, so how would FDA, as we're talking about these types of food recalls coming from manufacturers, but how would FDA respond if there could possibly be a terrorist attack?

Mr. Stearn. Thank you, Ms. Brooks. There's a number of points I would make. First, there is, as part of FSMA, there's an intentional adulteration rule in which we -- in which firms are to look at their own risks related to potential intentional adulteration from other parties. So there's one component.

We do have a food defense group within FDA that monitors some of the intelligence and works with some of the intelligence to try to make sure that we're able to monitor what's coming in from outside of the country, largely, in terms of food defense. And we also believe that, you know, having a preventative food safety system generally allows for closer monitoring of what's coming in and making sure that folks understand what's happening in their own supply chains. And that's the kind of danger that we've seen in some of these incidents that have happened historically is that sometimes there's something that happens in a supply chain, and it's brought into the United States, and then we have an issue.

And the system that's being created within FSMA helps to have

people monitor what's happening throughout the supply chain, which is, in part, also helpful to combat those issues.

RPTR DEAN

EDTR ROSEN

[10:00 a.m.]

Mrs. Brooks. I appreciate that, but now this is as of December 2016, and here we are January 2018, the FDA -- as of December 2016, so I'm curious if something has changed, the FDA still hadn't met a 2011 GAO recommendation to provide written advice to centers and offices on avenues to address economic adulteration. Has that changed? Has the FDA created a document that's been used to meet GAO's recommendation from 2011?

Mr. Stearn. I think -- I'm not aware of such a document. I do know that there was a group that looked at this issue, and they found it very challenging. I've spent a lot of my -- some of my career at FDA looking at the heparin issue for several years. I worked with the committee on that. And there is a lot of different ways that this can happen. So I think, in large part, the answer that the agency is looking for is to look at standards that get applied throughout the supply chain, because the places that we've seen this enter, were the places we've seen economically adulterated products coming in, it is usually where there is a lack of accountability within the supply chain, and that's what we think is sort of the most effective strategy.

Mrs. Brooks. And you indicate that there are a lot of, obviously, strengthening our systems against bioterror, are incredibly complex, but can you talk with us about some of the impediments and challenges

that your group, and those who work in that group are experiencing, so we can help breakdown those impediments?

Mr. Stearn. Coordination of intelligence can be a challenge. We do have a group that works with CBP at their counterterrorism center. And I would just say just generally, that's an issue, because a lot of coordination that needs to happen, and because it is secure information that can be a challenge.

Mrs. Brooks. I know but we've been working on that since 9/11. And it is now 16 years later. And so you're saying that there's still a challenge with your agency working with CBP on the supply chain?

Mr. Stearn. What I would say is it's -- one the issues that we deal with is to try to make sure the intelligence is where it needs to be. I'm not prepared to go probably any deeper than that at this point. I would say also the intentional adulteration rule is something that the agency has come out recently that does address that issue.

Mrs. Brooks. Thank you.

I yield back. My time is up.

Mr. Harper. The gentlelady yields back. The chair will now recognize the gentlelady from Florida, Ms. Castor, for 5 minutes.

Ms. Castor. Well, thank you, Mr. Chairman and Ranking Member DeGette, for calling that hearing today. And thank you to our witnesses for the work that you're doing.

The issues we're talking about today have serious real-world consequences, as single contaminated food product can have devastating impacts across the country, depending on what it is and how it spreads.

As an example, the OIG report cited a 2014 recall of cheese products contaminated with Listeria. That product contamination is particularly troubling because it led to one infant's death and two lost pregnancies.

According to OIG, 81 days elapsed it between FDA becoming aware of the adulterated product, and the firm recalling all of the affected products. I understand that this case is particularly complex and FDA was even given misleading information from the firm. But I'd like to walk through this recall and try to shed some light on the lessons learned.

Mr. Stearn, FDA learned about the contamination on July 28th, then spent a month inspecting, testing samples and requesting an update from the firm. You had previously mentioned that it's always important that FDA accelerate its recalls. Could you give greater detail on this case? How could FDA have shortened that phase of the recall?

Mr. Stearn. One thing I would point out, there were a number of different recall actions it that took place. There was actually four different recall actions that the firm took, that Oasis took during the course of this time period that was referenced. The first was after -- there was a positive sample where one of the firm's cheese products, and in less than a week, there was a recall that of that particular product. And then also, FDA initiated an inspection of the facility. So we did act quickly to follow up with that.

During the course of that inspection, there were environmental samples that were positive. We went in and did a lot of sampling in

the firm. There were a number of things that were positive and there was a frank discussion with the firm. After that, the firm made a series of promises. The firm actually -- well, first, the firm said they would stop manufacturing. The firm also said that they would stop distribution until they had consulted with FDA. And the firm said that they would bring in an expert, and to do additional testing. And the firm also committed to do a recall of some product, which they did initiate that was implicated by the environmental testing positives. And so, you know, that happened. And then after that, the firm continued to manufacture at a certain point and did distribution.

Ms. Castor. I also understand that after FDA conducted its test, it received a brief letter from the firm on September 11th that reportedly, "lacked significant supporting documentation." But then the firm, as you said, distributed potentially adulterated products after that and FDA, but then FDA didn't conduct another follow-up inspection until nearly a month later. Why didn't FDA take swifter action after receiving the response from the firm on September 11th?

Mr. Stearn. The firm -- FDA believed the firm was not manufacturing at that time, based on what they said and not distributing. I think that -- I say that at the same time I say I think there's more that FDA should have done in this case. And in some respects, it gets to the issue of a preventative mindset versus reacting.

Ms. Castor. Because when FDA conducted its follow-up inspection on October 7th, it, again, found the presence of Listeria. And at this

point, this was 45 days after FDA first learned about the contamination. However, it took the firm another 10 days before it voluntarily recalled all the potentially contaminated products. So at this point, what could FDA have done differently to either encourage or mandate a faster and fuller recall?

Mr. Stearn. So one of the things, and this gets back to you how some of these things can be complicated. The firm did act when FDA brought some sort of positive sample to it. They acted, they initially did a recall related to the first product sample. After there was an environmental, the firm made a series of promises which turned out to be lies, they were false. And we didn't find out fully about that until going back on inspection. But, you know, the firm said a lot of things that would be the kinds of things that FDA would want to hear, we're going to stop manufacturing --

Ms. Castor. So if they are not truthful with you or they don't follow through, how do we hold them accountable?

Mr. Stearn. I would say a couple of things. First, it is important always to verify, even this firm's recall activities should have been broader, there should have been a broader recall earlier. We had a product sample positive. We had environmental samples. We had bad practices that were documented in the firm. That is a pretty strong set. The firm made a lot of promises. The firm, I think, even given that, more should have occurred.

Ms. Castor. And -- but the accountability answered.

Mr. Stearn. So in terms of it -- one thing I would note is that

the owner was prosecuted. FDA does have an office of criminal investigation, so that, I think, the deterrent message is important. And also, we need to verify. I mean one of the reasons, and OIG mentioned about recall audit checks and whatnot, it is very important that we do those to make sure those things happen. It is important that we have follow-up inspections to make sure what was promised gets done. So FDA has verification procedures it needs to use. And if is a high-risk issue, like this one, we need to use them quickly.

Ms. Castor. Thank you. I yield back.

Mr. Harper. The gentlelady yields back. The chair will now recognize the gentleman from New York, Mr. Collins, for 5 minutes.

Mr. Collins. Yeah. I thank the chairman and the witnesses. Certainly, food safety is a universal concern and this is not a partisan hearing at all. We're generally trying to get to an understanding of what does happen.

So let me back off just a little. We say there's about 3,000 recalls a year, about 10 a day. Roughly, how many of those are voluntary firm-initiated, and how many of those would be, you know, mandatory recalls driven by the FDA?

Mr. Stearn. Virtually all are voluntary.

Mr. Collins. That's what I would expect. In the threat certainly the mandatory is there. So since these are voluntary, whether it is under pressure or not, how quickly does the FDA classify those as a class 1, 2 or 3?

Mr. Stearn. So I think OIG referenced some of the earlier data,

most recently we were doing that within 13 to 15 days in the food program.

Mr. Collins. And I'm assuming that if it is class 1, you know, that's when somebody's hitting the buzzer with the red lights and so forth, that you do a lot more detailed work, analysis, urgency for a class 1.

Mr. Stearn. It is a red flag.

Mr. Collins. So roughly, how many class 1s a year do we get versus 2 or 3?

Mr. Stearn. I think it is in my written testimony. I would have to get back to you with the exact number.

Mr. Collins. But, I mean, is it 10 percent or 80 percent class 1?

Mr. Stearn. It's in between those two. So I don't have the exact number. But I'd hesitate to give a number when I'm not sure, but it is -- it's the -- it is in between those. So there is a significant proportion, but it is not the majority.

Mr. Collins. So if it was 20 percent, that would be two a day, roughly?

Now do you have the staff that, you know, is one person given oversight of that particular recall? You've got two every day that is class 1 voluntary recalls. Is that a team that goes to work, or a single person, or --

Mr. Stearn. We have recall coordinators that are throughout the country. One of things that we've done in our recent reorganization

is we specialized that staff. So there's a recall coordinators who interact with the firms. There's also other components that do other things that are related to recalls. But a lot of that is run by our field staff locally.

Mr. Collins. So your inspectors are in these facilities every day?

Mr. Stearn. Yes.

Mr. Collins. Sometimes they literally have offices there.

Mr. Stearn. Yes.

Mr. Collins. And so we have to rely on the professional nature of the company itself. I'm thinking the quality manual. You, I'm sure, are always reviewing the quality manuals. As you said, though, I was a little disturbed to see you don't currently mandate a recall procedure or plan? With each company that you reduce, your inspectors are not auditing recall plans today?

Mr. Stearn. Well, right now, recall plans -- well before the passage of FSMA and the implementation of preventative control rule, there was not any kind of mandate that a firm have a recall plan.

Mr. Collins. That would be a concern.

Mr. Stearn. So I will say when there is a recall, and traditionally, we will follow up, and that happened in these very cases, other cases that have traditionally happened where there is a recall. We do follow up with that on inspection, ordinarily in the next inspection to make sure, and we try to do that quickly to make sure that there's some review of what occurred.

The difference is, is what's the, you know, legal requirement, what standard do they have to do? I mean we were talking about status reports, do it they have to do status reports? What do they have to do in a recall? FSMA helps standardize that. The firm has to plan where there is a hazard, to make sure there's some kind of plan to address recalls in particular. Whereas before, it was more reactive.

Mr. Collins. I mean, common sense, if you don't have a plan, then it truly would be haphazard at best. So I would hope your inspectors who are in there every day are constantly making sure that T's are being crossed, the I's dotted.

Mr. Stearn. Thank you, Congressman. Related to your earlier question, I got a note. So we are about 1,200 products class 1 out of our 36 -- a little bit more than 3,600, so that's roughly a third.

Mr. Collins. That's actually higher than I might have expected.

Now, how often -- I only have a few seconds left -- does your lab do independent testing, or your labs versus relying on the company data to assess the risk?

Mr. Stearn. So we do part of the things that you mentioned in some of these where we have a class -- it's where we -- there's a certain risk profile. If it hits a certain risk profile, we will do testing in the environment of that facility. In addition, if we have reason to, we have type -- different types of surveillance testing. We have it at import and we have it in a domestic realm, and those all go off to our labs. So we do a lot of testing ourselves. Firms also have their own testing programs.

Mr. Collins. Which you rely on as well?

Mr. Stearn. That is part of our oversight is to look at what they are doing.

Mr. Collins. My time's expired. I appreciate your answers. I yield back, Mr. Chairman.

Mr. Harper. The gentleman yields back. The chair will now recognize the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. Costello. Thank you, Mr. Chairman.

Mr. Stern, as you know, the OIG report identified a number of deficiencies in the food recall process. And I wanted to direct your attention to figure 1 that shows the days it took firms to initiate the recall after FDA learned a product was potentially hazardous, with specific reference to the new trucks research incident where it took 303 days to execute a recall after the warning letter was issued.

First, is it correct that in this particular case, it was found the firm continued passing out free samples after receiving their letter?

Mr. Stearn. I'm unsure about that specific fact.

Mr. Costello. Is that easily obtainable for you to provide us in short order?

Mr. Stearn. I could.

Mr. Costello. I appreciate that.

Are FDA actions, after a warning letter, typically delayed for 300 days?

Mr. Stearn. No.

Mr. Costello. How often, on average, or is it customary or within the realm of accessibility, for the FDA to take an enforcement action after issuing a warning letter? What's the typical --

Mr. Stearn. There's some variation by program, I would say ordinarily, we go back within 6 months. In certain areas, clinical trials for example it tends to be longer because there has to be enough data to actually monitor what has occurred, but this is not what ordinarily happens or what we should expect.

Mr. Costello. Are the delays of a recall more of a problem with dietary supplement products?

Mr. Stearn. I would say there are -- this is a good -- one of the issues that occurred here in these dietary supplements, there's an ingredient, DMAA; there's some controversy about that. There has been some litigation related to that. And I could follow up with you in some ways, but I would just say where we -- some of the issues are scientifically challenging, the firm did challenge some of the science about the safety of the ingredient in this case.

Mr. Costello. And then final question on this line of thought, what lessons can you share that you've learned from the new trucks research case?

Mr. Stearn. I would say overall, you know, in terms of the lessons, I think we would say it's important for the agency leadership to look very closely, especially at high priority things that we've had at class one, that is the kinds of things that have the highest risk. We need to do that prioritization, and we need to investigate,

and we need to make sure that we have systems in place to act when that occurs.

Mr. Costello. Were systems in place at that time and were not followed, or were the systems incomplete or insufficient?

Mr. Stearn. I think in this case, one of the issues that was related to the fact that this is not -- the safety of DMAA, or the unsafety of DMAA, which the ingredient at issue there, is not -- I will just say there's a controversy or different ideas about that. And, you know, to some extent, we have to resolve that sometimes in the court system.

Mr. Costello. To the extent that that a warning letter triggers the type of litigious activity surrounding the safety of a particular element, does that give it higher priority or does that add to the priority, or is that something within the systems that you have to address?

Mr. Stearn. I think we need to prioritize. And your question is a fair one. If we have -- there's a number of warning letters that come out. The agency has a lot of different issues. If it's an issue that we find to be one that has potential harm to consumers, it's a higher risk issue, we should make sure that that gets addressed.

Mr. Costello. Yes, because it strikes me that -- I didn't do this kind of work as an attorney, but if -- or if you were a GC for a company, if you have a product on the market, the product is doing well, you get an FDA letter that says, This is a warning letter, et cetera, et cetera, et cetera. Number one, I don't think a company -- I wouldn't

think many companies would put a product on the market that they felt was deadly or that would trigger that first tier -- well, any tier, but particularly, that first tier. The question becomes it is pretty reasonable or expectant to assume that you're going to get a response that says, Wrong, we're going to take you to court or this issue is going to be litigated. And that should not freeze you up in terms of addressing what you identified as a potential health issue. So how --

Mr. Stearn. I would agree.

Mr. Costello. What do you do about that?

Mr. Stearn. We need to make -- again, I think as is the kind of issue that you flagged, there may be disagreement. If it's something that the agency finds is a threat to consumers, we have to prioritize that and we need to make sure that we bring it forward.

Mr. Costello. Do you have sufficiently expansive regulatory authority in order to do that, or do you need statutory assistance?

Mr. Stearn. We are not asking for any authorities today.

Mr. Costello. Very good. I appreciate your answers.

I yield back.

Mr. Harper. The gentleman yields back. The chair will now recognize the gentlelady from Illinois, Ms. Schakowsky for 5 minutes.

Ms. Schakowsky. Thank you. I want to focus on FDA's mandatory recall authority. So the OIG's report describes some concerning contamination cases, and unfortunately, it is not the first time we're hearing about such outbreaks. In fact, this committee has been investigating FDA's food safety efforts and recall practices for well

over a decade.

Over 7 years ago, FDA told the subcommittee that mandatory recall authority would help it remove dangerous products from the market more quickly. Congress than passed the FDA Food Safety Modernization Act, FSMA which gave FDA this very authority and significantly reformed the agency's ability to prevent and respond to outbreaks. Now we are here again discussing these issues. So I want to find out how this law is working.

Mr. Stearn, overall, has FSMA helped FDA oversee food recalls, particularly regarding inspection resources.

Mr. Stearn. Yes.

Ms. Schakowsky. So you have had enough resources in order to do the job?

Mr. Stearn. I believe we have enough resources within the --

Ms. Schakowsky. Here is then -- Congress gave FDA this authority to help the agency respond to contaminated foods faster. However, the OIG reported that between 2011 and 2016 FDA used that authority just twice. And just yesterday Commissioner Gottlieb stated, and I quote, "recall authorities and how we deploy them are a cornerstone of our vital consumer protection mission."

So Mr. Stearn, given that your recall authority is the cornerstone of the agency's consumer protection mission. Can you explain why FDA has only used its mandatory recall authority twice, or a few times, anyway?

Mr. Stearn. Thank you for your question.

First I would say our goal is to remove the product from the marketplace if it's unsafe. So the first -- that we start with that as a precept. And ordinarily, if a company is willing to do that, that's going to be the fastest way to make sure that that gets done.

Now we have a number of, as I mentioned earlier, we do think that mandatory recall is one of the things that when we get to a certain stage with a company, generally convinces that company to recall, if it's the right thing, that it does play a role in the background in our discussions as well as some of the consumer communications that the agency uses. So I would say that's really one of the things in the background, which is also to say there may be cases where it's appropriate and we should be using it if other actions aren't happening quickly enough.

Ms. Schakowsky. So the FDA has to meet certain standards before it can invoke the mandatory recall authority. Is that correct?

Mr. Stearn. That's correct.

Ms. Schakowsky. So are there difficulties in meeting that standard, or do you feel that having it there as threat is sufficient. Is that what you're saying?

Mr. Stearn. I think -- well, what I would say is a lot of issues get into the facts, there some complexities about whether -- about identification of products sometimes and the level of hazard within products. We ordinarily don't have issues with firms when there is a pathogen in a particular lot of the product. A lot of the times that we have issues is, what about the other products made at that facility?

That happened actually in the cheese recall we mentioned earlier. And what level of evidence is needed for that. So sometimes there is a question, a scientific or factual question about identification, the level of risk and so forth.

And so those are things that I think -- again, back to why we have reacted to the OIG's report the way that we have is that our centerpiece really is poor, our centerpiece is to make sure that the leadership of the agency from different components when there is a red flag, make sure we do whatever we need to do to get to the right answer quickly. When we get to the right answer, we believe we can make it happen quickly.

Ms. Schakowsky. There is some concern that FSMA has not been fully implemented and enforced. Is there anything we can do to speed up that process?

Mr. Stearn. We are actively working on FSMA implementation now. I'm very much engaged in that myself. And I don't have anything today. I can bring that back to the agency if there's anything else to add.

Ms. Schakowsky. Thank you. I yield back.

Mr. Harper. The gentlelady yields back. The chair will now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. Carter. Thank you. And thank both of you for being here. This is obviously a very important subject, particularly for us in the State of Georgia. As you know, we had the unfortunate incident some years ago with the peanuts, and that's still fresh in our minds.

Mr. Stearn, let me ask you, when you released the updated guidance

yesterday on accelerating the recall process, part of it included stepping in if a company for the FDA -- the FDA to step in if a company hadn't sufficiently addressed a recall. How do you determine if they sufficiently addressed it or not?

Mr. Stearn. Right. So the guidance yesterday we released talked about public warning and notification. It talks about when we think a company should issue a warning and we describe how that should be done, and when FDA will issue public warnings, as well as some changes in notification. This goes back to the issue we were talking about earlier in terms of FDA has to get to the right answer in terms of evaluating the issue as soon as possible. So if we understand the issue, we think it's best when we have consistent message with a company that's responsible. There's not dueling messages, it's clear and that's what we --

Mr. Carter. How often does that happen that you have dueling messages?

Mr. Stearn. I would say the overwhelming number of times we can get to the right answer, you know, in terms of our communications with a company. There are times where -- and it's not the usual case.

Mr. Carter. Is the right answer always your answer or --

Mr. Stearn. I'm sorry?

Mr. Carter. Is the right answer always your answer or does the company --

Mr. Stearn. Well, we do have a dialogue with companies, I mean, we do listen to them, and some companies have -- I have been engaged

in a number of technical conversations where a company has said things that have changed our minds, so that does happen. Sometimes we're dealing with a company, though, where they are -- they don't understand the problem. We need to get a message to consumers and if they are not willing to do that, we have to be willing to do that.

Mr. Carter. If that is the case, sir, there are repercussions from that company?

Mr. Stearn. So ordinarily, I mean, most of our recalls, the firm prepares a press release, we comment on that press release. We want to make sure it is actionable for consumers. If a firm will not, or cannot do it that, the FDA will, or if we think it is appropriate even when a firm has done it, because we will have to reach a certain population, or there's a way to do it that we think is necessary, FDA will issue its own consumer communication.

Mr. Carter. You issue it, are there any penalties to the company?

Mr. Stearn. Oh, to the company? No.

Mr. Carter. If you have to step in and you have to exert that energy, and you have to exert that authority, there ought to be ramifications.

Mr. Stearn. Right. I do think, one of the things I go back to, which is not fully developed, but under the preventative control rule within FSMA firms have to their own recall plan, and --

Mr. Carter. Is that approved by FDA? The recall plan?

Mr. Stearn. Well, it is not formally approved. But it is, I would say, when we go in, we have do have oversight responsibility so

they have some obligation to do it and we could exercise some regulatory oversight if the firm did not act appropriately in that regard.

Mr. Carter. Okay. Let me ask you, in December, the inspector general's office of HHS released a report on food recall, the process. And understand when the FDA learned that a product was potentially hazardous, FDA stated that tracking this data for all recalls would be time consuming and difficult as the date may be located in different FDA systems are obtained from sources outside of FDA. What kind of sources outside of FDA are you talking about?

Mr. Stearn. Well, we may get information, I mean, we work with States a lot, so sometimes, States have their own -- there's a lot of State inspections that States may find a food safety issue that they communicate to us. Sometimes we have information that comes from foreign governments. Sometimes we have information that comes from third party sources.

Mr. Carter. If that's information that is concerning, is there a time when the State feels like the FDA needs to know this, they send you that information?

Mr. Stearn. Yes, that happens. In fact, it happened in one of these cases. You know, we worked with Virginia. Virginia did some testing that kicked off the cheese recall we were discussing earlier.

Mr. Carter. So you feel like you have all the information you need, that's the question, because I know you can't make a decision until you've got all the information.

Mr. Stearn. I think I would just say one of the challenges we

have, and I think it is a challenge, is that we deal with thousands of firms and there are a lot of different food safety issues. These days, we are also getting information from different sources, and that, in fact, happened in these cases. And we need to find -- we take the point, we need to find a way, it is part of the question is how, we need to find a way to make sure that we get all the relevant information in as soon as possible to make sure we get to the right answer. We take that point.

I think technically, there are challenges, there are some challenges within our data systems, we have a lot of different ones.

Mr. Carter. Is there anything we can do to assist you with that?

Mr. Stearn. I would have to take that back to the agency.

Mr. Carter. Know that we are ready and willing. Okay? Thank you for the work that you do it is extremely important, both of you. Thank you very much. I yield back.

Mr. Harper. The gentleman yields back. I want to thank you, Ms. Jarmon, and you, Mr. Stearn, to shed some light on where we are and recognizing the importance of this issue and we appreciate you being here today. I remind members that they have 10 business days to submit questions for the record. I ask that the witnesses agree to respond promptly to any questions that are submitted.

With that, this subcommittee's adjourned.

[Whereupon, at 10:30 a.m., the subcommittee was adjourned.]