

AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2020

HEARINGS BEFORE A SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND
DRUG ADMINISTRATION, AND RELATED AGENCIES

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JOHN R. MOOLENAAR, Michigan

NOTE: Under committee rules, Mrs. Lowey, as chairwoman of the full committee, and Ms. Granger, as ranking minority member of the full committee, are authorized to sit as members of all subcommittees.

MARTHA FOLEY, DIEM-LINH JONES, JOSEPH LAYMAN,
JUSTIN MASUCCI, PERRY YATES, and RANDALL STAPLES
Subcommittee Staff

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**PART 2—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION,
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**AGRICULTURE, RURAL DEVELOPMENT, FOOD
AND DRUG ADMINISTRATION, AND RE-
LATED AGENCIES APPROPRIATIONS FOR
2020**

WEDNESDAY, FEBRUARY 27, 2019.

**FOOD AND DRUG ADMINISTRATION—STATUS OF
OPERATIONS**

WITNESS

**SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD AND DRUG ADMINIS-
TRATION**

OPENING STATEMENT—MR. BISHOP

Mr. BISHOP. The Subcommittee for Agriculture, Food and Drug Administration, FDA, and related agencies will come to order.

Good afternoon. I would like to welcome everyone to today's hearing, which is our first in the 116th Congress.

Before we get underway, I would like to personally welcome all of the returning members to the subcommittee, as well as our new members. Although they have not all arrived, Ms. Lee of California; Ms. McCollum of Minnesota, Mr. Cuellar of Texas, and of course, Ranking Member Fortenberry of Nebraska, and Mr. Moolenaar of Michigan.

I would also like to thank Mr. Aderholt for his work on the subcommittee. He served as chairman for the previously six years.

I look forward to working with all of the members of the committee in a productive and a bipartisan manner.

I also would like to thank Commissioner Gottlieb for allowing us to start the hearing two hours later. We are very appreciative for your flexibility.

The work of this subcommittee touches the lives of every citizen on a daily basis. As we have said so often, many do not recognize the far-reaching jurisdictions and programs that this subcommittee addresses, a little bit of everything from food safety to agriculture research, to drug approval, to rural development, to protecting market integrity, through the Commodity Futures Trading Commission.

Part of our efforts include providing necessary resources to the Food and Drug Administration, which plays a critical role in the lives of every single American.

In addition, we have a duty to make sure that those resources are put to the best possible use by the agency.

With that, I would like to welcome our witness, Dr. Scott Gottlieb, Commissioner of the Food and Drug Administration. We are delighted to see you. Today we would like to discuss the status of operations at the Food and Drug Administration, including the impacts and the recovery from the longest and the most pointless shutdown in U.S. history.

Before we begin, I would like to thank you and your very committed employees for your efforts during the shutdown, many of them working without pay. While the full impacts of the shutdown will not be known for some time, there are undoubtedly accrued backlogs of inspections, delayed drug and medical device reviews, and potentially exhausted pools of user fees as a result of the shutdown.

We look forward to hearing the processes put in place to work through these backlogs as efficiently as possible and other efforts to return to more standard operations.

And I would like to thank you for being with us today, and I look forward to today's discussion.

I will defer the opening statement from our distinguished Ranking Member, Mr. Fortenberry, until he arrives.

And at this time I would defer the comments from our chairwoman of the full committee, Congresswoman Lowey, who I believe is en route, and she will have some opening remarks.

Before Dr. Gottlieb begins, I would like to give a reminder to members that as is customary with our subcommittee, members will be recognized by seniority, for those who were here when I gavelled the hearing to order and then in the order of their arrival after that.

We will alternate majority/minority members, and we will adhere to the 5-minute rule.

Commissioner Gottlieb, without objection, your entire written testimony will be included in the record.

I will recognize you now for your statement, and then we will proceed with questions from members.

OPENING STATEMENT—COMMISSIONER GOTTLIEB

Dr. GOTTLIEB. I thank you, Mr. Chairman, and I want to thank the ranking member as well, whom I had an opportunity to meet with a couple of weeks ago, and I look forward to his arrival.

I also want to thank the Members of the Subcommittee. I want to thank all of you today on behalf of the FDA for your continued support of our public health mission. We are witness to, quite simply, a period of historic scientific advance right now, and the opportunity that we have across our entire portfolio to advance health and well-being and protect consumers exceeds any comparable period of rapid technological change, in my opinion.

And your support is helping us seize those opportunities. The initiatives that Congress supported in our 2019 Budget will help us uncover new treatment options for patients suffering from debilitating conditions; improve competition to help lower drug costs and improve patient access to medicines; and advance the developments for rare diseases and secure good safety, among many other initiatives.

To complement the support that you have given us and to secure these scientific advances, we are also undertaking one of the most significant policy modernizations at the Agency in decades. And I would like to take this opportunity to tell you about some of the elements of this undertaking and how I believe they extend the opportunities and the resources that you have provided with us.

These steps begin at the outset of a new drug development process when a sponsor files an Investigational New Drug (IND) seeking permission from the FDA to administer an investigational drug or a biological product to patients for the first time.

Beginning in the next few months, our Center for Drugs will adopt a new standard template for the review of these protocols. By using standardized templates for the submission and review of these INDs, we believe it will help investigators more efficiently advance new research while making sure that the FDA has the information it needs to safeguard patients.

As part of our pursuit of more standardized methods for the assessment of information across all aspects of our drug review progress and to improve the rigor and predictability of these methods, we are also extending these same approaches to how we assess product safety.

We are launching a safety signal tracker to serve as a repository for important information and potential safety issues throughout a drug's life cycle, from early in IND development, through application review and well into the post market.

This consolidates information about safety concerns during drug development in a single location, and in this way the safety questions can be more consistently tracked and annotated and continuously evaluated through every stage in the life cycle of a new medical product.

It will help cement a more systematic approach to how we continue to evaluate certain safety questions throughout the new drug and biological products application review and could measurably improve the drug development process.

This same commitment to using modern tools and policies to achieve a more structured approach to drug development extends into our review of clinical evidence in new drug applications. For the first time in more than 20 years, we are undertaking the first update of our guidance outlining how we assess the clinical effectiveness for drugs, a large change in the last few decades. We have much more opportunity as a broader array of data is confirmatory evidence to help support new product review, and this includes real-world evidence and real-world data.

These same general approaches also extend to our efforts to modernize how we assess post market drug safety. As part of the new drug program modernization that we have launched, we have put in place a new effort to analyze more safety data more efficiently across the entire drug life cycle, including in the post market.

We are implementing changes to capture more types of safety data, enhance our data analytics, and grow our sentinel database's ability to detect potential new safety problems.

We will be working to link claims data in our post market sentinel system to electronic health records to improve our ability to conduct active surveillance and use real-world data to improve pa-

tient outcomes, and we will be using the new resources as part of the 2019 Budget to help advance these efforts.

By linking information from the electronic health records to the data that we have on medical claims through our existing sentinel system, we will be able to get a much more complete picture of potential safety issues post approval and advance the use of real-world data to study drug effectiveness.

As another part of these efforts, I am pleased to announce that FDA's adverse event reporting system for drugs will be expanded to cover more types of safety data, and for the first time, this system will also include pre-market drug safety data.

The support of this Committee is key to all of these efforts, and it is key to our goal of helping leverage the tools of science innovation to advance the public health.

I look forward to working with you on these shared goals and many other endeavors and look forward to answering your questions today.

Thank you.

[The information follows:]

For release only by the
House Committee
on Appropriations

**Statement by
Scott Gottlieb, M.D.
Commissioner of Food and Drugs, Food and Drug Administration
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

Chairman Bishop, Ranking Member Fortenberry, and Members of the Committee:

The 35-day lapse in appropriations that began on December 22 was a significant operational challenge for FDA. Through the collective efforts of the professional staff of the agency, we maintained our critical public health functions, safeguarded the public health and safety, averted challenges to our public health protection role, and continued to perform review activities supported by user fees.

But even as we maintained our most important obligations that we owe to the American people, it was hardly business as usual at the agency.

We were at partial strength. Many programs, where the primary support is through budget authority rather than user fees, faced substantial furloughs. Our strength is our people. And many of our people were not at their posts.

These include many people in our food program, our inspectorate, our Center for Veterinary Medicine, and our blood program, to name some of the parts of the agency that were impacted the most by the lapse in funding.

Equally challenging, many of the policy, legal, administrative and communications staff that support the entire agency, and help advance our mission across our entire public health portfolio, were also on furlough. The absence of so many valued colleagues and the critical functions that they play was notable.

Many of our professional staff that continued to carry out critical activities did so unpaid. Our field force continued to perform inspections of foreign and domestic high-risk food and medical product facilities and our special agents continued their criminal investigations, even while they were unpaid and accruing per diem expenses on their government travel cards. Our operations staff and many other key functions faced significant furloughs even while their skills were in greatest need during the lapse. But working together, we maintained our vigilance.

We tracked outbreaks and addressed them; we continued import entry review making admissibility decisions and key sampling of imports at our ports of entry; we maintained post market safety assignments across our medical product centers, and so much more.

A unique spirit of public health mission guides the FDA. It animates our efforts. It binds our staff in a common mission. And gives purpose to our collective work.

The agency's staff knows how important their efforts are. They know that each one of them plays a critical role in the exercise of our expansive mission, whether they're on the front lines inspecting a manufacturing plant, analyzing data as part of a review function, providing administrative and logistical support that makes all of these and many other efforts possible, or performing one of the many other roles that advance our key public health functions.

Everyone at the FDA is essential to our collective mission.

Even though the lapse in appropriations has ended, we are still responding to its effects. During the 35-day lapse, we could not accept new medical product applications that required a user fee. As a result, we could not initiate the review of medical product applications from sponsors that we received during the lapse. With continued hard work and careful planning by our medical product centers, we will work to review this bolus of drug and medical device applications in timeframes that are consistent with our user fee goals. Despite the impacts of the lapse, we will endeavor to mitigate any observable impacts on our review performance goals in the coming year. We're committed to making sure that patients continue to have access to the treatments they need, and never wavering from our gold standard for safety and effectiveness.

We're lowering our inspectional and import and field sampling goals for the year. We won't be able to conduct as many inspections of food and medical product facilities, and reviews of imports, as we had originally planned. This is because we focused on the highest risk establishments during the lapse, and many other types of inspections didn't take place. The effected programs include human and animal food, biologics, and devices.

In setting new targets for the year, we'll use our risk-based approach, focusing on high-risk products, facilities that were never inspected, and firms with troubling compliance records, so that we can continue to protect consumers and carry out our public health mission. We believe we'll still hit our original goals for pharmaceutical and compounding inspections. And across all products, we'll continue to safeguard the public by targeting our efforts around high-risk inspections.

Certain policy work will also be delayed, especially in our food and animal health programs. Because protection of "animal health" does not often meet the Anti-Deficiency Act standard of "imminently threaten the safety of human life or the protection of property," work that impacts animal life and health generally was not permissible during the lapse.

Ultimately, FDA's greatest strength is its people. I've spent much of my time talking to our staff about the impact of the lapse in appropriations on their work and their personal lives. I know they're relieved to be back at work, and dedicated to FDA's mission. But I also know that Federal service is hard. The FDA can be hard. There's a lot at stake in the work that we do. That's what gives our work its purpose. But it also adds to the challenges that we face every day in performing our serious obligations.

Supporting the men and women of FDA, and improving our hiring process, has been one of my top priorities. So, in the coming weeks, a significant part of my focus is going to be on continuing to solidify our hiring and retention efforts, in supporting the men and women of the FDA, and doing my best to remind the people of the FDA how critical they are to the collective mission of one of the most vital agencies in the federal government.

Our work helps consumers expand opportunities to improve their health and happiness, improves animal health, and quite literally can save lives. These are just some of the obligations we perform on behalf of Americans. It's what makes our mission so challenging, but also what makes service at the FDA so rewarding. I hope you'll join me in saluting the professional staff of the agency for their dedication, perseverance, and expert execution during a challenging moment in the agency's storied history. I appreciate the opportunity to testify today about our work during the lapse, and look forward to answering your questions.

Mr. BISHOP. Thank you, Dr. Gottlieb.

We will proceed with questions. As I mentioned in my opening statement, I applaud the efforts of you and your agency's employees during the shutdown, and it is a testament, I think, to their dedication. They were a bright spot in the pointless shutdown.

IMPACT OF GOVERNMENT SHUTDOWN

My question is: where does FDA stand in terms of getting the agency back on track?

What kind of backlog accrued for your review work?

How long will it take to get it back to normal?

What is your assessment of the shutdown's impact on employee morale, on hiring and recruitment issues?

I am very concerned about what would happen should we have another shutdown.

What impact would a future shutdown have at FDA?

Finally, I am interested in understanding some of the long-lasting effects of the shutdown. So if you would, could you just take a moment to discuss the activities that FDA conducted during the shutdown and how it was carried out by your workforce, and in addition, what informed FDA decisions to continue, reduce, or stop altogether its regular activities during the shutdown?

Dr. GOTTLIEB. Well, Mr. Chairman, I appreciate the question. I want to just start out by acknowledging the work of the people at FDA, both those who continued to work in exempt and accepted statuses, meaning that they were able to continue their work because they were either being supported by user fees or their work was considered critical to the protection of the public health, as well as those who were on furlough.

I think being on furlough and being disconnected from the Agency and the work that is important to them was perhaps the most difficult position to find yourself in, and I want to just commend their dedication, and especially the fortitude of their families through what I have said was perhaps the most difficult operational challenge that we have faced in modern times through this extended shutdown.

I feel confident that things are back on track. I do not think we are going to see significant impacts on our work going forward as a result of the shutdown. I think that owes to the dedication and the hard efforts of the men and women of FDA.

We will meet, for example, our user fee goals related to medical products across most of our programs. There will be some impacts. Certain policy work was delayed. Certain centers were hit particularly hard by this shutdown. For example, our Food Center was. Probably 90 percent of the Food Center was on furlough. So policy work was delayed for the 5 weeks of the shutdown.

Inspectional work over the course of the year, the number of inspections that we are able to conduct, will be diminished by an amount that's commensurate with the length of the shutdown, probably by about ten percent from where we would have been.

But across the board, as we get back to full operational strength, and we are there now, and as we assess the impacts across our programs, I continue to feel confident that we are able to mitigate the hardest impacts and that we remain a strong Agency.

Mr. BISHOP. I wanted to discuss a topic related to food safety. I would like to stress I am not criticizing you or your decisions during the shutdown.

The Antideficiency Act, which governs legal determinations during the shutdown, says an officer or employee of the United States Government may not employ personal services exceeding that authorized by law, except for emergencies involving the safety of human life or the protection of property.

In 1995, the Justice Department advised OMB, "We believe that the emergencies exception applies only to cases of threat to human life or property where the threat can be reasonably said to be near at hand or demanding of immediate response."

And as you know, we also fund and oversee Food Safety and Inspection Service. When there is a shutdown, all FSIS inspectors are required to be on the job, and while FSIS operates under different authorization, the Antideficiency Act only looks to the threat to human life.

So can you tell us why you did not initially bring back inspectors to ensure continuation of high-risk food safety inspections?

Dr. GOTTLIEB. Well, we were guided by prior decisions, but none of those prior decisions were sufficiently robust to accommodate all of the circumstances that we encountered through this shutdown. The decisions that we made were consistent with the Antideficiency Act, as you mentioned, Mr. Chairman, and the legal advice that we obtained, and the public health considerations of the circumstances that we encountered in this shutdown.

I will say that initially, if you remember, the shutdown occurred just prior to Christmas and there was thinking that the shutdown would end just after Christmas, and we would not have been in the position of conducting inspections over the 2-week period of the Christmas break, as well as the week following that. Typically, we would not have many inspections scheduled during that time period.

When it became apparent to us that this shutdown was going to be prolonged and when it became apparent to us that the routine inspection work met the standard under the Antideficiency Act for the protection of human life, we very quickly initiated an effort to recall inspectors to begin conducting those inspections.

I do not believe that we missed that many inspections. At best we were delayed perhaps a week from ramping inspections back up from where we would have been coming off a holiday where we would not have been doing inspectional work.

I just want to close by acknowledging that these were inspectors who were in unpaid excepted positions who were accruing routine expenses on their government credit cards even though we were able to offload the expenses of travel and lodging. So they did endure hardship to carry out this mission, and we received an overwhelming response from our inspectional workforce when we recalled them into these important roles, and I just want to acknowledge their commitment.

Mr. BISHOP. Thank you, Dr. Gottlieb.

We have been joined by the distinguished chairman of the full Appropriations Committee, and at this time I would like to yield

to her for an opening statement of whatever comments she might care to make.

OPENING STATEMENT—MRS. LOWEY.

The CHAIRWOMAN. Well, thank you very much to our distinguished chairman, and welcome, Dr. Gottlieb.

Excuse me, Doctor. I need a little help today. I do not have a voice.

First of all, I would like to thank our chairman, Sanford Bishop, and Ranking Member Jeff Fortenberry for holding this hearing, Commissioner Gottlieb, and I welcome you back before this subcommittee.

Among the many effects of the 35-day government shutdown was a sharp reduction in FDA inspections of the Nation's food supply. Routine safety inspections of food at high risk of contamination, including seafood and vegetables, grounded to a halt as hundreds of inspectors were furloughed without pay.

And while I commend the FDA for taking steps to restore food surveillance, any unexpected break in inspections designed to prevent contamination is simply unacceptable, particularly with foodborne illness sickening 48 million people and killing 3,000 every year in the United States of America.

Of course, food inspections were not the only FDA service curtailed by the shutdown. Applications for new jobs and biologics submitted during the shutdown were also suspended as policy statements and guidance documents related to drugs, medical devices, review activities for products not funded by UCs, such as over-the-counter medicines were also put on hold. And pharmaceutical manufacturing inspections were delayed.

In short, unfortunately, we cannot repeal the shutdown, and to that end, everyone, including the Trump administration, must work together productively as we head into the fiscal year 2020 budget and appropriations process.

And, Commissioner Gottlieb, you know that every time you come before this subcommittee there is that one topic that hangs over our conversation, and that is tobacco products. I do believe that we share a similar goal to eradicate addiction to nicotine and improve public health.

But I remain concerned where our paths part. I continue to believe that the FDA's decision to exempt e-cigarette manufacturers from pre-market review until 2022 gave the public the false perception that e-cigarettes are safe. They are not.

And FDA's decision to take its foot off the gas while thousands of products have entered the market has led to the epidemic we face today. I implore you. Do whatever you can to take aggressive action to combat this public health emergency.

I know you have a lot to say on this subject, and I look forward to discussing it during questions.

I appreciate the generosity of the chairman because, as you know, I end up with roller skates, and I do not want to take advantage as I go from hearing to hearing, but you are very kind.

Thank you very much.

SESAME ALLERGEN

Commissioner Gottlieb, as you know, eight major allergens are required to be disclosed on food packaging. Although sesame is estimated to afflict nearly a half million Americans, making it one of the six or seven most common food allergens, manufacturers are not currently required to label it in compliance with the Food Allergen Labeling and Consumer Protection Act, which I am proud to have authored.

It took a long time, by the way. It took a long time. It took 5 years, but I should tell you that still is one of my proudest achievements because although it took full time, could not get one Republican cosponsor until 5 years later, it passed on a voice vote. That is an important, important lesson for all of us that when you are out there in the community, they finally do what is right.

So in May of 2016, I wrote to the FDA in support of adding sesame and requesting information on the status of the petition. I am pleased that in October, FDA announced it would open a 60-day comment period to receive feedback on adding sesame to the list of major allergens, scheduled to conclude in late December in the midst of the shutdown.

Did the shutdown add to a delay in processing comments from the scientific community and the public?

And when will the FDA announce whether sesame will be added?

Dr. GOTTLIEB. Is that a question?

The CHAIRWOMAN. I have one other question because the chairman is so generous to me, but you can answer that, and he gave me permission to do one other question, and you can guess what that will be about.

Dr. GOTTLIEB. OK. Thank you. Thank you, Mr. Chairman.

We received about 4,000 comments to the docket related to sesame. There is no question that the shutdown delayed our processing of those comments. We were not doing work on the petition over the course of the 5 weeks that we had a government shutdown.

I share your concerns. You know, when you look at sesame, the prevalence of sesame allergy is about on par with the eighth allergen. The severity is significant, and I do not want to prejudge the outcome of our process, but I will tell you that, as you know, a public health professional, we are concerned about it and are actively looking at whether it would meet the criteria for inclusion.

We are going through the comments and are going to follow the process prescribed by the law, but we are going to do it very expeditiously.

E-CIGARETTES

The CHAIRWOMAN. Because of the generosity of the chairman, I will go on to the next question. Thank you.

And now, Commissioner Gottlieb, you know the issue that I am so passionate about. I have some e-cigarette questions for you.

Juul argues that its products are intended only for adults looking to transition from cigarettes. Yet it is clear that products are being widely used by kids.

In prior comments, you alluded to FDA estimates on the proportion of Juul sales that are going to children. Can you share with us what percentage of Juul sales are to children; what percentage of Juul sales from individuals who do not use tobacco products, who did not use tobacco products prior to using Juul?

Dr. GOTTLIEB. Well, I will just say at the outset, Mr. Chairman, that this is one of the biggest public health challenges that we face right now at the Agency, the rising use of these products. We see an opportunity for these products to be a vehicle for adults, currently addicted adult smokers, to transition off of combustible tobacco onto less harmful, but not harmless, products, especially at a time that we are advancing regulation to try to regulate nicotine and combustible products to render them minimally or non-addictive for adults who still want to get access to nicotine.

But these are not products for children, and we are deeply concerned about the youth use and will be taking very aggressive steps going forward.

With respect to your specific question, we did an analysis internally with publicly available data to try to estimate what percentage of Juul's reported sales are actually sales to minors. In all candor, our analytics do not meet the level of rigor that I would expect from its sponsor, and that is why I have not put out that information. I do not believe it is reliable.

But if you want where we ended up, we ended up with an estimate somewhere between 10 or 20 percent of Juul's sales, and this was data looking back at last year.

But, again, I did not believe that based on our ability to look at publicly available data and make estimates off of that that it was a reliable estimate. That is why we have not officially put it out.

FLAVORED TOBACCO

The CHAIRWOMAN. Well, thanks to the chairman.

I have one other question, but I can tell you I visit high schools, junior highs. Every youngster I have interacted with tells me 60 percent of the class at a minimum is using Juul, and I guess Altria thinks it is pretty good because I read about their recent purchase.

So I am very concerned, and I am glad you are skeptical.

In my judgment, from what I see, flavored tobacco products have flooded the market. According to one estimate, there are more than 15,000 e-cigarette flavors available. It should come to no surprise that flavors such as Swedish Fish, Fruit Loops, Gummy Bear appeal to youth.

Studies have shown that an estimated 96 percent of 12 to 17-year-olds who have used e-cigarettes started with a flavor product.

And while I appreciate FDA's announcement that it will limit where certain flavored products are sold, to be honest, I do not think that is good enough. FDA needs to take a more aggressive approach to reduce the youth e-cigarette epidemic.

Now, you said you do not believe statistics. I am glad about that, but what would it take for FDA to ban flavors altogether?

And I ask this question because I go to schools all throughout my district, and just one student came to me just recently and said, "You know, one of my classmates takes the lunch money, goes to

the local bodega and buys these,” Tutti Fruity or Chummy Gummy or whatever you want to call them.

So what data will it take for the FDA to ban flavors altogether?

Dr. GOTTLIEB. Well, I hear your stories, Congresswoman. I will be speaking at a high school about this next Friday.

We outlined a series of measures in November. We plan to implement that very shortly. I will implement those measures.

We are trying to thread a public health needle here where we preserve some element of the availability of these products for adults, while foreclosing them for kids or at least really dramatically curtailing the ability of kids to access these products.

But I have said to the industry that this is an existential threat, and what I mean by that is that if we are not successful at dramatically curtailing the youth use of these products, and you are right that the flavors are the primary vehicle by which the children are finding these products attractive, we will change the application deadlines on these products.

And I am willing to pull them off the market if we continue to see the trends going in the direction that they are.

The CHAIRWOMAN. I know you are a father of a couple of kids, two I think you said, and I appreciate your understanding.

Dr. GOTTLIEB. Three.

The CHAIRWOMAN. Oh, three. I made a mistake.

Dr. GOTTLIEB. The five-year-old is going to be upset. [Laughter.]

The CHAIRWOMAN. Well, I know you are sensitive to this.

We all make mistakes, but this was a big, big whopping mistake. So I look forward to your work in this.

And I thank you so much, the generosity of the chairman, for giving me this time. Thank you very, very much. Thank you.

Mr. BISHOP. Thank you, Madam Chair.

At this time, I am pleased to recognize the new ranking member of the subcommittee, Mr. Fortenberry, who was not here to give his opening statements. So I would like to recognize him at this time for an opening statement, and if he would like, he can proceed with his questions.

OPENING STATEMENT—MR. FORTENBERRY

Mr. FORTENBERRY. Thank you, Mr. Chairman.

I apologize for the delay, but thank you for your generosity in allowing me to combine an opening statement plus some questions.

And first let me say though, Mr. Chairman, I have enjoyed our pre-meeting conversations and our robust interest in many, many things in terms of our own food security in this country and how we develop and continue to lead the world in terms of food innovation, and I am grateful for your leadership in this regard and continue to look forward to working with all of you in this space.

Dr. Gottlieb, welcome. Thank you for your service. We appreciate your expertise and your commitment to, again, the highest ideals of public service as well.

I would venture to guess that most Americans do not fully grasp the breadth and depth of the agency that you head. The FDA’s mandate touches our food, our drugs, our medical devices, much, much more, regulating roughly 25 cents of every consumer dollar spent in America.

So our work covers not only the expenditures supporting the professionals whom you work with overseeing these products and services, but we also have to ensure that these resources are spent wisely.

In this coming appropriation that you just received, you have got a significant increase, about 9 percent, over the previous year. Of course, in Washington, we operate off good intention. More money means good outcomes, but we have to be careful about that set of working assumptions.

So I want to hear about what you intend to do about outcome, and I will be a little more specific. Tell us about your plans regarding faster generic drug approval; advancements in digital health technology; the continuous manufacturing of drugs; as well as keeping our food safe.

I think it is important for the panel, and I know it is a clear personal interest to you, regarding the grim factors, the grim epidemic of drug overdose that is taking 70,000 American lives each year. It is a particularly devastating problem among young people.

So but I am particularly interested as well and worried about the safety of certain foods. Recently I held an informal gathering of agricultural pioneers in my home State of Nebraska in which food safety issues were of particular concern.

While we are increasingly and excitingly getting more of our food from local sources where the prominence of the product can reliably be determined, we still import a lot of food from around the world, where the standards of inspection potentially do not match our own.

So as I understand it, 90 percent of our seafood, over half of fresh fruit, and over a third of our fresh vegetables are imported, which are certainly staggering numbers.

Americans, again, are worried about drug prices, and while I realize you only play a partial role in debating the policy as to how to bring down these prices and increasing values to patients, I hope that we will see a robust plan to accelerate generic approvals and to minimize the perverse effects of circumventing drug and device patents, as well as to encourage more safe manufacture of the generics themselves.

So, Dr. Gottlieb, you have many challenges. So I look forward to your responses. Imbedded in that statement, I think were enough questions for you to leverage off of.

Dr. GOTTLIEB. Should I respond?

Mr. FORTENBERRY. It is your time, yes.

DRUG PRICING

Dr. GOTTLIEB. Thank you, Mr. Ranking Member.

Well, let me start with the pricing issue, if that is OK, since that is where you ended. I think that when it comes to drug pricing, I see three challenges.

First is that there are situations where we lack product competition, and I think there is a lot that I can do to help solve that challenge.

There are situations where we have branded drugs that are off-patent, off-exclusivity, but are not subject to the generic competition that Congress intended for either because branded companies

are gaming the system in ways that are blocking competition or we do not have the scientific tools to allow the genericization of certain drugs.

The second challenge that I see is once there is competition in the market, we have payment systems set up that sometimes do not allow government programs to take advantage of that competition. And I see that particularly in the injectable drug market with respect to Medicare Part B, where the government is largely a price taker, and those drugs are not competitively bid.

I think this is particularly acute as we see more biosimilars coming to the market where government could be taking advantage of effectively generic-like versions of biological products, but do not competitively bid those drugs.

And then the third challenge is that when we do have competition in the market and the competition does drive discounting, the discounting comes in the form of back-ended rebates that do not flow to the consumer. They flow back to the health insurer. They are used to offset the cost of everyone's premiums, but it effectively means that the patient who is using the expensive drug and is either paying full freight or is out of pocket for a large portion of that drug is spending money that is being paid back later, but paid back in a form that is used to subsidize the premium cost of healthy people, which is the exact inverse of what we expect when it comes to an insurance scheme.

But we at FDA are focused on the first element of that challenge, which is how do we operationalize programs to bring more generic competition to the market. The resources we have gotten from this Committee will help advance those goals.

We are putting in place a structured review for the generic drug program that is going to make it much more efficient to adjudicate the generic review process, and we are also going to spend some of those resources proactively updating the labels on old generic drugs to try to drive their utilization.

We have generic drugs that form, for example, the backbone of chemotherapy regimens that have labels on them that are decades out of date, and there is no sponsor in the market who is able to update that label anymore. The branded company has long since gotten out of the market or maybe does not even exist anymore.

With the resources that you provided us, we are going to proactively take it upon ourselves to update those labels with modern information so that we can help drive use of those drugs where those drugs are still clinically relevant.

Mr. FORTENBERRY. How much will this lower drug costs?

Dr. GOTTLIEB. You know, it is a good question, Congressman, and we have quantified the impact of our work. The Council of Economic Advisors put out a report about 3 or 4 months ago where they quantified the impact of the increased rate of generic approvals that we have achieved over the last 2 years.

And if I remember correctly, we have increased the sort of run rate for approvals, if you will, by 18 percent a month, and we have had incremental improvements in our productivity, and they did tie a number around that. I am forgetting it off hand, but it was substantial.

I am hopeful that the resources that you provided and the policies we are implementing over the course of this year are going to continue to help us advance more generic development, not just more approvals, but more approvals of drugs that face obstacles being genericized, and what I am talking about are particularly the complex drugs, drugs that are either inhaled drugs; they are topical drugs; they are injectable drugs, where there are complex formulations and cannot be easily measured in the blood.

So the traditional framework of Hatch-Waxman makes it hard to copy those drugs. That is where we have been focused. This is not a trivial category of spend. One analyst has estimated, that that is about \$20 billion a year in drug spending for drugs that are off-patent, off-exclusivity, but still sold as branded drugs because they do not face generic competition because they are hard to copy.

We are focused on that category. EpiPen was one such example, and some of the metered dose inhalers for asthma were another example, and we have been able to genericize those in recent months.

Mr. FORTENBERRY. So, Doctor, if you could give an estimate, even if it is rough, that you will not be held to if this set of policies is fully implemented over a short period of time, in the aggregate, what would that impact be on drug prices?

Are we looking at 10 percent, 20 percent, 30 percent?

Dr. GOTTLIEB. Well, the estimate that CEA put out was, if I remember correctly, in the billions of dollars. Twenty-six billion was the estimate that CEA put out. So over a year they estimated—

Mr. FORTENBERRY. Maybe we can get a better stat, just the percent of how much that will, in fact,—

Dr. GOTTLIEB. We could translate it into that.

Mr. FORTENBERRY. Throughout the hearing if you could get that, that would be helpful.

Dr. GOTTLIEB. The stat would be in the aggregate. We could translate it into the aggregate.

SAFETY OF IMPORTED FOOD

Mr. FORTENBERRY. OK. Before my time expires, is our imported food safe?

Dr. GOTTLIEB. I believe our imported food is safe, and I have confidence in it.

You made the opening statement that about 15 percent of our food is imported overall, but to your credit, you made the comment that it varies across food types. Seafood is a very high percentage. Produce, I think you mentioned, is about half.

We employ different methods with respect to imported foods than we do to domestic food. We have a multilayered approach. We rely on foreign regulators. We target inspections very carefully with our PREDICT system. We rely on third party certification. We rely on verification by importers that they have conducted certain audits.

We have a multilayered system when it comes to imported food. I have confidence in the imported food, but across our entire portfolio, we still have a lot of work to do to continue to provide the assurance of safety that consumers expect when it comes to the food that they eat.

Mr. FORTENBERRY. All right. Thank you, Mr. Chairman.

Mr. BISHOP. Thank you.

Mr. Pocan.

OPENING STATEMENT—MR. POCAN

Mr. POCAN. Thank you, Mr. Chairman.

And, thank you, Commissioner, for being here. I appreciate it.

First just let me say, from what I understand your department may be one of the few federally where morale is up in the last couple of years, and I want to give you credit and kudos for that because it stands out and it is what we are hearing talking to folks.

As you know, a lot of companies in my area work with the FDA. I know you know Kevin Conroy from Exact Sciences, for example. I would love to extend the invitation if you would like to visit some of the companies. Maybe wait a couple of months if you are coming to Wisconsin. I would not recommend it next week.

Dr. GOTTLIEB. Go ice fishing.

Mr. POCAN. I still do not understand ice fishing, but we would love to have you come to Wisconsin.

GENERIC DRUGS

So I would like to try to get into three different subjects if I can. One is around what you were just talking with about generics.

You have talked about that a number of times before the committee, and I really appreciate your efforts on that. As we know, there are a large amount of drugs that are under the generic area. You get one competitor and you can lower the price 6 percent; another one, 48 percent; you get six of them and you are down to a quarter of the price.

What are we doing specifically to spur the development of multiple generic competitors?

Dr. GOTTLIEB. So we have implemented a policy. I will be brief. We have implemented a policy to prioritize the review of generic applications until we have three generic competitors within a category because that is where you see the biggest price break.

And we have actually updated that data. That data was developed the last time I was at the Agency back in 2005, when we updated it, and it is very consistent. The new findings are very consistent with the old findings in terms of where you see the sharp price reduction. It is when three competitors enter the market.

Mr. POCAN. So you are working specifically?

Dr. GOTTLIEB. We are specifically prioritizing applications until there are three competitors within each category.

CBD REGULATION

Mr. POCAN. Great. Second issue area around some CBD issues. It has got kind of an A and a B.

The first one is you know under the Agriculture Improvement Act of 2018, hemp was removed as a Schedule 1 controlled substance. I was just wondering if the FDA has plans to work with the USDA on CBD regulations.

Secondly, I know there was recently an issue around CBD and food. I think the statement that came out at the end of last year said there could be a possible pathway by which certain hemp-de-

rived compounds such as CBD might be permitted in food or dietary supplements.

I guess my question is: how actively is the FDA pursuing this pathway?

And what is the likelihood and timeline for the FDA to issue a regulation to clarify the lawful circumstances under which CBD could be used in food or dietary supplements?

Dr. GOTTLIEB. Well, I will say at the outset, Congressman, we heard Congress loud and clear with respect to that legislation, and I understand Congress wants there to be a pathway for CBD to be available.

This is not a straightforward issue. Congress specifically preserved our authority with respect to CBD. Our drug authorities in CBD, as you know, exist in a higher formulation as a pharmaceutical product and cannot be legally put in the food supply at this time not only because it is a drug product, but it is also the subject of substantial clinical investigation, and we have active INDs.

So even if it was an approved product, it would still be the subject of substantial clinical investigation, and statutorily, it could not go into the food supply.

Now, the law does allow us to go through a regulatory process and go through notice and comment rulemaking to establish a framework to allow it to be put in the food supply. We would have to work through that.

We plan to begin with a public meeting at some time in April. We will be announcing that shortly. We will solicit comments, and we have got to work through what that regulation would look like.

You know, I can speculate at a high level about theoretical frameworks that you can contemplate. For example, the product existing in a high concentration, pure formulation as a pharmaceutical product while existing in a different concentration as a food product or a dietary supplement because we want to preserve the incentive to study CBD as a pharmaceutical product. We believe it does have therapeutic value and it has been demonstrated.

But I will tell you this is not a straightforward process. There is not a good proxy for us doing this through regulation, and if we get comments back and find that this is sufficiently complicated for the Agency, we will come back and have a discussion with Congress about how we might be able to work together on this.

Mr. POCAN. Great. Thank you.

DRUG SHORTAGES

And a third one I will try to get in if I can. This is around drug shortages. There has been conversation around the abbreviated new drug application. It is designated for priority renewal when reviews are directed to prioritize the review every step of the way beyond the initial priority designation stage.

Is there a way to shorten timelines more aggressively and actively communicate and advise folks to get faster approval under this issue to address drug shortages?

Dr. GOTTLIEB. Well, we have a drug shortages list, and we maintain a lot of transparency around that, and that group, it is a large group now, works to try to provide timely information about where shortages persist in the market.

Congress gave us very explicit authority to allow us to receive notification from sponsors of an impending shortage, and we provide notification around that.

And when we do have a drug that we believe either is going to go into shortage or is on the shortage list, we do prioritize the ability to get product on the market either through other approvals or sometimes we have allowed limited reimportation under very specific circumstances to help mitigate the shortages.

Mr. POCAN. And thank you.

Mr. BISHOP. Dr. Harris.

OPENING STATEMENT—DR. HARRIS

Dr. HARRIS. Thank you very much.

And thank you, Dr. Gottlieb. I think we are getting a lot of things right over at FDA.

I have four or five different topics. I will be brief about them. First of all, with regard to fiber, I know we have communicated about it, and I want to thank you for continuing to handle dietary fiber petitions in front of the FDA.

And I know the food manufacturers in Maryland want to comply with the January 1st deadline. They hope that FDA will work with them to make sure they can figure out what is a dietary fiber and what they ought to do with their labeling, et cetera.

I want to thank you for, you know, paying attention to that.

FLAVORED TOBACCO

With regard to the cigar issue, we talk about it a lot. First off, I want to say it is great that combustible product use is going down in the United States. Clearly, the youth usage of cigars goes down year after year, and yet there is a plan to ban all of the flavored cigars, which are not really used by youth.

Again, cigar use going down year by year. What is the justification for banning all of the flavored cigars?

Dr. GOTTLIEB. Well, Congressman, I will be direct on this. I do not believe that there should be characterizing flavors in combustible tobacco. Data show that the characterizing flavors in the combustible tobacco drive use. Congress made an explicit decision to take characterizing flavors out of cigarettes, and then we saw a lot of flavors go into these cigarillos.

When you look at youth use patterns of tobacco products, cigars is the fastest growing tobacco segment among black youth, and a lot of that is the flavored cigar use among that population. But we see rising use of flavored cigarillos across the board.

So I have a lot of public health concerns around the flavors in cigars. I mean, if I had an optimal configuration with respect to tobacco, if adults wanted to get access to flavored products, they would get access to flavored products that were not combustible products and did not have all of the health risks associated with combustion of tobacco.

Dr. HARRIS. Well, you talk as though all combustible tobacco is equal, and obviously something that is not inhaled has a much lower risk profile than something that is inhaled.

So that is why I say, you know, the one size fits all approach I am just not sure is justified here.

So anyway, the other thing is I know we have worked with you on marketing tobacco rolling paper to children. I do not think that, you know, the Center for Tobacco Products has come to a satisfactory result with this. I think there is still marketing going on to children.

Obviously, rolling paper is not used for anything but a combustible product, whether it is marijuana or tobacco, and I know you have the authority to regulate and to take enforcement action, and I hope you do.

CO-PRESCRIPTION OF NALOXONE

With regards to opioids and the locks on co-prescription, I think that your statement yesterday on FDA's policy and regulatory agenda to combat opioid abuse did not mention co-prescription of naloxone.

Could you just give me an update on what your efforts are and what your thoughts are on allowing co-prescription?

Dr. GOTTLIEB. We are actively considering the co-prescribing of naloxone with opioids. We had a discussion around this at an advisory committee recently, probably about 6 weeks ago, and we are going through different formulations of under what circumstance that would be appropriate from a public health standpoint.

You know, mandating co-prescribing of naloxone across the board for all opioids would be costly to the system, but there might be circumstances where there is a strong public health justification for mandating that.

Dr. HARRIS. Thank you very much, and I appreciate the thoughtful consideration of that.

I am going to agree with the gentleman from Wisconsin about the CBD, and we have also talked about. You know, I go into markets now and see these displays of CBD containing products, and it is not at the pharmacy, behind the counter, obtained with a prescription.

So, again, I think this is something that crept up on us, and I know I appreciate your answer to Mr. Pocan on that.

SODIUM

Finally, with regards to sodium, you know, I have asked for years, you know, again, if a one size fits all approach is the appropriate approach on sodium. I know that your predecessor, Dr. Califf, other established scientists, and an American Heart Association publication last July have called for perhaps it is time to do a randomized trial on sodium and to answer the question: where is it harmful? Where is it helpful?

Yes, the majority of people probably might benefit from a sodium reduction, but there are individuals who would not. Would not a randomized controlled trial actually help inform regulation?

Dr. GOTTLIEB. I think we would welcome more research on any dietary subject, and there is certain precedent where Congress has helped support this kind of research through the NIH, for example.

It is obviously hard to study dietary habits. You cannot randomize people carefully in the way you would in a drug trial, for

instance, but we have done research on diet and have gotten good results from those research efforts in the past to inform decision making.

Dr. HARRIS. Thank you very much.

I yield back.

Mr. BISHOP. Mr. Cuellar.

Mr. CUELLAR. Thank you, Mr. Chairman.

OPIOID USAGE

Commissioner, let me ask a question following what my colleague asked. Prior to 2001, opioids such as oxycontin were solely approved for short-term pain relief. However, in 2001, the FDA decided to change the label for that, allowing it for daily, around-the-clock, long-term treatment.

And I think the problem that I have with that is I do not think there were any studies that were showing the impact of its long-term effects of opioids.

Now, I do not want you to go back and explain the reasoning of the FDA in 2001, but I would like if you can explain why, after scientific studies have shown the negative long-term effects of opioid usage, why the FDA has not acted or changed the wording of oxycontin and issued strong warnings about opioid usage.

Dr. GOTTLIEB. Well, I appreciate the question, Congressman.

I have gone back and looked at the history and spoken to my staff about what was done in 2001, and in 2001 the specific label change that was made that is the subject of some analysis now was an attempt to try to restrict or narrow the use of the drug.

I think in retrospect the Agency probably got some of the wording in that change wrong. It was an attempt to try to drive long-term use away from some of the IR drugs. If you look at the utilization of opioids, more than 90 percent of all the use of opioids is actually immediate release formulations of the drug, not the extended release of the drug. And the Agency at the time was trying to obviate the use of extended release drugs just to situations where patients had syndromes that required longer term use of opioids.

Now, that said and recognizing that some of that language was done in a way that ultimately allowed for promotion that was inappropriate and, I think, criminally sanctioned ultimately, we have undertaken a process to use the authority that we received under the SUPPORT Act to now mandate that the sponsors of existing opioids that are on the market, as well as opioids in development, must conduct long-term studies looking at the long-term effectiveness with chronic administration of opioids to see, to demonstrate whether or not there is a declining effectiveness.

If we are able to demonstrate that there is a declining effectiveness with prolonged administration of these drugs in rigorous studies, which are the types of studies that we are mandating, we could act to restrict the labels further to contraindicate certain use, to narrow the circumstances when opioids could be used in a long-term fashion, to implement other risk management measures.

So we are undertaking that process very quickly, using the authorities you gave us under the SUPPORT Act to get the evidence we need to support a careful regulatory decision here.

Mr. CUELLAR. Well, I would and I think all of us would appreciate it if you can keep us posted on that work. As you know, we appropriate billions and billions of dollars to address the opiate issue that we have. So we appreciate you keeping us informed.

COMPOUND PHARMACISTS

The other question I have has to do with compound pharmacists. FDA has heard concerns about health care provider groups about the need for immediate access to compound office use medications to address health emergency. The FDA enforcement action against 503(a) facilities for providing office use medications, despite being permitted by State law and/or regulation in a majority of States, continues to restrict.

And I understand the history. There was an issue of people being killed. I understand that, dying, but I guess my question is when we talk about compound pharmacists or the pharmacist and how they are regulated, there is a little confusion between the State/Federal definitions, especially with the definitions of distribute and dispense.

Are you all looking at trying to somehow align those definitions? Because if you have a State and then you have a Federal definition, that will cause some sort of confusion.

Dr. GOTTLIEB. Well, I think that the intent of Congress was clear here and clear in terms of how the Agency is implementing it. I think we have been clear that we do not believe that a 503(a) pharmacy can engage in large-scale manufacturing and advanced shipping. A 503(a) pharmacy should be engaged in the traditional practice of pharmacy where they are compounding the drug in response to an individual patient prescription.

Now, I understand some 503(a) pharmacies do want to engage in larger scale manufacturing and stock local doctors' practices and will argue they have done that for years and they have done it safely. I recognize that.

But those are the kinds of conditions that created the public health risks that led to the passage of the DQSA and the implementation of a new regimen.

Now, from my standpoint, what I want to do is try to make it as efficient as possible for the 503(a) pharmacies that want to engage in that activity to become 503(b) pharmacies where they are subject to at least good manufacturing practices' oversight, to ensure the safety of those products.

So I am very actively trying to work through policy, and we are going to be issuing guidance imminently that I hope will make it more affordable for some small 503(a) pharmacies to engage in the business that they want to, but to do it as 503(b) pharmacies.

So to do that conversion, it does not cost millions of dollars. So a smaller pharmacy can do it.

I will say, and I will close here, from an economic standpoint, if a 503(a) pharmacy is doing this on a small scale, they might be able to do it and evade notice. But once they try to do it on any scale, they are going to get on the radar of not just the State officials, but the Federal officials. So they are effectively capped.

If they would convert to be a 503(b) pharmacy, they would be able to grow their business into that segment that they want be in,

and I think it would be a much more enviable position for them to be in. I am trying to make it efficient for them to get there.

Mr. CUELLAR. Yes. I know my time is up, but I appreciate the efficiency on that.

Thank you.

Mr. BISHOP. Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And, Commissioner Gottlieb, thank you for your comments today and also your leadership, and especially in the area of keeping the price of drugs down and promoting competition and reducing barriers to the generic development and promoting competition.

NON-OPIOID ALTERNATIVES

One of the areas kind of along those lines I wanted to ask you about is that we have invested, I know, in NIH and in other areas where there is nonaddictive pain medicine. There is a lot of research going on in that area.

Is that something you are seeing as a potential answer to this opioid crisis?

And what role does the FDA have in that?

Dr. GOTTLIEB. Well, it is one opportunity. I think what we do to address this crisis is going to be an all of the above approach, and there is no silver bullet given the magnitude of this public health crisis that we are facing.

But there are opportunities for us, I believe, to help advance the development of non-opioid alternatives for the treatment of pain that we will be issuing over the course of this year.

We withdrew our guidance document that delineated what sponsors needed to do to get pain drugs onto the market because we felt it was out of date and overly burdensome, and in its place we are going to be issuing a series of guidance documents, at least four, that look at what sponsors need to do to develop alternatives to opioids for the treatment of specific kinds of pain.

And we think that that will make the process for trying to develop the alternatives that you are talking about much more efficient. So we are focused on this.

PREMIUM CIGARS

Mr. MOOLENAAR. OK. Wonderful. And I want to just change gears a little bit to go to your rulemaking area.

Almost a year ago the FDA announced an advanced notice of proposed rulemaking regarding regulatory treatment of premium cigars, and can you tell me what the status is of that rulemaking?

Dr. GOTTLIEB. We received a lot of comments. I forget how many in all, but it was a robust administrative record. We are continuing to go through those comments, and you know, we will keep you updated.

We specifically asked questions around whether or not there were different patterns of use associated with premium cigars that would cause us to consider whether we should regulate them differently than other tobacco products. That was among the questions that we asked.

So we are still actively engaged in that rulemaking process.

Mr. MOOLENAAR. Thank you.

SUNSCREEN REGULATIONS

And then yesterday the FDA published a proposed rule aimed at strengthening regulations of over-the-counter sunscreen. I am 100 percent in agreement we want to make sure these sunscreen products are effective and available.

Some of the concerns that have been raised are that the tentative final over-the-counter sunscreen monograph will essentially ban all but two of the approved UV filters used in sunscreen products. And my understanding is there are only 90 days to comment and provide data for widely used ingredients that have no known safety concerns.

I am wondering if you could elaborate on where things stand on that. Does the FDA have plans to ensure there is no disruption in the supply of these critical products as we start to approach the summer months?

Dr. GOTTLIEB. Right. So they will not be banned, and they will not be forced to come off the market. There were 16 currently marked active ingredients that were assessed in that notice of proposed rulemaking. Two were determined to be generally regarded as safe and effective (GRASE), zinc oxide and titanium oxide. Two were determined not to be GRASE. So they have to come off the market, but they are actually not currently marketed in the U.S.

The other 12 ingredients had insufficient data for us to make a final determination. In the course of the 90 days, if a sponsor wants to, they can ask for a deferral of a decision on those other 12 ingredients.

We expect at least six to eight of those ingredients to request and be granted deferrals, and we can finalize the rule, allow those products to stay on the market while we continue to collect data.

We did the same thing with respect to the rulemaking on the antiseptics. We were under a court order to finalize that rule, but we did not have the data we needed to make a final determination on all the antiseptic products. So we were able to issue deferrals on some of those products and finalize the rule while we continued to collect information.

So they will not necessarily be coming off the market just because we have insufficient information to make a safety determination at this time.

Mr. MOOLENAAR. OK. Thank you.

DAIRY LABELING

And then one last question I had for you is relative to milk. My district is a strong agriculture district, very diverse. Dairy is a big part of that, and one of the questions I have is, you know, the labeling of milk, what constitutes milk, you know, the FDA's definition, and how we protect that definition.

Can you comment on where we are on that? Because I continue to hear concerns from my constituents about this.

Dr. GOTTLIEB. Well, we are going through a regulatory process right now where we are soliciting public opinion about the use of the term "milk" on non-dairy products, on plant-based milk products, which I think is where your question is getting at.

You know, we are going through that process. I do not want to prejudge the outcome, but from a public health standpoint, the threshold where we would make a decision about that standard of identity and when you can use the term "milk" would be, to give you one example, a situation where we are able to demonstrate with data or people that consumers perceive a certain nutritional content through the use of the term "milk" that they are not getting with plant-based products, and that is having an adverse health impact on them.

And we have, in fact, seen examples of that where parents said their children were using certain milk products, and they did not have the vitamins and nutrition of dairy milk products, and you saw adverse consequences.

So that is what we would be looking at.

Mr. MOOLENAAR. Thank you.

Thank you, Mr. Chairman.

Mr. BISHOP. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair.

REGULATING COSMETICS

Sir, I am going to kind of dovetail on a little bit of what the last question was about, not milk, but cosmetics.

A recent New York Times editorial highlighted the FDA's role in ensuring of cosmetic products on the market and how little authority you actually have in regulating them. It is a \$70 billion cosmetic industry, which includes not only makeup, but products every single one of us use in this room.

Any of you use toothpaste? Deodorant? Well, it is regulated with an \$8 million budget only, and 27 staff members at the FDA.

The law giving you the authority to ensure the safety of these products is only 2 pages long, and it has not been updated since 1938.

While there have been several attempts to enact legislation that would provide the FDA with expansive authority and oversight, Congress has been unsuccessful in passing any substantial legislation.

To this day, 80 years have passed. Cosmetic companies still do not need to submit safety data to the FDA before marketing a product. They are not held to basic good manufacturing practices. They do not have to register with the agency. They are not required to report adverse events that consumers may relay to them.

Further, the FDA can currently not do a mandatory recall of a product even if it is thought to cause serious harm. It cannot inspect facilities to ensure that the products are being made in a safe and clean environment. And less than 1 percent of imported cosmetics are even inspected.

Clearly, you do not have the authority to meaningfully regulate the cosmetic industry the way I am sure most Americans assume that you do. In just talking to mothers, fathers, elders, and young adults, they think that these have all been tested and are safe to use when they go to the store to buy a product for themselves or their families.

The FDA has taken steps with sunscreen, and I applaud the FDA for doing that because that is a serious health risk if someone

is applying something to their skin thinking it is going to block or delay or prevent cancer.

So I am asking you: what are some of your biggest hurdles in ensuring the safety of these products? Because I am sure you get calls and you do hear from consumers who say, "Well, I thought you inspected this. I thought there was consumer protection."

So Congress needs to update these antiquated laws, and so what are some of the changes that you would suggest that we work on in a fashion to make sure that these products are safe as many people assume that they are?

Thank you.

Dr. GOTTLIEB. Well, I will just say briefly, Congresswoman, I think you outlined some of the challenges very well, and this is an area that we want to work on.

We very much look forward to working with Congress to try to modernize not just this framework, but we can always do more with more with respect to the resources.

You are right that it is a small team. Now, when you are looking at our portfolio from a risk-based approach, these products clearly pose a smaller degree of risk than a complicated medical device or a pharmaceutical product. But they are not risk-free, and we have not been able to expand the scope of what we are able to do commensurate with the expansion in the scope of this industry.

And so we would like to work with you on this and see how we can make the system more robust.

Ms. MCCOLLUM. Mr. Chair, as was pointed out, we do not even know how much harm these products could be because there is no accumulation being reported on it. I know that drugs that we take and medical devices, as the doctor pointed out, can have an immediate effective, good outcome or a terrible outcome, and those are reported, and we do know about it.

But as with sunscreen, there is a false sense of security in the public that they read a label. They think it has been inspected.

So, Mr. Chair, I think it is something that our committee should take a look at. I thank the FDA is for looking at this issue, and I look forward to working with the chair on this.

Thank you. I yield back.

Mr. BISHOP. Thank you.

Mr. Aderholt, the distinguished former chair of this subcommittee.

Mr. ADERHOLT. Thank you, Mr. Chairman.

And congratulations on your chairmanship, and on especially this first hearing of the subcommittee. It is great to be alongside of you.

And, Commissioner Gottlieb, welcome. Thank you for joining us this afternoon.

Of course, I am no longer chair of the subcommittee, but I wanted to remain on this subcommittee and asked to have a seat on the subcommittee, and I continue to actively be interested in the matters that you work on and this subcommittee works on and look forward to working with you.

RAISING TOBACCO AGE TO SELL

I want to follow up on what the chair of the full committee was asking about tobacco.

I think all of us remain concerned about youth access to flavored tobacco products, and particularly e-cigarettes, and it is not a partisan issue. Democrats and Republicans alike are very concerned about that issue, especially with the youth access.

Some members of Congress propose raising the Federal minimum tobacco age to sell to 21. What is FDA's position on that?

Dr. GOTTLIEB. We would support that, and I will tell you my position is that I would be supportive of that.

From my perspective with respect to the e-cigarette challenge we are facing right now, where we want to preserve this opportunity for currently addicted adult smokers, but face a sheer epidemic of youth use of these products, and the numbers are going to go up this year as well and perhaps significantly.

A lot of the youth access is not just 14-year-olds and 15-year-olds going into convenience stores and buying these products. It is enterprising 18-year-olds in high school buying them legally and creating a business in their high school selling them back to 16-year-olds and 15-year-olds.

And if we had a 21-age limit across the board on these products, it would make it harder for that kind of activity to take place.

And so I think it could help me address the most immediate problem that I am facing with respect to tobacco, which is the epidemic of youth use of these non-combustible products.

Mr. ADERHOLT. Yes. And I have been supportive of that as well.

Of course, raising the minimum tobacco age of sale to 21 could drive more minors to purchase flavored tobacco products online. I think that is one issue that we deal with.

AGE VERIFICATION FOR ONLINE TOBACCO SALES

What does FDA need in terms of authority to implement effective age verification policy for online sale of tobacco products?

Dr. GOTTLIEB. We have all the authority we need and will be promulgating guidance that is going to outline age verification requirements for online sales that we think are sufficient to allow online sales to continue.

Currently, only a small percentage of the e-cigarette sales that are taking place are online. It is actually a small number of the products that are being bought online, but I do think that the online route provides the opportunity for heightened age verification requirements that—while not foolproof, nothing is foolproof and that is not the standard that I think we are going to be able to reasonably achieve—make it much more difficult for youth to get access to those products online.

You see, for example, wine sales online, liquor sales online that require adult signature on delivery and very stringent verification requirements that, again, while not foolproof, are pretty good.

And we can look for a similar technology with respect to online e-cigarette sales.

Mr. ADERHOLT. Do you have the authority to mandate age verification?

Dr. GOTTLIEB. We believe we do. We are going to be promulgating guidance that is going to require significantly heightened age verification requirements for flavored e-cigarette products sold

in convenience stores and products sold through online channels. And we will be implementing that shortly.

Mr. ADERHOLT. Juul requires online customers to either upload a government-issued ID or the last four digits of their Social Security number or other identification information. Is this something FDA could require of all the companies that sell tobacco products online?

Dr. GOTTLIEB. I do not want to judge one process over the other. What we are going to do is give some representative examples of some processes that could be sufficient and allow sponsors to submit other alternatives, other creative alternatives.

But we do believe that there is technology and ways to put in place online verification requirements that could be robust and could meet a standard that we would think is sufficient.

CELL CULTURED MEAT

Mr. ADERHOLT. I know my time is running out, but let me ask you. Of course, FDA and USDA have signed the MOU outlining how both agencies will be involved in this regulating cell cultured protein in October.

What is the status of the MOU?

Dr. GOTTLIEB. Very close to completion and public release. We will absolutely meet the 60-day deadline that was in the appropriations legislation.

And so I look forward to hopefully having an opportunity to brief you on that, and I would just want to close by thanking you for the support that you showed the Agency over the years when you chaired the Committee.

Mr. ADERHOLT. Sure. And one last: will FDA allow USDA to play a role in the collection of the cell from animals, both post and ante mortem?

Dr. GOTTLIEB. I am not sure I am quite understanding the question, but the way that we have designed the process is we have designed a pre and post-harvest phase, and so the pre-harvest phase is the living biosystem. Once that living system is basically closed and the meat product is taken out of the biological replication process, all of that jurisdiction shifts to USDA.

So there is a handoff there somewhere. USDA plays a role in that handoff and then has jurisdiction over all aspects of how the product is formed, spiced, packaged, labeled, everything else.

Mr. ADERHOLT. OK. Thank you.

Mr. BISHOP. Ms. Pingree.

Ms. PINGREE. Thank you very much, Mr. Chair. Thank you, Dr. Gottlieb, for being here with us. I also appreciate the time you take with our committee and the thorough answers that you give on every topic. So thank you. And thank you for your vigilance on flavored e-cigarettes. That is an issue that we hear a lot about in our communities as well.

CBD REGULATION

Let me try to fit in two issues and be quick about it. My colleague Mr. Pocan already got into the CBD discussion. And so he has reviewed quite a bit of that with you. And, as you know, we recently sent a letter. And I realize this is complicated, but I just

want to emphasize the need for some sense of urgency around it and, the timing of this because so many of our states have legalized hemp.

As you have heard from many other members, CBD is being sold in a lot of places. And it has created an enormous amount of confusion. My own state legislature is working on legislation around it right now, but the role of the FDA confuses everyone. So I guess I am wondering about how soon you can do this. Are there resources available or do you need further assistance to get this done?

And maybe this is premature, but I know you alluded to the potential for a legislative fix and that you are looking at it kind of. And what might be a pharmaceutical component? And then what might be other sized doses or products that would not be regulated in the same way?

Dr. GOTTLIEB. I will tell you that we are deeply focused on this. We have taken on other hard challenges before. I think we have a good track record of trying to come to resolution on other challenges. And you have my commitment that I am focused on this one.

I am going to announce shortly a high-level working group that is going to report to me on this with some senior officials in the Agency who are going to be chairing that. We want to wait for the public meeting and solicit comments and get input. I will tell you that if we make a determination that the pathway here is going to be a multiyear regulatory process that could take two, three, four years, I will come back to Congress and have a discussion about whether or not there are other frameworks that could help address this.

Again, I want to preserve the pharmaceutical opportunity here while recognizing that Congress intended for there to be a pathway for this product to be available in other forms. And I think that there are different things we can contemplate scientifically. I don't want to get too far ahead of myself, but you could think about concentration and formulation and other thresholds. That might or might not be something we can do in regulation.

We might need a statute that either addresses this as a whole framework or addresses CBD specifically. If that is the case, we will work through a process to have a discussion around that.

Ms. PINGREE. Great. Well, we will stay in close touch and look forward to any decisions that you make soon.

PRESCRIPTION DRUG PRICING

The second question is on the pricing of prescription drugs. And you have already had several questions about this. I really appreciate your answers relating to generics, rebates, negotiating, all of the things that could be done that you have some say over. I know in July of 2018, Secretary Azar directed the FDA to establish a working group to examine safe importation of prescription drugs.

That is an issue I have been concerned about for a long time living in a border state, which Maine is. We have toyed with this at a state level and had to go back and forth. So I am very interested in what the FDA's working group is thinking about this.

And just to emphasize the point because prescription drug pricing is so critical, we called a couple of pharmacies. You know, in our state, you can literally cross the border. And if you have a duly licensed physician who writes you prescriptions, you can buy prescription drugs across the border. Advair, which, as you know, is used to treat asthma and bronchitis, one of the top-selling drugs, was a cash price of \$378 at the Maine pharmacy. Across the border, it was \$140 in Canada.

Even worse, given the crisis that we have with insulin right now, cash price for a vial of insulin, which was first used in 1922, was \$200 in Maine, a price many families can't afford and we are hearing more and more about every day, but that same vial of Humalog is available for \$35 at the Canadian pharmacy.

You know, I have worked on this issue for so long. And people try to raise red flags, you know, Maybe it is not safe. I know from living in a border state that Canadians have safe drugs and pleasant, well-lit pharmacies where they go to purchase them. And you really can't tell the difference in any way. So I would love to be updated and follow your progress in this.

Dr. GOTTLIEB. Canadians have safe drugs. And if you go into a Canadian brick and mortar pharmacy and you purchase a drug, you are getting a safe and effective drug. I have confidence in the Canadian drug regulatory system. The places where we have deep concerns is when people go online and buy drugs from online pharmacies that are purporting to source their drugs in Canada or other First World markets but are not. And we have a lot of concerns, and we are seeing a lot of counterfeit drugs being sold through those channels. We have a lot of ongoing investigative activity and some fairly egregious things that we are finding when we look at these websites. And so we have deep public health concerns.

With respect to the workgroup, the work continues to go forward. That was designed to specifically address a more narrow circumstance of a situation where there is a big price increase. It creates an access dislocation, so certain situations of hardship that patients might face.

Ms. PINGREE. I am out of time, but I would love to continue the discussion with you.

Dr. GOTTLIEB. Thank you.

Ms. PINGREE. Thank you very much.

Mr. BISHOP. Ms. Lee.

Ms. LEE. Thank you very much. Thank you, Mr. Chairman and Ranking Member. This is my first hearing, and I am excited to be on this committee.

I get a chance, actually, Commissioner, to drill down on two of my favorite subjects: Cuba and cannabis. [Laughter]

APPROVAL PROCESS OF HEBERPROT-P

Ms. LEE. I co-chair the bipartisan Cuba working group and the bipartisan cannabis caucus. A couple of issues that I want to raise with you about those two issues.

One is, you know, 30 million Americans, about 9.4 percent of the population, has diabetes. For African Americans, those numbers are even worse. African Americans are 80 percent more likely to

get diabetes than their white counterparts. And currently 13 percent of African Americans have diabetes.

Now, as I mentioned in our meeting, Cuba currently has a diabetes drug called Heberprot-P. It has helped and prevented deep foot ulcers, and it is not just being used in Cuba, but in 20 countries around the world. It does prevent amputations. Seventy-one thousand Cuban patients have been treated. And overall, 300,000 patients worldwide have been treated.

Now, it is my understanding that as of March last year, Cuban and U.S. companies came together and signed an agreement to begin to look at how to move forward with clinical trials and getting approved. They are still waiting, though, approval by FDA. And so I am wondering if you could give us a status report of this approval process. I have been working on this for 10 to 12 years—for this drug. And do you think we will see the approval for this in the United States? Because this is a very, very serious issue and for everyone, especially in minority communities, in terms of diabetes amputations.

CANNABIS-DERIVED COMPOUNDS

Secondly, just in terms of cannabis, it is my understanding to date that FDA has approved only one plant-derived medicine from cannabis and that it was awarded, quite frankly, to the British pharmaceutical company GW Pharmaceuticals because they are licensed by the U.K. Government to privately grow strains of cannabis for the purpose of drug development. Many members of Congress support medical cannabis research to facilitate Federally approved clinical trials. And so it is really important to understand cannabis therapeutic applications and its impact on health and wellbeing. So I am wondering if you believe it is possible that under our U.S. Federal system, whereby cannabis is still a Schedule I substance, can a U.S.-based company similarly bring a plant-derived cannabis-based drug to market via the traditional FDA review and approval process? Because so many states now have passed medical marijuana initiatives, and it is a shame that we haven't been able to move forward with the research.

APPROVAL PROCESS OF HEBERPROT-P

Dr. GOTTLIEB. Well, on the first question, Congresswoman, I appreciate our discussion about this when we met. We owe you an answer. And I want to be careful because I am not sure which aspects of where they are in the application process constitutes commercial confidential information that I shouldn't reveal in this setting, but I will get back to you, one way or the other, on what we can tell you about where that process stands. And I look forward to following up with your office.

Ms. LEE. OK. I appreciate that because it has been going on a long time and a lot of people are waiting for this.

Dr. GOTTLIEB. I understand. We will. I will make sure we get you as much information as we can about that. And I recognize and appreciate your interest in that matter.

CANNABIS-DERIVED COMPOUNDS

With respect to hemp-derived or cannabis-derived compounds, it really depends on which active ingredient you are talking about, whether you are talking about THC or CBD, and whether or not it is being derived from marijuana or hemp. I think one of the active questions on the table is whether or not CBD—so GW Pharma was marketing a product that was a purified form of CBD derived from marijuana, if I remember correctly, in that case, but the active question on the table right now is whether or not CBD derived from hemp, which Congress made the decision to deschedule hemp, whether or not the CBD derived from that is also descheduled and can be studied in a more fluid fashion. And I think that that is an active question right now on the table.

I have my own personal opinion reading the plain language of the statute, but if I give a legal opinion, my lawyers are going to grimace at me. So I won't offer it. But I think we are going to have a resolution on that very soon about whether or not the CBD derived from hemp doesn't fall under the scheduling process.

Ms. LEE. Yes. OK. Thank you very much, but I want to clarify this British pharmaceutical company, GW Pharmaceuticals. They are licensed by the U.K. Government to privately grow strains of cannabis for the purpose of research. Did FDA award this contract to this British company or—

Dr. GOTTLIEB. No.

Ms. LEE. Could you clarify that?

Dr. GOTTLIEB. I mean, so it is the case in the United States that the ability to conduct research with marijuana is more restricted, more heavily regulated. You have to use product that is sourced from the government. I don't know all the nuance of it. So, you know, over the years, you have seen, in all candor, you have seen, companies go overseas to conduct research with foreign-grown product that is more easily sourced for the purposes of clinical trials. And so the issue that you are getting at is a valid one. The only thing I could say is that the environment here is changing quickly.

Ms. LEE. Very quickly.

Dr. GOTTLIEB. And we would certainly support more research.

Ms. LEE. OK. Thank you very much. Thank you, Mr. Chairman.

Mr. BISHOP. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman. And welcome, Dr. Gottlieb. It is a pleasure to be with you today. Just a couple of points, and I have two questions.

With regard to the issues of prescription drugs, which was mentioned, and the issue on generics, I just make you aware—I am sure you may be aware—with the renegotiated NAFTA agreement, the way it is currently constructed would delay generics and biosimilars given the way the patent exclusivity has currently been awarded to pharmaceutical companies. So just take a look at it because it directly affects where I think you want to go.

With regard to food safety, according to—Centers for Disease Control and Prevention studied imported food safety. Both the number and proportion of outbreaks from imported food has increased. Since 1996, outbreaks associated with imported produce

and fish were the most common. My two questions have to do with both. One is food safety, and then it is the safety of imported pharmaceutical drugs.

FOOD SAFETY AND POST-OUTBREAK INVESTIGATIONS

Last year, FDA investigated the outbreak, multistate outbreak, of *E. coli* infections that were linked to romaine lettuce from the Yuma growing region. Total reported illness is 210 people across 36 states, 96 hospitalizations, 5 deaths. The outbreak highlighted the devastating effects of FDA's inadequate oversight of food safety, particularly among fresh produce. The investigation with regard to that, the agency did not conduct sampling for the environmental assessment until June 2018, more than 2 months after the outbreak started. It confirmed that the outbreak's frame was positively identified in an irrigation canal used by many growers in the region.

What was located next to this irrigation canal is a large cattle feedlot operation, significant because *E. coli* is naturally found in the intestinal tracts and manure of cattle. In fact, FDA sampling at the feedlot found multiple positive samples of dangerous *E. coli* strains, though not an exact match to the outbreak strain. Noted in FDA's written environmental assessment, the sampling conducted at the feedlot was "limited" and is "not possible to draw valid conclusions."

I am curious to know why FDA did not conduct additional sampling at the feedlot operation, especially given its proximity to the irrigation canal and the fact that cattle are carriers of *E. coli*. In your opinion, as a matter of public health, should large feedlot operations, like that in Yuma, be located near irrigation canals and fields growing fresh produce? Given all of these findings, why is FDA still pursuing its delay of the agricultural water testing requirements under the produce safety rule?

Dr. GOTTLIEB. Well, there is a lot that we could have a discussion around on these issues, and I know my time is brief. Look, we have gotten a lot better when it comes to these post-outbreak investigations. And if you look at what we were able to do with respect to romaine lettuce in California, we were able to make much more rapid determinations about what the potential source was of that outbreak. So I think we are getting better and continue to get better. The resources that this Committee provided is going to go specifically, at least in part, to building out the teams that do these post-outbreak investigations because this is a very important part of our overall approach to food safety and public health.

With respect to the Concentrated Animal Feeding Operation (CAFO) and its proximity to the irrigation canal, there have to be measures put in place to make sure that there isn't direct proximity that can lead to the kinds of contaminations that you talked about. There are rules in place. They need to be reexamined in terms of what measures farmers are taking.

And with respect to the agricultural water rule, you know, we have implemented most of the major parts of the Food Safety Modernization Act (FSMA). The ones that we have either delayed or still have to implement are the ones that are really hard, and this one is really hard. Trying to get in place agricultural water stand-

ards that are not only rigorous and are going to provide the measure of safety that you expect and want, and that I want for the American people, but that can be actually implemented across a very diverse array of farmers where, if you look in the Pacific Northwest, they trade water on a daily basis, and we have to make sure our testing requirements accommodate much different practices with respect to where farmers get their water in different parts of this country.

Ms. DELAURO. Well, I hope we will move on these issues and take a look at where we go with dealing with feed lots.

SAFETY OF IMPORTED PHARMACEUTICALS

I've got about 27 seconds left, but the issue is safety of imported pharmaceutical drugs. Largest prescription drug recalls in recent history, class of blood pressure medications manufactured in China found to be contaminated with impurities that cause cancer; the bigger issue outsourcing pharmaceutical manufacturing to countries like China—they don't have the same level of consumer protection and safety laws of those in this country; long been concerned about FDA's oversight of foreign drug manufacturers. GAO released their findings on the issue and found that with despite the foreign offices that have been opened, FDA has not assessed these offices' contributions to drug safety. Nearly half of their authorized positions are unfilled. GAO made recommendations, I will not go through that, I am sure you know what it is.

Foreign offices—why are they not being utilized as they can for the safety of pharmaceuticals coming into the United States? Are we on track to meet previous targets of inspections of foreign drug facilities?

My time has run out, but I think that these are important issues I am suspected I can not—

Dr. GOTTLIEB. May I take 15 seconds, Mr. Chairman? Foreign inspections have gone up, Congresswoman, in recent years. The number of warning letters that issued have gone up substantially as a result of us targeting our inspections better. They will continue to go up. The other thing I would add is that we will be undertaking the first significant modernization of our Good Manufacturing Practice (GMP) standards with respect to active pharmaceutical ingredients, particularly with respect to generic firms, in probably over 20 years. I share your concerns. I have confidence in the manufacturing of generic drugs, but we can always be doing a better job.

Ms. DELAURO. If you can just get back to me on the pursuit of this largest prescription drug recall in recent history and where we are going on that.

Dr. GOTTLIEB. Absolutely. Absolutely.

Ms. DELAURO. Thank you so much. Thank you, Mr. Chairman.

THIRD-PARTY LOGISTICS

Mr. BISHOP. Dr. Gottlieb, let me just ask you about third-party logistics. As you know, the Drug Supply Chain Security Act of 2013 was enacted to protect patient safety, and ensure security of the drug supply chain through a single, national, uniform product serializing and traceability system. Despite the passage of federal legislation in 2013 that would provide third-party logistics companies

who have the preemption from state licensing requirements, FDA's failure to right implementing regulation has resulted in states trying to fill the void by introducing new licensing regulations.

The Drug Supply Chain Security Act required the FDA to issue final regulations for the licensing of third-party logistics providers and wholesale distributors by November 2015. However, as of today, not even the proposed license of standards have been issued. Where is the rulemaking package related to licensure? When can we expect to see the proposed licensure standards? And don't we need to have some uniformative (sic) licenses secured to keep the supply chain moving?

Dr. GOTTLIEB. That rule is moving through the Agency and through the process. I can get back to you with an exact target date on when it will be displayed. I have been briefed on it recently. It was crafted in a way that is going to provide uniformity across the country and a federal preemption standard.

E-CIGARETTES

Mr. BISHOP. I wanted to go back to a subject that you and I have frequently discussed, and that is e-cigarettes. On the comprehensive plan for tobacco and nicotine regulation that you announced July 2017, the deadline for noncombustible e-cigarette market applications has moved to 2022. That was 19 months ago.

I continue to be concerned about how smaller companies that make these products are going to be able to afford the cost of the required applications. I fear that they are going to have to go out of business unless we find a way to address this. If we do not, we will have a smaller market controlled by big companies with fewer choices for adult smokers, higher prices and probably less innovation. If adult smokers who wish to use e-cigarettes to reduce or end their use of combustibles cannot find the products that they like, they may not make that change, and the public health will suffer.

What have you done to address the costs that may devastate the smaller companies in this industry, and what do you plan to do going forward?

Dr. GOTTLIEB. Well, we are cognizant of this concern, Mr. Chairman, and in part, you know, our desire to extend the application deadlines on these products and give them until 2022 is to give us the time to put in place the implementing regulations and guidance that would not only provide the rules of the road for how to effectively traverse the PMTA process, but also take into consideration the kinds of challenges that you bring up about how we can build into our regulation and guidance accommodations for small manufacturers. We have tried to do that in other areas of tobacco regulation. We will try to do that in this context as well.

GE SALMON

Mr. BISHOP. Thank you. AquaAdvantage Salmon was approved by FDA in November 2015 after an exhaustive and rigorous review. Despite FDA approval, the company is still not able to market its salmon in the United States. As you know, our bill over the past few years has carried language from the Senate that prohibits market and production of genetically engineered salmon until FDA issues final labeling guidelines "for informing consumers of such

content.” Your website says the FDA has determined that no additional labeling of food from AquAdvantage Salmon is required.

Am I correct in believing that as the law stands now, FDA will not do what the Senate language asks it to do, and therefore the product will continue to be barred from entering the United States?

Dr. GOTTLIEB. This is a very active area of discussion inside the Agency right now. We hope to have something to say on this very shortly, hopefully within a matter of weeks, not months, but we are working through the question of whether or not the final rule that USDA put out in conjunction with the 2016 law where they are now assuming jurisdiction over the labeling of these products, what that does to the language that is in our appropriations rider, and what, if any, continued jurisdiction or obligations FDA has in this regard.

Mr. BISHOP. Thank you very much. Let me call on my colleague, Mr. Fortenberry.

IMPORTED FOOD INSPECTIONS

Mr. FORTENBERRY. Thank you, Mr. Chairman. I want to go back to the discussion that Ms. DeLauro had raised regarding imported food. You said 13 percent of our consumption, as I recall, you said is imported.

Dr. GOTTLIEB. Fifteen.

Mr. FORTENBERRY. Fifteen? How much of that comes from China? And you may recall some years back the head of China’s Food and Drug Administration was executed because of tainted pet food. Now if you make an error we’re not going to do that, but nonetheless I understand we have about 50, at most, 50 inspectors worldwide for food and drugs, and then how much of our food comes from China? How many inspectors do we have?

Dr. GOTTLIEB. We do not have inspectors that are just dedicated to foreign inspections versus domestic inspections. We do have a foreign inspectional cadre, but we do use inspectors across both domestic and foreign inspections. We conduct about 1,600 foreign inspections a year of facilities. About, as I said, 15 percent of the food that we eat is imported. I do not have an overall number of what percentage of food comes in from China offhand. I can get back to you on that. What you will see is that it is going to vary by food product. So for example, a high percentage of fish might be imported from China; other products, a high percentage might be imported from other regions of the world.

We put out this week a framework for how we intend to try to improve our overall oversight of foreign inspection of food products. I recognize this is an area of concern for Congress; it’s an area of concern for me, as the percentage of the food that we eat grows from imports. I have confidence in the system right now, but that is only because we continue to invest in this, and I believe that we are going to continue to do a good job by modernizing these approaches.

Mr. FORTENBERRY. So how many inspectors do we have in China? Or elaborate on the framework of inspection in China. How does that work?

Dr. GOTTLIEB. I would have to get back to you on that. We have a dedicated office in China that I think has allocated 26 FTEs. I

believe that there are six FTEs there right now and six more that are in the process of being on order, but that is not really the operative number of people because inspectors that we would use to do Chinese inspections would be domestic inspectors that would be based here and going over to do foreign inspections.

What I could tell you is the number of inspections that we conduct by country. That might give you an indication as opposed to FTE levels allocated to country. But we can get back to you with all that data. I just do not have it offhand.

Mr. FORTENBERRY. Yes, I am assuming FTEs means outcomes. If there is some other metric that determines safety levels, that would be helpful to know.

Dr. GOTTLIEB. Number of inspections by region relative—

Mr. FORTENBERRY. Obviously it is a variable but, so, yes, help us understand is it robust enough? That is my concern.

Dr. GOTTLIEB. I understand. I would just, if I may, I would just say that the metric that I would—I would not use the metric of inspections by region or inspections by percentage of imports coming from an area because so much of our foreign oversight is contingent upon shared oversight with foreign regulators, third-party audits, requirements we impose on importers, and so it is a multi-layered system. So for example, we rely on regulators in New Zealand, Canada and Australia. We have joint agreements with them, and we are negotiating one with the UK, so in those countries we may conduct fewer inspections because we trust the Canadian regulators, we trust their inspections. So it is going to depend by the region and what other tools we have—

Mr. FORTENBERRY. Even China's inspections?

Dr. GOTTLIEB. China currently is not on the list of regulators whose inspections we recognize.

Mr. FORTENBERRY. No?

Dr. GOTTLIEB. No.

NON-OPIOID ALTERNATIVES

Mr. FORTENBERRY. All right, thank you. Let me go two other quick questions. It was touched on earlier I believe by Mr. Moolenaar. What is your plan to develop abuse deterrent formulations to replace opioids, the current opioid?

Dr. GOTTLIEB. We continue to feel that this is an opportunity, both non-opioid alternatives for the treatment of pain, as well as abuse deterrent formulations of opioids, is an opportunity as one of the tools to address this crisis. We promulgated guidance just this last year on some of the standards for developing generic versions of abuse deterrent formulations. We are working through a process to readjudicate the nomenclature that we use to describe the abuse deterrent formulations, so we are trying to get in place a robust regulatory framework to allow these products to go forward.

You know, one of the conditions that we would consider if we were to sweep the market of a non-abuse deterrent formulation to allow just abuse deterrent formulations within a category of drugs, is could you have the availability of generic versions of that drug, and that is why the guidance on allowing generic versions of the ADF drugs to come forward was so important. It opens the door to our ability to convert the market to ADFs.

Mr. FORTENBERRY. So that would replace the immediate-release opioid?

Dr. GOTTLIEB. Well, you know, the abuse deterrent formulations that have been put in development, to my knowledge right now are the extended release, long-acting formulations. But there are early development with some abuse deterrent formulations of the immediate-release drugs. And you are right in pointing that out because 90 percent—more than 90 percent of utilizing are the IR drugs. That is where the exposure is happening.

Mr. BISHOP. Mr. Cuellar.

Mr. CUELLAR. Thank you, Mr. Chairman. Commissioner, on the question that I asked you about, the oxycontin and the work that you all want to do about possible relabeling, and then on the compound pharmacist's efficiency work that you all want to do, what is the time table on each of them just so we can get an idea? What are you talking about? Months? Years? Decades?

Dr. GOTTLIEB. So on the guidance that I believe will help to find a more efficient pathway for 503A compound is to convert to being 503B compounders, days to weeks. With respect to the studies, the studies to look at the implications of the long-term use of opioids and whether or not this diminished effectiveness with chronic administrations of opioids, that will be a multi-year process. I think that those studies, once we put the mandate on the companies, which we are going to do in the next several months, I think those studies can potentially be conducted within a year, and you are looking at potentially another year to read out the results. And so it is a multi-year process.

As much as it seems intuitive that there is declining efficacy with prolonged administration of opioids, and there is some evidence in the literature to suggest that there is an evidence that meets the statutory standard that we are required to meet in order to effect regulatory change. We need to conduct rigorous perspective randomized trials. These are going to be randomized withdrawal studies. And so those do take time to conduct, but they can form the basis of the enduring regulatory change, which is what I think we need in this space.

APPROVAL OF DSUVIA

Mr. CUELLAR. OK. I sit on the Defense Approps so I have a question dealing with that and your agency. Last November the FDA announced the approval of another opioid, Dsuvia, a drug that is 10 times more powerful than fentanyl. Commissioner, you admitted to the potential dangers of this drug but have said that Dsuvia could be beneficial for the military in use in the battlefield situations because the drug can be administered under the tongue. You have stated that it "fills a specific and important but limited unmet medical need in treating our nation's soldiers on the battlefield."

My question, Commissioner, is has the military given you a requirement for this type of drug? Have you talked to the military about the need for this potent of a drug on the battlefield? And you said that the main benefit will be to the military, but how do you intend to limit the drug's use to solely military battlefield environments? And again, I do not want to see, with all due respect, a 2001 situation again.

Dr. GOTTLIEB. I understand. And so let me just give a little bit of a table set if I may, and I will be quick here. It is a very potent formulation of fentanyl but it is a very small piece of the drug. So it is actually the equivalent of 15 milligrams of morphine, which is not a trivial dose of morphine but it is not an extremely large dose of morphine. If I have a patient coming in with a kidney stone, I would routinely use 15 milligrams for morphine.

The reason why you need to use a very potent formulation of the drug in order to deliver 15 milligrams of morphine, which is really a standard dose of analgesia for a bedside surgical procedure, is because you want it to be absorbed quickly. If you were using something that was not potent, it might be this big and it is not going to be absorbed under the tongue. So you had to use a very potent formulation of fentanyl in order to allow sublingual delivery of that drug.

With respect to the Department of Defense, in particular, we made a commitment to Congress as part of the MDAA that was passed last year that we would prioritize drugs and medical products that were important to the frontline soldiers and to the DOD and give them priority status and soft touch from the FDA. Dsuvia was on the list of products that the DOD prioritized. That list was about 10 products and so this was important to the DOD, at least as they identified it to us, and so we did work collaboratively around this product.

Mr. CUELLAR. So they did give you a requirement for this type of drug?

Dr. GOTTLIEB. Not a requirement, but they did flag this as something that was a priority of theirs on the priority list that they gave us of, if I remember correctly, around 10 products.

Mr. CUELLAR. So how do we make sure that this stays on the battlefield? Because I mean you have soldiers, they became veterans, they might need some help afterwards and we—with all due respect, I do not want to see a 2001 situation.

Dr. GOTTLIEB. I understand, and I will tell you that this is—Dsuvia is going to be, as it is used in hospital settings—and it does play a role there, too. If you are a doctor and you need to do a bedside surgical procedure, and I have been there where I had to put in chest tubes and could not get a line in the patient and could not give them any analgesic, and that is not a comfortable position to be in, this can be a useful product for that niche kind of circumstance. This is a product that will be dispensed in hospitals under tight controls. It will probably be secured in Pyxis systems. That does not mean that there is not opportunity for some diversion in hospitals. The kind of diversion you are talking about would typically be among healthcare providers, unfortunately. We do see some abuse of drugs by anesthesiologists and other physicians and providers in the hospital setting, that goes on. But there are much tighter controls on that kind of activity and it does not go on as much as it used to, and I am not saying it is not going to happen.

When it comes to fentanyl, this is a challenge, but this is a challenge where perhaps dozens or maybe hundreds of people can potentially be exposed, and I am not trying to trivialize that. The biggest challenge we face with fentanyl, quite frankly, is the illicit

fentanyl that is pouring across the international mail facilities and God knows where else, but we are——

Mr. CUELLAR. Do not say the southern border because we know——

Dr. GOTTLIEB. Yes, no, I am talking about the international mail facilities where I have jurisdiction. That is where I am also focused, Congressman.

Mr. CUELLAR. Thank you so much, Commissioner, thank you.

Mr. BISHOP. Thank you. Dr. Harris.

DIETARY FIBERS

Dr. HARRIS. Thank you very much. Just one follow-up on the fiber question I had. How many dietary fiber petitions do you currently have in review? And what is the timeline for that response, again? And will you respond by rulemaking or are you going to be communicating directly with the petition?

Dr. GOTTLIEB. I believe we have three to five petitions currently in house, and we will be communicating directly with the petitioners. You know, we are doing what we can to try to get as many people over the line as possible, and that has been our goal from the outset.

RECALL STANDARDIZATION

Dr. HARRIS. OK, good, again, because, you know, I know that our food manufacturers really want to comply with that January 1st deadline. With regards to recall standardization, the USDA has standardized its food recall communications, particularly with respect to disclosure of retailers, and that streamline approach has been pretty effective at disseminating consistent, accurate retail information to consumers. It would probably be—I think it might be helpful for the FDA to take the same approach.

Is there an initiative to do that? And are you also considering an online submissions process like Canada has that would negate the differences that you see now between what different FDA regional offices are requiring?

Dr. GOTTLIEB. When I look at food safety, Congressman, I look at it from the perspective of the consumer, what the consumer wants. They want timely recalls and adequate information, and able to know whether or not they have a violative product. They want effective track trace so they can know where their products are coming from, and they want the assurances and safety that we provide through things like the inspections.

We have taken steps in recent years to try to make our recall process more robust, including providing information about where a product may have come from, if you went to a local store and a recalled product was purchased in that local store, highlighting the stores where products may have been sold. We are going to continue to try to modernize that product because I think this is one of the core pillars of what consumers want when they think about food safety.

Dr. HARRIS. Sure, and, again, do you think it would make sense to unify the process between the FDA regional offices so it is a uniform requirement?

Dr. GOTTLIEB. Yes, I am not aware that it is not, and I can get back to you on that in terms of specifically what concerns you may have about where there may be discrepancies about what we do from region to region, because we do try to have, you know, nationalized standards in place to these kinds of core elements of our food safety approach.

FISH CONSUMPTION ADVICE

Dr. HARRIS. Sure, no, thank you. I appreciate you getting back to me on that. Finally, one issue that has come up is the—and I know this is an issue personally in the family because my oldest daughter is expecting my eighth grandchild, and I just talked with her yesterday—two days ago, actually, about fish consumption and how the potential benefits of fish consumption, both on neurological development, and now the latest on basically resulting in—increasing fish consumption especially after 24 weeks resulting in an increased body weight, but lean body weight, as a child.

Has the FDA calculated an updated benefits of fish consumption on fetal development? And why aren't—why isn't the FDA actively encouraging fish consumption for pregnant women given the scientific evidence that it is actually beneficial?

Dr. GOTTLIEB. First of all, congratulations. We do actively encourage fish consumption, and we think fish is under consumed by pregnant moms, expectant moms, and we have taken steps to try to encourage more fish consumption. And the changes we made to how we define what fish is safe to eat during pregnancy was intended and designed to try to promote more fish consumption. This continues to be a goal of the Agency.

Dr. HARRIS. And, for instance, on your website available to the public, I mean, does it mention the calculated benefits of fish consumption, or does it just say eating some fish is good?

Dr. GOTTLIEB. I believe it does. We can get you the specific language that we use on the website, but I believe it does, and we have had campaigns in the past. I see your chief of staff shaking his head no, but we can take a look at that and there may be more that we can be doing there because this is a public health goal of ours, we share your concern.

Dr. HARRIS. I thank you very much, and again, thank you for appearing before the subcommittee.

Mr. BISHOP. Thank you. We are winding down and I think last question, I will recognize Mrs. DeLauro.

IMPORTED SEAFOOD

Ms. DELAURO. Thank you very much, Mr. Chairman. Just to respond to, if I can, my colleague Mr. Fortenberry. First of all, 94 percent of our seafood is imported into the U.S. In terms of top imports from China: tilapia 78 percent; cod 51 percent. I might add to that that is farmed. They farm their fish. I do not have to describe what that process is about. I might also add that most of our shrimp comes from Malaysia or Thailand, and in fact, that is farmed as well.

So I would just say to my colleague from Maryland, I would be wary of what kind of fish my pregnant daughter was eating and where it was coming from, know where it is coming from. Apple

juice is 50 percent from China; mushrooms 34 percent; garlic is 31 percent. This issue, at a longer discussion, gets into equivalence and what are the standards under which this regulatory framework, whether, yes, Australia, Canada, et cetera, but we do business with a whole lot of other countries who do not have the kind of regulatory framework we do, and that, I think, presents a problem for food safety.

IMPORTED PHARMACEUTICALS

Another point, again, in terms of the safety of the imported pharmaceutical drugs, just let me highlight that it is about the outsourcing of pharmaceutical manufacturing to countries, which is something I think we have to talk about, and that's like China. They don't have the same level of consumer protection and safety laws as those of this country. It is estimated that as much of 80 percent of active ingredients in U.S.-branded pharmaceuticals and over-the-counter drugs originate from either China or India. I think that is an area that we have to explore and to find out, what again—we've got food, we've got pharmaceuticals coming from places that have potentially—I'll just say potentially—I believe it puts our people at risk.

E-CIGARETTES

I, too—because we're all going down the vaping and e-cigarette road, Dr. Gottlieb—I happen to believe that that is the growing epidemic of youth vaping has reversed decades of progress that we made in reducing youth nicotine addiction. In 2019, the vaping industry is still exempt from any meaningful FDA oversight and regulation. Your tweet December 2018 on riding CEOs of e-cigarette manufacturers asking them to meet to discuss commitments they made last month and why some are changing course. This is an urgent matter. January 4, 2019, New York Times, Juul and Altria made very specific assertions in their letters and statements to the FDA about the drivers of the youth epidemic. Their recent actions and statements appear to be inconsistent with those commitments. Altria—industry actions coupled with Altria recently purchasing 35 percent stake in Juul demonstrate to you that the industry cannot be relied upon to take voluntary action to solve the epidemic.

Why has the agency refused to implement mandatory rules which the industry must follow? Let me ask that question.

We also have deeply false and misleading and frankly illegal marketing advertising of e-cigarettes and vapor products. Family smoking and prevention of tobacco products prohibits health claims about reduced risk tobacco products where such claims are not scientifically proven or would cause net public harm. FDA continues to allow e-cigarettes to make implicit, explicit, unauthorized, modified risk claims. FDA, as I understand it, you tell us, FDA has not granted such authorization for such modified risk claims, nor has the FDA approved any e-cigarette as a cessation device.

You are on their website, Dr. Gottlieb, of Juul's website. It's called harm reduction. You are quoted. This is about—they talk about potential harm reduction, less risky products, and—read it if you haven't read it. So Altria is quoting you on that promotional

website. What about these claims that they are making? Why are we refusing to implement mandatory rules on this industry?

Dr. GOTTLIEB. Well, Congresswoman, I share all your concerns. This is the biggest challenge I face right now that I don't feel we have all the policies in place to deal with it. The biggest public health crisis we face is clearly the opioid crisis. I feel like we have policies in place that allow us to try to address it within the scope of what we are capable of doing. With respect to e-cigarettes, we still don't have those policies in place. We will. This is one of my highest priorities right now. I am working through my own process within my own administration to get these rules and guidances out. I am hoping they will be out very soon.

Ms. DELAURO. Watch their advertising because in my state of Connecticut the radio ads are on about harm reduction and there are billboards now going up, full page ads in the Washington Post, Wall Street Journal, New York Times from July. The advertising has to got be watched and very, very closely. Thank you very much, and thank you, Mr. Chairman, for the time. I appreciate it.

CLOSING STATEMENT—MR. BISHOP

Mr. BISHOP. All right, well, I think this meeting has been a very, very exhaustive hearing. I appreciate your patience, Dr. Gottlieb. You have been very helpful and forthcoming. And if any members would like to submit anything to the record or would like to submit questions to Dr. Gottlieb that he can get back with us, please feel free to do so. With that we will adjourn this hearing of the Agriculture, Food and Drug Administration, Rural Development Committee, Appropriations.

[Questions and answers for the record follow:]

FDA Priorities

The Committee:

1. Please inform the Committee of FDA's top five most pressing issues or priorities in fiscal year 2019 and anticipated for fiscal year 2020.

Response: Protecting the safety of the food and medical products consumers use every day is FDA's ultimate goal. To sustain this goal and keep pace with the constant threats of an ever-changing world, the Agency must make significant progress on several important fronts; including promoting the development of innovative medical products, modernizing food safety and strengthening foodborne illness response, combatting the opioid epidemic, tackling the youth tobacco crisis, and implementing the 21st Century Cures Act (Cures).

Enhancing the Safety of Medical Devices: While FDA has been improving policies and processes to address scientific advances and enhance the safety of medical devices, FDA's information technology systems are not well-suited to support these activities. With additional resources, FDA plans to build an integrated knowledge management system and portal for medical devices to enable safety issues to be monitored, and effectiveness to be evaluated, across the total life cycle of the device and to build out our digital health program.

Advancing Food Safety: One of FDA's top priorities in FY 2019 is to advance the implementation efforts related to FSMA and strengthen the response capabilities for foodborne outbreaks to provide Americans the benefits from access to a highly diverse food supply while reducing the risks from foodborne illnesses. To accomplish this goal, FDA will need to improve the capacity to detect early signals associated with foodborne illnesses and shorten response timelines once human or animal food contamination is detected.

E-cigarettes: One of our most important public health efforts is to continue standing up a framework to make sure we can put e-cigarettes through an appropriate series of regulatory gates, and aggressively confront youth use of these products to make sure children do not become addicted to nicotine.

Opioids: One of the Agency's highest priorities is combatting the ongoing crisis of opioid addiction. The FDA has changed its approach to the opioids crisis and is taking a much more aggressive approach to regulatory action, focusing on the following four priorities:

- Decreasing exposure and preventing new addiction,
- Supporting the treatment of those with opioid use disorder,
- Fostering the development of novel pain treatment therapies, and
- Increasing enforcement and assessing benefit-risk.

21st Century Cures Act: Implementation of the 21st Century Cures Act (Cures) continues to be a top priority for the Agency. Cures includes provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The law complements many efforts underway at FDA. All these efforts are aimed at transforming the way we support product development and maintaining FDA's gold standard for safety and effectiveness.

The Committee:

2. Please provide a list and status of all funding increases in the fiscal year 2019 Omnibus.

Response: Please see table below for the increases provided in the FY 2019 Omnibus. FDA only recently received this funding, so the funds have not yet been obligated.

<i>(Dollars in millions)</i>	FY 2019
Medical Product Safety	257.6
<i>Promote Domestic Manufacturing</i>	38.5
<i>New Domestic Drug Industry</i>	12.0
<i>MedTech Manufacturing</i>	6.0
<i>New Medical Data Enterprise</i>	50.7
<i>Transform Medical Device Safety, Cybersecurity, Review, and Innovation.</i>	25.0
<i>New Platform for Drug Development</i>	43.3
<i>Modernizing Generic Drug Development and Review</i>	25.1
<i>Investment and Innovation for Rare Diseases</i>	10.0
<i>Opioids</i>	47.0
Food Safety	13.8
<i>NARMS-Seafood</i>	0.5
<i>Standard of Identity and Product Labeling</i>	2.0
<i>Consumer Education and Outreach Regarding Biotechnology</i>	1.5
<i>FSMA Cooperative Agreements</i>	2.0
<i>Import Safety</i>	2.8
<i>Strengthening Response Capabilities for Foodborne Outbreaks</i>	5.0
Total BA Increase	271.4

Information Technology

The Committee:

3. Please provide the Committee with FDA's actual spending on Information Technology in fiscal years 2017 and 2018, estimated for fiscal years 2019. Please describe future plans for Information Technology investments.

Response: This chart represents actual spending on Information Technology for FY17 and FY18 and estimated spending on Information Technology for FY19.

Information Technology Spending by Year (Dollars in millions)	
FY17	\$ 749
FY18	\$ 820
F19 Projected	\$ 746

FDA's FY 2020 budget request includes critical funding for IT investments to support efforts to improve medical product development, review, and innovation.

Transform Medical Device Safety, Cybersecurity, Review, and Innovation: +\$30M (vs. FY 2019 Enacted)

- Currently, FDA's premarket device review and post market surveillance processes use information from many legacy IT systems that are aging and siloed. These critical components of FDA's existing IT infrastructure are time-consuming to use, have increasing maintenance costs, and are built on older platforms that can no longer be upgraded, which significantly increases the risk of threats and vulnerabilities until the functionality is replaced with current, supported technology.
- This initiative will allow FDA's Center for Device and Radiological Health (CDRH) to build an integrated knowledge management system and portal for medical devices using modern, agile information technology systems with secure cloud-based data storage that will enable safety issues to be monitored along the total life cycle of the device from bench testing to premarket clinical trials to post market adverse events and real-world evidence. This capability to better leverage pre-existing and new data in near real time is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity.
- Through this initiative, FDA will establish customer-friendly interfaces with industry, patients, and providers that will foster greater and more transparent interactions between FDA and its customers, including providing industry with the ability to track their premarket submissions.
- Funding will also support building reliable, connected environments that allow reviewers and users access to integrated data, tools, and knowledge. This transformation will reduce duplicative efforts and create one integrated environment for reviewers to analyze complete information to more efficiently process applications and respond to regulatory questions.

New Platform for Drug Development - Drug Innovation Platform: +\$6.7M (vs. FY 2019 Enacted)

- FDA requires a comprehensive knowledge management approach to its significant number of precedential decisions, and to the underlying data, including data from trials, data generated by FDA, and real-world data.
- Additional funds would support development of a knowledge management system and framework that would provide rapid access to and in-depth analysis of the vast and diverse information submitted to FDA. Such a knowledge management system would advance FDA's ability to rapidly develop scientific evidence as questions arise, including questions about drug safety or quality.
- The requested FY 2020 funding would provide an investment to enable improved IT infrastructure to support regulatory review and knowledge management, and support further expansion of the platform, tools and cloud-based functionality.

Modernizing Generic Drug Development and Review: +\$1.9M (vs. FY 2019 Enacted)

- Funds are to support an updated review platform would significantly modernize generic drug review by improving clarity for generic sponsors and decreasing the number of review cycles, greatly increasing efficiency at FDA.
- Funds will support consistent drug product evaluations and knowledge management across applications that would enhance product surveillance based on quality risk. In addition, a new platform would enable the automation of elements of the application review that are currently performed manually, streamlining the application review process.
- Funds would also allow FDA to advance the quality assessment of sponsor-provided drug product applications and ultimately improve patient care and facilitate access to new and generic therapies.

New Medical Data Enterprise: +\$9.3M (vs. FY 2019 Enacted)

The New Medical Data Enterprise will advance the use of real-world experience to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product reviews, support active surveillance of medical products, and promote innovation. The Agency will evaluate the added value of real-world evidence from electronic health record data to address specific drug use and safety questions.

GAO/OIG Reports

The Committee:

4. Please provide a listing of all GAO reports conducted on FDA programs and activities in fiscal years 2017, 2018 and 2019 to date.

Response:

Final Report	Report Number	Final Report Title and number
10/13/2016	GAO-17-14	Open Innovation: Practices to Engage Citizens and Effectively Implement Federal Initiatives
10/16/2016	GAO-17-119	Environmental Protection: Information on Federal Agencies' Expenditures and Coordination Related to Harmful Algae
10/27/2016	GAO-16-833	Opioid Addiction: Laws, Regulations, and Other Factors Can Affect Medication-Assisted Treatment Access
11/2/2016	GAO-17-35	Emergency Funding for Ebola Response: Some USAID Reimbursements Did Not Comply with Legislative Requirements and Need to Be Reversed
11/17/2016	GAO-17-64	Drug Compounding: FDA Has Taken Steps to Implement Compounding Law, but Some States and Stakeholders Reported Challenges

Final Report	Report Number	Final Report Title and number
11/28/2016	GAO-17-98R	Food Safety: FDA's Efforts to Evaluate and Respond to Business Concerns Regarding the Produce Rule
12/8/2016	GAO-17-123	Federal Building Management: Building Disposal Authorities Provide Varying Degrees of Flexibility and Opportunities for Use
12/9/2016	GAO-17-115	Prescription Drug Labels: Actions Needed to Increase Awareness of Best Practices for Accessible Labels for Individuals Who are Blind or Visually Impaired
1/6/2017	GAO 17-87	FDA Facilities: Planning Efforts for White Oak Campus Should Further Incorporate Leading Practices to Address Ongoing Challenges
1/17/2017	GAO-17-143	Drug Safety: FDA Has Improved Its Foreign Drug Inspection Program, but Needs to Assess the Effectiveness and Staffing of Its Foreign Offices
1/18/2017	GAO-17-212	National Institutes of Health: Kidney Disease Research Funding and Priority Setting
2/6/2017	GAO-17-129	Foster Care: HHS Has Taken Steps to Support States' Oversight of Psychotropic Medications, but Additional Assistance Could Further Collaboration
2/8/2017	GAO-17-231	Medical Devices: Cancer Risk Led FDA to Warn Against Certain Uses of Power Morcellators and Recommend New Labeling
2/10/2017	GAO-17-150	Defense Civil Support: DOD, HHS, and DHS Should Use Existing Coordination Mechanisms to Improve Their Pandemic Preparedness
2/13/2017	GAO-17-74	Food Safety: A National Strategy Is Needed to Address Fragmentation in Federal Oversight
3/2/2017	GAO-17-189	Antibiotics: FDA Has Encouraged Development, but Needs to Clarify the Role of Draft Guidance and Develop Qualified Infectious Disease Product Guidance
3/28/2017	GAO-18-292	Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts
5/11/2017	GAO-17-360	Avian Influenza: USDA Has Taken Actions to Reduce Risks but Needs a Plan to Evaluate Its Efforts
5/23/2017	GAO-17-445	Emerging Infectious Diseases: Actions Needed to Address the Challenges of Responding to Zika Virus Disease Outbreaks
6/8/2017	GAO-17-507	Open Innovation: Executive Branch Developed Resources to Support Implementation, but Guidance Could Better Reflect Leading Practices
6/15/2017	GAO-17-416	Memory Supplements: Clarifying FDA and FTC Roles Could Strengthen Oversight and Enhance Consumer Awareness

Final Report	Report Number	Final Report Title and number
6/26/2017	GAO-17-452	Generic Drug User Fees: Application Review Times Declined, but FDA Should Develop a Plan for Administering Its Unobligated User Fees
7/11/2017	GAO-17-564	Investigational New Drugs: FDA Has Taken Steps to Improve the Expanded Access Program but Should Further Clarify How Adverse Events Data Are Used
9/13/2017	GAO-17-347	Technology Assessment: Medical devices: Capabilities and Challenges of Technologies to Enable Rapid Diagnoses of Infectious Diseases
10/1/2017	GAO-18-155	Biodefense: Federal Efforts to Develop Biological Threat Awareness
10/2/2017	GAO-17-443	Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residue
10/5/2017	GAO-18-32	Newborn Health: Federal Action Needed to Address Neonatal Abstinence Syndrome
10/26/2017	GAO-17-546	Low-Dose Radiation: Interagency Collaboration on Planning Research Could Improve Information on Health Effects
10/31/2017	GAO-18-44	Opioid Use Disorders: HHS Needs Measures to Assess the Effectiveness of Efforts to Expand Access to Medication-Assisted Treatment
11/15/2017	GAO-18-61	Sunscreen: FDA Reviewed Applications for Additional Active Ingredients and Determined More Data Needed
11/20/2017	GAO-18-22	Federal Regulations: Key Considerations for Agency Design and Enforcement Decisions
11/28/2017	GAO-18-85	Food Safety: FDA Continues to Evaluate and Respond to Business Concerns about the Produce Rule
12/1/2017	GAO-18-40	Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals
12/1/2017	GAO-18-12	Workplace Safety and Health: Better Outreach, Collaboration, and Information Needed to Help Protect Workers at Meat and Poultry Plants
1/16/2018	GAO-18-80	Generic Drugs: FDA Should Announce Plans to Issue and Revise Guidance on Nonbiological Complex Drugs
1/16/2018	GAO-18-140	FDA Medical Device Reviews: Evaluation is Needed to Assure Requests for Additional Information Follow a Least Burdensome Approach
1/29/2018	GAO-18-219	Inter-American Organizations: U.S. Agencies Support Oversight Mechanisms but Could Enhance Their Monitoring of U.S. Assistance Agreements

Final Report	Report Number	Final Report Title and number
3/5/2018	GAO-18-174	Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities
3/14/2018	GAO-18-271	Customs and Border Protection: Automated Trade Data System Yields Benefits, but Interagency Management Approach Is Needed
4/12/2018	GAO-18-205	Illicit Opioids: While Greater Attention Given to Combating Synthetic Opioids, Agencies Need to Better Assess their Efforts
4/16/2018	GAO18-199	Food Safety: Federal Efforts to Manage the Risk of Arsenic in Rice
4/18/2018	GAO-18-272	Food Safety: USDA Should Take Further Action to Reduce Pathogens in Meat and Poultry Products
5/31/2018	GAO-18-459	Animal Use in Federal Research: Agencies Share Information, but Reporting and Data Quality Could Be Strengthened
6/14/2018	GAO-18-446	Cybersecurity Workforce: Agencies Need to Improve Baseline Assessments and Procedures for Coding Positions
8/10/2018	GAO-18-381	Paperwork Reduction Act: Agencies Could Better Leverage Review Processes and Public Outreach to Improve Burden Estimates
10/3/2018	GAO-19-119SU	Federal Law Enforcement: Purchases and Inventory Controls of Firearms, Ammunition, and Tactical Equipment.
10/23/2018	GAO-18-685R	Opioid Crisis: Status of Public Health Emergency Authorities
11/30/2018	GAO-19-83	Orphan Drugs: FDA Could Improve Designation Review Consistency; Rare Disease Drug Development Challenges Continue
12/11/2018	GAO-19-63	Information Technology: Agencies Need Better Information on the Use of Noncompetitive and Bridge Contracts
12/11/2018	GAO-19-36	Federal Budget: Government-Wide Inventory of Accounts with Spending Authority and Permanent Appropriations, Fiscal Years 1995 to 2015

Antibiotic Resistance

The Committee:

5. What are the FDA's current efforts related to antibiotic resistance? Please specify any coordination with USDA or any other public or private sector group.

Response:

As part of its regulatory mission, FDA's Center for Veterinary Medicine (CVM) ensures the safety and effectiveness of animal drugs, including antimicrobial drugs, and coordinates the development and implementation of regulations and policies intended to help slow the development of antimicrobial resistance in association with the use of medically important antimicrobial drugs (i.e., antimicrobials important for treating human disease) in animals. In September 2018, CVM announced its five-year action plan for supporting antimicrobial stewardship in veterinary settings.¹

This plan builds upon the important steps CVM has taken to eliminate production uses (such as growth promotion) of medically important antimicrobials in food-producing animals and to bring all remaining therapeutic uses of these drugs under the oversight of licensed veterinarians. It also supports the judicious use of antimicrobials in food-producing animals and is driven by the concept that medically important antimicrobial drugs should only be used in animals when necessary for the treatment, control, or prevention of specific diseases.

Certain actions within the plan include collaboration with public- and private-sector groups. For example, in 2018 FDA funded for the third year two cooperative agreements with researchers from the University of Minnesota and Kansas State University to develop data collection methodologies and conduct pilot studies to characterize the use of animal drugs in food-producing animals. This information is being collected to improve FDA's understanding, at a national level, of how antimicrobials are used in various animal production settings.

CVM also works closely with government agencies such as the U.S. Department of Agriculture and Centers for Disease Control and Prevention to collaborate on multiple surveillance activities related to antimicrobial use and resistance, including the two cooperative agreements mentioned above and the National Antimicrobial Resistance Monitoring System, which monitors antimicrobial resistance in enteric (intestinal) bacteria in food-producing animals.

Beyond veterinary settings, FDA also continues to advance broader agency-wide efforts related to antimicrobial resistance. The Agency has established a website for regular updates to strategic approaches, initiatives, and collaborations.²

¹ FDA Center for Veterinary Medicine, "Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019-2023," September 2018, available at <https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf>.

² FDA, Antimicrobial Resistance Information from FDA," available at <https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm620149.htm>.

Third Party Verification Services for FDA Inspections

The Committee:

Over the past several years the Committee has provided FDA with additional resources to develop a targeted, risk-based, and efficient inspection model for high-risk establishments for onsite verifications.

6. Given the challenges of expanded geography, constantly expanding inventory of foreign exporters, and finite budgetary resources, how will FDA operationalize third party site verification services to select and prioritize FDA foreign facility inspections for the following FDA Centers: Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Food Safety and Applied Nutrition (CFSAN).

Response: FDA will continue to use third-party site verifications to identify high-risk facilities for inspections, better understand the supply chain relationship between regulated entities, and verify the accuracy of information provided at registration. For food facilities (Center for Food Safety and Applied Nutrition) and medical device facilities (Center for Devices and Radiological Health), FDA is continuing to contract with Dun & Bradstreet (D&B) to perform on-site verifications. The Center for Drug Evaluation and Research is developing the scope of a project to use data from a partnership with D&B and the University of St. Gallen (Switzerland) on benchmarking the quality of foreign drug manufacturing facilities.

Foreign Drug Inspection Program

The Committee:

According to a 2017 GAO report, the FDA improved its foreign drug inspection program through the Agency's use of a risk-based approach to select which manufacturing establishments to inspect has been a positive program, according to the GAO.

7. Can you detail successes of this program? How is the FDA planning on building upon this success in 2020? Are there plans to expand this successful program?

Response: Last year, FDA published its internal policy for how manufacturing facilities are prioritized and scheduled for surveillance inspections. FDA's policy explains how a facility's compliance history, recall trends, time since last inspection, inherent risk of the drug being manufactured, processing complexity, and other factors are all weighed and considered. The risk-based site selection model governance process requires an annual review and approval process wherein the Center for Drug Evaluation and Research and the Office of Regulatory Affairs jointly assess the model. FDA expects to build upon the success of the inspection program by continually reassessing the risk factors, weights, and methodology of the site selection model and identifying areas for improvement, modification, and enhancement.

The Agency's inspections program is a large-scale endeavor. As of March 2019, there were about 5,000 human pharmaceutical sites worldwide subject to routine surveillance inspection – 2,718 of those were foreign-based. In Fiscal Year 2017, FDA conducted 1,516 drug surveillance inspections, including 822 on foreign soil, to help ensure that manufacturers follow Current Good Manufacturing Practice (CGMP) requirements and maintain high quality standards. To accomplish this critical work, the Agency needs to maximize resources around the globe, which

is why FDA uses a risk-based site selection model to ensure that inspectional resources are allocated in the most efficient and appropriate manner to protect patient health. The risk-based site selection model is structured so that the inspection frequency for all facilities, regardless of where the facility is located, prioritizes inspections of sites where the drug being produced and the manufacturing processes used pose the greatest potential risk for problems that could harm patients.

In addition to identifying the facilities of greatest risk and prioritizing those inspections, FDA has also made efforts to ensure resources are effectively deployed to address inspection demands. Last year, for example, the Agency modernized the field organization structure, including inspection operations, to direct focus and organization around the types of programs regulated. Previously, FDA had organized field activities and resources based on geographic regions. The new structure, which focuses resources based on areas of specialization, enables staff to work more closely with the Agency's scientific and technical experts on complex scientific, manufacturing, and other regulatory challenges.

FDA's operational models continue to adapt to meet challenges and improve efforts to protect public health. FDA has also been able to work toward clearing the backlog of drug establishments that the Agency has never inspected. This effort has led to an increase in FDA's administrative and enforcement actions. The Agency is on track to complete this effort in the current fiscal year.

High Risk Inspection

The Committee:

8. Can you provide an overview on the benefits of the FDA's High-risk inspection program? Please detail what if any impact the government shutdown had on the FDA's high risk inspection program, both for domestic and foreign high risk inspections?

Response: FDA's high-risk inspection program affords FDA the ability to prioritize inspections of food facilities with the highest risk to public health. These facilities are identified based on a risk-profile assessment framework, established by the FDA Food Safety Modernization Act, which takes into consideration the type of food a facility produces, the manufacturing process involved in its production, and the facility's record or history of compliance with the law. These inspections target facilities and products that FDA believes have the greatest potential to cause harm to public health.

During the lapse in appropriations, FDA continued domestic and foreign inspections of high-risk facilities.

Center for Drug Evaluation and Research International Mail Facilities

The Committee:

9. As it relates to the funding Congress appropriated in FY 2018 and FY 2019, the Agency had plans to purchase new equipment and deploy the resources at or near the International Mail Facilities. Can you update the Committee on these efforts, any new inspection requirements, and plans for increasing these efforts in FY 2020?

Response: Through the first quarter of FY 2019, the Office of Enforcement and Import Operations, Office of Regulatory Affairs (ORA) has reviewed 5,619 packages across all International Mail Facilities (IMF), a 36% increase over the first quarter of FY2018. In addition, ORA has hired or reassigned 60 staff as designated IMF staff funded by appropriations made available in the 2018 Consolidated Appropriations Act.

As last reported in our 2018 questions for the record, the Agency expects to hire, train as necessary, and have all additional IMF-related staff on board before the end of FY 2019. FDA continues to work closely with Customs and Border Protection (CBP) and the United States Postal Service (USPS) to secure additional space and infrastructure at the IMF facilities to accommodate the additional staff. In addition, FDA continues to work with USPS and CBP on advancing our targeting strategy by obtaining data collected by the USPS and applying our targeting rules to identify possible targets for screening.

FDA will deploy additional rapid screening tools to the IMFs to help identify counterfeit products and products containing undeclared or non-permitted drug ingredients. We are in the process of hiring qualified scientists, purchasing analytical equipment, and identifying and procuring appropriate space to conduct screening operations. The Agency plans to have trained personnel and additional screening tools at selected high-risk/high-volume IMF facilities by FY 2020, which will result in increased efficiency and strengthened investigative capabilities.

Opioid Epidemic Spending

The Committee:

10. Please provide FDA's total resources – dollars and FTE – spent on the opioid epidemic for fiscal years 2017 and 2018 as well as planned expenditures for fiscal years 2019?

Response:

(Program Level, in millions of dollars)

	FY 2017 Actual		FY 2018 Actual		FY 2019 Estimate		FY 2019 vs FY 2018
	FTE	\$	FTE	\$	FTE	\$	\$
FDA, Opioid Related Base Activities ¹	138	\$40	169	\$60 ²	170	\$60	\$0
FDA, Interdiction Activities at International Mailing Facilities ³		\$0	141	\$94		\$0	-\$94
FDA, regulatory science, enforcement, and innovation activities.		\$0		\$0		\$47	\$47
Total FDA		\$40		\$154		\$107	-\$47

¹ This table reflects total funding for CDER, CVM, ORA and NCTR, including \$35M of User Fee funding in FY 2017 and \$39M of User Fee funding in FY 2018-FY 2019 (estimate).

² Actual 2018 Opioid spending has been updated from that reported in the 2020 FDA CJ.

³ The FY 2018 Omnibus provided \$94 million in one-time, no-year funding for Interdiction at IMF's. The total FTEs indicated reflects the target FTE level once the IMF activity has been fully established.

Bulk Drug Compounding Guidance

The Committee:

The Committee appreciates FDA's efforts last March to issue draft guidance on bulk drug substances. This guidance represents an important step to enforcing the Food, Drug, and Cosmetic Act's restrictions on these substances. As the draft guidance explains, the use of bulk drug substances poses additional risks to patients, undermines the drug approval system, and it also disadvantages those facilities that are doing the right thing by compounding from FDA-approved drugs. But there remains a great deal of confusion among customers about what outsourcers are using, and what the additional risks are for patients.

11. Can you update the Committee on FDA's efforts in finalizing its March 2018 draft guidance *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*? Additionally, the Committee would also like an update to FDA's efforts in developing the list of 503B bulk drug substances.

Response: On March 1, 2019, FDA issued a final guidance for industry, *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.³ This guidance addresses FDA's policies for developing a list of bulk drug substances that can be used in compounding under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), also known as the 503B bulks list, including the Agency's interpretation of "bulk drug substance for which there is a clinical need," which is the statutory standard for compounding from bulk drug substances. The guidance also addresses the factors and processes by which the Agency intends to evaluate and list bulk drug substances.

Under section 503B of the FD&C Act, an outsourcing facility can only use a bulk drug substance in compounding if (1) it is used to compound a drug that appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing, or (2) it appears on a list developed by FDA of bulk drug substances for which there is a clinical need ("bulks list"). FDA is currently evaluating bulk drug substances that have been nominated for the list. As explained further in the March 2019 guidance, FDA develops the bulks list by: issuing a notice in the Federal Register proposing to include or not to include bulk drug substance on the list and explaining the Agency's rationale; allowing at least 60 days for public comment on the proposals; then issuing a Federal Register notice that identifies the bulk drug substance that it has decided to place or not place on the list.

On August 28, 2018, FDA issued a notice in the Federal Register proposing, for public comment, not to include three bulk drug substances on the 503B bulks list. On March 4, 2019, FDA finalized this proposal with respect to two of the substances, nicardipine hydrochloride and vasopressin. The third bulk drug substance, bumetanide, remains under consideration. Because these bulk drug substances are not on the 503B bulks list and there are no products containing these substances on FDA's drug shortage list, outsourcing facilities may not use them in compounding under section 503B of the FD&C Act.

³ <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm602276.pdf>

Developing the 503B bulks list is a priority for the Agency. FDA intends to evaluate the bulk drug substances nominated for this list on a rolling basis. FDA will evaluate and publish in the Federal Register its proposed and final determinations in groups of bulk drug substances until all nominated substances that were sufficiently supported have been evaluated and either (1) placed on the 503B Bulks List or (2) identified as bulk drug substances that were considered but determined not to be appropriate for inclusion on the 503B Bulks List.

The Committee:

12. While the new draft guidance is an important step toward establishing a process to evaluate bulk substances, what steps will FDA take to ensure the law is being adhered to as instructed by Congress?

Response: As the Committee is aware, entities that are registered with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) may use a bulk drug substance in compounding only if it appears on a list developed by FDA of bulk drug substances for which there is clinical need (503B bulks list), or if the drug compounded from the bulk drug substance appears on FDA's drug shortage list at the time of compounding, distribution, and dispensing. Section 503B(a)(2)(A).

In March 2019, FDA finalized the guidance referenced in your inquiry, *Evaluation of Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. The guidance describes the analysis that FDA intends to conduct to determine whether there is a clinical need to compound using a bulk drug substance that the public has nominated for inclusion on the list and addresses the Agency's processes for making its determination. Applying that analysis, FDA has concluded that there is no clinical need to compound using the bulk drug substances nicardipine hydrochloride and vasopressin. Because FDA has made a final determination that these bulk drug substances will not appear on the 503B bulks list, drug products containing them are not eligible for the exemptions in section 503B.

The Committee may also be aware that in June 2016, FDA issued a guidance, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act (amended January 2017)*. The guidance describes the conditions under which FDA does not intend to take action against outsourcing facilities for compounding using certain bulk drug substances nominated for inclusion on the 503B bulks list until the Agency makes a final determination about whether they will be placed on the list. Because FDA made a final determination that nicardipine hydrochloride and vasopressin will not be placed on the 503B bulks list, these bulk drug substances are no longer eligible for the interim policy. Accordingly, during inspections, FDA intends to determine whether outsourcing facilities compound with nicardipine hydrochloride or vasopressin, and to take appropriate action when violations are identified. The Agency will do likewise as it determines, in the future, that additional substances will not be placed on the 503B bulks list.

In addition, section 503B(b)(2) of the FD&C Act requires outsourcing facilities to report to FDA, upon initial registration and each June and December, the drug products that they compounded during the previous six-month period. FDA intends to review these drug product reports to

identify any outsourcing facilities that produce drug products containing bulk drug substances that FDA made a determination to not place on the 503B bulks list.

As a general matter, monitoring compliance with the law and taking action when appropriate is a cornerstone of FDA's oversight role because of the ongoing and serious risks that unsafe, ineffective, or poor-quality compounded drugs can pose, as well as the threat that inappropriate compounding can present to the integrity and effectiveness of the drug approval process that is in place to protect patients. Since enactment of the Drug Quality and Security Act, FDA has conducted over 700 inspections of compounders, issued more than 220 warning letters advising compounders of significant violations of federal law, issued more than 110 letters referring inspectional findings to state regulatory agencies, overseen more than 230 recalls involving compounded drugs, and worked with the Department of Justice on multiple civil and criminal enforcement actions.

Drug Compounding and Budget Request

The Committee:

13. How many compounding pharmacies did FDA inspect in fiscal years 2015 through 2019 to date?

Response:

ORA Field Human Drugs Program Workload and Outputs	FY 2015 Actuals	FY 2016 Actuals	FY 2017 Actuals	FY 2018 Actuals	FY 2019 Estimate
Compounding Inspections ¹	115	135	141	127	142

¹ The number of compounding inspections includes inspections of compounders that are not registered with FDA as outsourcing facilities.

The Committee:

14. Please update the record from last year on how many inspections FDA believes it will need to inspect on a continuing basis?

Response: Based on the funding provided in the FY19 Omnibus, FDA estimates performing 142 compounding inspections annually.

The Committee:

15. How many staff and how many FTE are devoted to the enforcement of human drug compounding activities in fiscal years 2016 through 2019 and plans for FY 2020?

Response: For fiscal years 2016 through 2018, over 150 FTEs have supported the oversight of human drug compounding, annually. FDA estimates that in FY 2019, approximately 194 FTEs from the Center for Drug Evaluation and Research, Office of Regulatory Affairs, and Office of the Commissioner will continue to support the oversight of human drug compounding, and in FY

2020, approximately 237 FTEs will support the program if the Agency's FY 2020 budget request is approved.

The Committee:

16. How many staff and how many FTE are devoted to the enforcement of animal drug compounding activities in fiscal years 2016 through 2019 and estimated FY 2020?

Response: In fiscal year (FY) 2016, there were approximately nine FDA Center for Veterinary Medicine (CVM) full-time equivalents (FTE) devoted to the oversight of animal drug compounding activities. In FY 2017 through FY 2018, CVM estimates seven FTE supported the oversight of animal drug compounding activities. This number includes three FTE for surveillance, two FTE for compliance, and two FTE for policy. With the appropriated increase in FY 2019, CVM will hire one FTE for compliance, bringing the total CVM FTE devoted to the oversight of animal drug compounding activities to eight. CVM plans to sustain this level of effort in FY 2020.

The Committee:

17. Under what conditions can a licensed pharmacist provide compounded pharmaceuticals to a licensed physician or licensed practitioner for administration by a licensed physician or licensed practitioner in advance of receiving a patient specific prescription?

Response: Generally, there are two types of compounders: those seeking to produce drug products that qualify for the exemptions in section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and firms registered with FDA as outsourcing facilities under section 503B of the FD&C Act.

Section 503A of the FD&C Act describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician, to be exempt from certain provisions of the FD&C Act. One of the conditions that must be met to qualify for the exemptions in section 503A is that the drug is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (see section 503A(a)).

A drug product can be compounded under section 503A of the FD&C Act by a licensed pharmacist or licensed physician in *limited quantities* before the receipt of a valid prescription order for an individual patient, if all of the conditions of section 503A are met, including the following conditions: (1) the compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and (2) the orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the prescriber who will write such prescription order (see section 503A(a)(2)). Importantly, although drug products can be *compounded* under section 503A in advance of receiving a valid prescription for an identified individual patient, the compounder must receive that prescription before the compounded drug product leaves its facility.

FDA's final guidance *Prescription Requirement under Section 503A of the Federal Food, Drug, and Cosmetic Act*⁴ explains that:

[t]he prescription requirement under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, are not subject to the requirement that labeling bear adequate directions for use, and are not subject to [current good manufacturing practice] requirements, are provided to a patient only based on individual patient need. The prescription requirement is also an important factor that distinguishes compounding by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or by a licensed physician under section 503A from compounding by an outsourcing facility under section 503B of the FD&C Act.

Regarding outsourcing facilities, Congress created this category of compounders in the wake of a public health tragedy, a 2012 fungal meningitis outbreak resulting in more than 750 cases of illness and more than 60 deaths. Outsourcing facilities may engage in non-patient specific distribution of compounded drug products under more stringent quality standards and increased federal oversight. Section 503B of the FD&C Act states that outsourcing facilities can compound and distribute drugs without receiving prescriptions for identified individual patients provided certain conditions are met (see section 503B(d)(4)). Drug products compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist and that meet the conditions identified in section 503B qualify for exemptions from certain provisions of the FD&C Act (see section 503B(a)).

21st Century Cures

The Committee:

18. Please provide a detailed description of how FDA is spending the \$70,000,000 provided to the Agency in the fiscal year 2019 Omnibus and as well as any additional resources within the Agency?

Response: In FY 2019, CDER received \$25.2 million in Innovation Funds. CDER plans to spend funds for the following provisions:

- **Section 3001. Patient Experience Data and Section 3002. Patient-Focused Drug Development Guidance:** Spend funds towards multiple competitive grant awards for development of disease-specific sets of minimum standard core clinical outcome assessments and endpoints, which will advance the quality and utility of sponsor-submitted patient experience data to inform new drug application review and decision making.
- **Section 3011. Qualification of Drug Development Tools (DDT):** Spend funds on grants to establish an updated qualification process for DDT including biomarkers, clinical outcome assessments (COAs), and animal models for proposed contexts of use for drugs and biologics. Once a DDT is qualified under the new process, it can be used for its qualified context of use to support regulatory decisions.

⁴ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>.

- **Section 3016. Grants for Studying Continuous Manufacturing:** Spend funds to continue funding grants at Massachusetts Institute of Technology (MIT), Georgia Institute of Technology, Rutgers University, and University of Connecticut and award 1-2 new grants for studying and recommending improvements to the process of continuous manufacturing of drugs and biological products and similar innovative monitoring and control techniques.
- **Section 3022. Real World Evidence Development:** Spend funds on initiatives to explore the potential of real-world evidence to help support the approval of new indications of approved medical products or to satisfy post-approval study requirements for marketed products.
- **Section 3038. Combination Product Innovation:** Spend funds to ensure inter-center collaboration and alignment, and coordination of communications to sponsors; the agency is leveraging an IT system to modernize several processes and collaborating with the medical product centers to support the Intercenter Consult Request (ICCR) process and data auditing.

CBER plans to spend approximately \$15.3 million in Innovation Funds with the majority of resources being targeted in the following provisions:

- **Section 3001. Patient Experience Data:** To support the development of tools to capture patient experience data that can be used by FDA and sponsors to capture patient experience data to support biologic development.
- **Section 3016. Grants for Studying Continuous Manufacturing:** For grants to study continuous manufacturing which provides external grants to enhance innovations in emerging technologies for continuous manufacturing of biological products.
- **Section 3022. Real World Evidence Development:** For ongoing evaluation of real-world evidence to support regulatory decisions.
- **Section 3033. Accelerated Approval for Regenerative Advanced Therapies:** For accelerated approval for regenerative advanced therapies to support training for CBER staff in scientific and regulatory issues related to products eligible for Regenerative Medicine Advanced Therapies designation.
- **Section 3036. Standards for Regenerative Medicine and Regenerative Advanced Therapies:** For standards development and research to facilitate the approval of Regenerative Medicine Advanced Therapy products.
- **Section 3058. Least Burdensome Device Review:** To provide ongoing training for CBER staff on Least Burdensome Device Review.
- **Section 3073. Establishment of FDA Intercenter Institutes:** To coordinate activities with FDA Oncology Center of Excellence for review of oncology products and supporting activities.
- Budget Authority and PDUFA funds have and will continue to supplement CURES activities, such as supporting the new RMAT program, and evaluation of real world evidence.

CDRH plans to spend \$21.7 million in Innovation Funds for the following provisions:

- **Section 3038: Combination Product Innovation.** CDRH will use resources to manage the increased workload for combination products incurred by this provision and fund contracts for services to improve linkages across information systems within FDA.

- **Section 3051: Breakthrough Devices.** CDRH will utilize resources to expedite the review of devices that represent breakthrough technologies and assist with the full implementation of the breakthrough device program by hiring and developing staff, supporting information systems, and improving business processes.
- **Section 3060: Clarifying Medical Software Regulation.** CDRH will use resources to help establish the Digital Health Center of Excellence (COE) which will provide a unified and collaborative environment at CDRH for consistently applying best practices, conducting research, and providing training on software and digital technologies. The funding will be used to support the development of the digital health Pre-certification program, build IT capabilities, and help fund database connectivity, guidance, testing, software tools, and infrastructure.

OMPT plans to spend \$7.8 million in Innovation Funds for the following provisions:

- **Section 2052: Compliance Activities Reports:** OMPT will use resources to leverage existing IT systems and work with the National Library of Medicine to develop a data system to assist with identifying ClinicalTrials.gov compliance and enforcement actions in real time.
- **Section 3023: Protection of Human Research Subjects:** OMPT will use resources to harmonize FDA's human subject regulations, to the extent practicable, with HHS's Common Rule (human subject regulations applicable to certain federally conducted or supported research). These harmonization activities will be designed to, among other things, increase efficiencies of the clinical trial system, reduce ambiguity in interpretation of FDA and HHS regulations, protect vulnerable populations, and alleviate burden on clinical investigators. The funding will be used for rulemaking; revising or creating relevant guidance and forms; training; and providing assistance regarding the revised regulations.
- **Section 3024: Informed Consent Waiver or Alteration for Clinical Investigations.** This provision changed the law and enables FDA to issue regulations to allow an Institutional Review Board (IRB) to waive the requirement for informed consent for certain minimal risk research if human subject protection safeguards are met. OMPT issued a guidance on July 25, 2017, a proposed rule on November 15, 2018, and will use resources to finalize this provision. The ability to waive informed consent for certain minimal risk research is important to the conduct of studies that could contribute substantially to the development of products to diagnose or treat diseases/conditions or address unmet medical needs.
- **Section 3038: Combination Product Innovation.** OMPT will use resources to develop and enhance a cross-center information technology platform to streamline data sharing, enhance transparency, and improve efficiency in combination product review processes. The funding will be used in a phased approach to: stand up the platform and development team resources; perform initial development and training; launch the new technology to users across the Agency; enhance the initial process; enable new processes; integrate the platform with the centers' applications; and perform ongoing maintenance. The Agency will also develop an appropriate audit framework and process for ensuring the efficiency, clarity, and consistency of combination product regulation (including classification/assignment, premarket review, CGMP and other post-market oversight).

Patients' Real World Experience

The Committee:

The Committee has for years worked to enhance the level of attention and recognition given by the FDA to the voices and experiences of patients and caregivers in its complex work of new drug evaluations. This is particularly important when addressing the tight time frames and small patient populations available for research into rare diseases such as Duchenne Muscular Dystrophy, which affect a limited number of children and progress at a devastating pace. The Committee has been a part of efforts to expand the tools available to the agency in this regard - through the FDA Safety and Innovation Act of 2012, the 21st Century Cures Act of 2016, repeated directions through our annual appropriations reports, and more. The Agency has announced recent steps to continue building the role for patient input and experience into its deliberations.

19. Please provide the Committee with an update us on those efforts and tell us what additional measures you are exploring that will help to facilitate full consideration in the timeframes patients need.

Response: FDA has multiple efforts underway to advance the utility of data that reflects patients' experiences. This includes efforts to explore how best to analyze and use patient experience data to support regulatory decision making, for example:

- Building on previous work, and as part of its implementation of the patient focused drug and biologic development-related provisions of the 21st Century Cures Act, FDA has held a series of workshops, followed by issuance of guidance documents, on topics related to the generation, measurement, and use of patient experience data to support product development and regulatory decision making. Most recently, FDA conducted a public workshop, *Methods to Identify What is Important to Patients, and Guidance on Selection, Development, or Modification of Fit-for-Purpose Clinical Outcome Assessments*, in October 2018.⁵ This was followed by another workshop and draft guidance on *Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data* in December 2018.⁶ Other FDA efforts to capture the patient's experience are outlined in our 2017 document titled *Plan for Issuance of Patient-Focused Drug Development Guidance*.⁷
- In the medical device space, FDA's Center for Devices and Radiological Health (CDRH) is committed to including the views of patients during the medical device development process and considering patient perspectives in our regulatory decision-making.
 - Since CDRH launched its Patient Preference Initiative as part of its medical device regulatory decision-making process in September 2013, CDRH has seen increasing evidence of the benefits of soliciting patient feedback.
 - The initiative is designed to identify and develop methods for assessing patient valuations of benefit and risk and outcomes that matter most to patients related to specific device types and specific illnesses and conditions that can be used to inform product review decisions.

⁵ <https://www.fda.gov/Drugs/NewsEvents/ucm607276.htm>

⁶ <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM628903.pdf>

⁷ <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM563618.pdf>

- To better understand their needs, CDRH engages patients throughout the regulatory process.
- FDA encourages medical device manufacturers to include in their premarket submissions information about how patients consider tradeoffs between benefits and risks, and to consult with the agency early when considering patient preference studies.
- It is these efforts that help assure a systematic and thorough approach to patients communicating how a disease or condition impacts their daily lives and their care partners' lives, and the types of treatment benefits and risks that matter the most to them.

FDA is enhancing the use of real-world evidence (RWE) that is developed from real-world data (RWD) sources such as electronic health records, registries, claims, and patient-generated data. Examples include the following:

- In 2018, the Agency released a *Framework for FDA's RWE Program relating to drugs and biological products*. As required by the 21st Century Cures Act, the Framework provides a strategic approach for evaluating potential use of RWE to help support approval of a new indication for certain approved drugs or biological products or to satisfy post approval requirements.
- Funding for the Sentinel system allows FDA to access anonymized health data from more than 100 million American patients. By using RWE from the Sentinel System, FDA eliminated the need for post marketing studies on 9 potential safety issues, making post market evaluation of safety more efficient. The Agency has also used Sentinel to better understand patterns of opioid use.
- In 2018, FDA published guidance on the *Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry* to provide recommendations for sponsors, clinical investigators and others on using such data in FDA-regulated clinical investigations.
- In 2018, FDA released the MyStudies app, a new mobile application that enables stakeholders to collect data directly from patients enrolled in clinical trials, prospective observational studies, or registries. It has a data storage environment that is compliant with FDA's regulations. Collected data can be linked to clinical trial electronic data capture systems and/or RWD sources. This app is "open source" and it can be configured for multiple different drug effectiveness endpoints (e.g., PROs) or safety questions.
- As the Committee notes, RWE is promising when it comes to evaluating treatments for rare conditions, such as rare tumors. FDA has accepted the use of RWE such as data from clinical care or registries to support effectiveness in certain product approvals.
- In the veterinary medicine space, consistent with section 305 of the recently-enacted legislation reauthorizing the Animal Drug User Fee Act, FDA will hold a public meeting in July 2019 at its Center for Veterinary Medicine. This meeting is intended to provide a forum to encourage comment and suggestions from the public on novel investigational designs (including adaptive design), application of data from foreign countries, real world evidence, and biomarkers and surrogate endpoints to be used in the approval of new animal drugs.

- Regarding medical devices, since early 2015, FDA has approved or cleared more than eight new medical devices and expanded the indications for use of more than six technologies based on evidence that included RWD. This includes drug-eluting stents, transcatheter heart valves, and technologies for spinal cord stimulation, esophageal atresia, and in vitro diagnostics (IVDs).

Immunotherapies

The Committee:

20. What guidance documents have FDA issued as it relates to the submission of drug applications for personalized drugs such as immunotherapies?

Response: FDA has recently updated the guidance *Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics*, December 2018 and issued a draft guidance on the use of minimal residual disease as a biomarker in drug development, *Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in the Development of Drug and Biological Products for Treatment*, October 2018.

The Agency also has issued the following draft guidances that address in vitro companion diagnostic devices that may be used in precision medicine:

- *Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products - Draft Guidance, December 2018*
- *Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination Guidance for Industry - Draft Guidance, April 2018*

Many immunotherapies are cellular products that are considered regenerative medicine therapies and may qualify for FDA's programs to help expedite the development and review of drugs and biologics intended to address unmet medical needs in patients with serious conditions. In February 2019, FDA published the final guidance, *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*, which provides information on the new Regenerative Medicine Advanced Therapy (RMAT) designation program established under the 21st Century Cures Act as well as other expedited programs that may be available to sponsors of regenerative medicine therapies for serious conditions such as Breakthrough Therapy designation, Priority Review designation, Accelerated Approval, and Fast Track designation.

Genomic Editing

The Committee:

21. Please describe FDA's role in reviewing applications related to genetic modification of human embryos. Please specify if FDA has consulted with the stakeholders on genetic modification of embryos in fiscal year 2017 or FY 2018 to date.

Response: Since December 2015, Congress has included provisions in the Agency's annual federal appropriations laws that prohibit FDA from accepting or reviewing investigational new drug (IND) applications in which a human embryo is intentionally created or modified to include a heritable genetic modification. Because FDA cannot accept such an IND application, clinical use and/or research utilizing germline gene editing resulting in a heritable modification of

embryos cannot legally proceed in the United States in compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations.

In August 2017, FDA posted on its website an advisory on the use of mitochondrial replacement techniques (MRT) to introduce donor mitochondria into reproductive cells for transfer into a human recipient, which advised readers of the provisions in federal appropriations law that prohibit FDA from accepting IND applications for such research. As noted in the Advisory, FDA maintains the authority to investigate and take enforcement action if FDA becomes aware of noncompliance with the laws and regulations administered by FDA.

The Committee:

22. Please describe FDA's role in reviewing applications related to the genetic modification of animals or other species. Are applications currently pending for genetically modified animals or other species?

Response: FDA reviews applications for genetic modifications in animals (also referred to as intentional genomic alterations in animals) under the authority of the Federal Food, Drug, and Cosmetic Act.

The agency regulates intentional genomic alterations (IGAs) in animals under the new animal drug framework. Review of an application for approval includes an evaluation of safety (including animal and food safety) and effectiveness and is based on the risk profile of the product. In general, IGAs in animals are required to obtain FDA approval prior to marketing but, the agency does not intend to enforce approval requirements for IGAs that it finds to pose minimal risk. For example, FDA determined an IGA that causes aquarium fish to glow posed a sufficiently low risk and therefore did not enforce approval requirements for this product. For IGAs in animals that do go through the approval process, FDA ensures that the IGAs approved in animals are safe to the animal, safe to anyone that eats food derived from the animal (if it is a food-producing animal), and that the alteration does what it is intended to do, i.e., the product is safe and effective. Consistent with the requirements under the National Environmental Policy Act, FDA also evaluates whether there would be any significant environmental impact resulting from its approval of IGAs in animals.

The existence of a pending application is considered confidential commercial information; therefore, FDA cannot confirm or deny the existence of any pending applications for IGAs in animals.

The Committee:

23. What is the FDA's process for receiving an application related to genomic editing for humans and animals?

Response: FDA's regulatory framework applies to human medical products that incorporate genome editing, including human cell and gene therapy products, as well as human cells, tissues, and cellular and tissue-based products when such products are intended for implantation, transplantation, infusion, or transfer into a human recipient.

Since December 2015, Congress has included provisions in the Agency's annual federal appropriations laws that prohibit FDA from accepting or reviewing investigational new drug (IND) applications in which a human embryo is intentionally created or modified to include a heritable genetic modification. Because FDA cannot accept such an IND application, clinical use and/or research utilizing germline gene editing resulting in a heritable modification in humans cannot legally proceed in the United States in compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations.

However, FDA may accept an IND application related to genome editing of human somatic cells which cannot pass a genetic alteration from one generation to another. Certain genome editing products for human somatic cells may be eligible for a number of FDA programs intended to help expedite the development and review of drugs and biological products intended to address unmet medical need in patients with serious conditions.

Additionally, FDA receives and reviews new animal drug applications related to intentional genomic alterations (IGAs) in animals in the Center for Veterinary Medicine's (CVM) Office of New Animal Drug Evaluation, Division of Animal Bioengineering and Cellular Therapies. This division comprises 15 scientists, including veterinarians and others with specialized expertise in genome editing technology. Sponsors of new animal drug generally submit sections of their applications as part of a phased review process under an investigational new animal drug file. This allows sponsors the flexibility of submitting technical sections as they are completed. Typically, CVM and sponsors are in close communication during this process. For IGAs in animals, CVM's communication with sponsors often begins in the early development stage.

Through CVM's newly established Veterinary Innovation Program, sponsors of certain IGAs in animals are offered many benefits throughout the development and approval process, including intensive interactions with CVM, a dedicated review team composed of experts from across the center, senior management involvement, pre-and post-review feedback, the ability to stop and restart the review clock so the sponsor can address inadequacies in submissions and maintain their place in the review queue, and hands-on assistance with post-approval requirements. This ultimately allows for greater certainty in the regulatory process and supports an efficient and predictable pathway to approval. Once the sponsor has completed all technical sections and has demonstrated that the IGA is safe and effective, the product is then ready for approval. At this stage, the sponsor generally files an administrative new animal drug application that can be quickly processed based on the agreements reached throughout the investigational phase.

Sunscreen Ingredients

The Committee:

24. When can the Committee expect decisions on sunscreen ingredients?

Response: On February 26, 2019, FDA published a proposed rule to update regulatory requirements for most sunscreen products in the United States and will issue a final rule, as required by the Sunscreen Innovation Act (SIA), after considering public comments to the proposed rule.

This significant action is aimed at bringing nonprescription, over-the-counter (OTC) sunscreens that are marketed without FDA-approved applications up to date with the latest science to better ensure consumers have access to safe and effective preventative sun care options. Among its provisions, the proposal addresses sunscreen active ingredient safety, dosage forms, and sun protection factor (SPF) and broad-spectrum requirements. It also proposes updates to how products are labeled to make it easier for consumers to identify key product information.

For sunscreen active ingredients, this rule proposes that, of the 16 currently marketed active ingredients, two ingredients – zinc oxide and titanium dioxide – are generally recognized as safe and effective (GRASE) for use in sunscreens; two ingredients – PABA and trolamine salicylate (which are not currently being marketed) – are not GRASE for use in sunscreens due to safety issues. There are 12 ingredients for which there are insufficient safety data to make a positive GRASE determination currently. To address these 12 ingredients, the FDA is asking industry and other interested parties for additional data. Importantly, this proposed rule does not require any sunscreen active ingredients to be removed from the market at this time. FDA will consider requests to defer further rulemaking with respect to a specific sunscreen active ingredient to allow the submission of new safety and/or effectiveness data to the record if such requests are submitted to the docket within the comment period. In other words, if industry tells FDA within the comment period that they are planning to provide adequate data on a particular ingredient, FDA will consider deferring action on that ingredient when the Agency finalizes the rule and continuing enforcement policies for marketing that ingredient while data is being developed and reviewed. Trade associations representing sunscreen manufacturers have already indicated to FDA that sponsors will be providing data for some ingredients. FDA looks forward to working with sponsors and reviewing the necessary data.

In addition, for the eight sunscreen active ingredients being reviewed under SIA which are not currently included in the sunscreen monograph, in late 2014 and early 2015 FDA issued eight proposed sunscreen orders covering all requests that were pending when SIA was enacted. FDA tentatively determined that the data are insufficient to classify each ingredient or combination of ingredients as GRASE and not misbranded for use in nonprescription sunscreens and requested that the sponsors submit the missing data. FDA will make final GRASE determinations when it receives the necessary data from industry. As of March 2019, FDA has not received any additional data from industry for these ingredients.

Antimicrobial Resistance Efforts

The Committee:

25. Please describe what FDA is currently doing to address antimicrobial resistance as it relates to prescribing practices of human drugs and any new plans in FY 2020 related to this effort?

Response:

Labeling

The labeling for all systemic antibacterial drug products intended for human use is required to contain information about unnecessary use and the link between such use and the emergence of drug-resistant bacterial strains (see 21 CFR 201.24). FDA believes that product labeling can contribute to ongoing educational efforts by reminding prescribers that their individual prescribing decisions have a collective impact on antimicrobial resistance. Clinical trial results

provided in labeling inform physicians about the risks and benefits when prescribing a particular product, and better enable informed decisions regarding which antimicrobial agents may work best for a given patient.

Antimicrobial Susceptibility Testing Information

FDA is implementing section 3044 of the 21st Century Cures Act (Pub. L. 114-255), which clarifies the Agency's authority to efficiently identify and update (via its website) susceptibility test interpretive criteria (referred to as "breakpoints"), including those established by standards development organizations, that may be utilized by sponsors of antimicrobial susceptibility testing devices. Susceptibility testing is performed in laboratories to determine which antibacterial drugs are likely to be active against the particular bacteria that are causing a patient's infection.

On December 13, 2017, FDA announced the timely launch of webpages required under section 511A(b) of the FD&C Act. These webpages contain a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA.⁸ At the same time, FDA published a guidance providing recommendations on fulfilling the new labeling requirements for susceptibility test interpretive criteria for prescription systemic antibacterial and antifungal drugs.⁹ FDA re-opened a docket in March 2018, which will stay open indefinitely, to accept public comment on the susceptibility test interpretive criteria recognized by the Agency in the Federal Register.¹⁰

The Agency has updated the FDA Susceptibility Test Interpretive Criteria webpage. The Agency updated the format of the webpage in response to stakeholder feedback to improve the functionality of the webpage and updated the standards recognition and many of the individual susceptibility test interpretive criteria.¹¹

In addition, the labeling for antimicrobial drugs now refers prescribers to FDA's susceptibility testing webpage for continuously updated information regarding breakpoints, rather than waiting for labeling to be updated with the latest information.

Research

FDA's National Center for Toxicological Research, in collaboration with FDA's other centers, is conducting research to provide valuable information used to combat antimicrobial resistance. Two of these projects aim to provide research data to better understand the mechanisms of virulence and antimicrobial resistance of the pathogens salmonella and *Staphylococcus aureus*. Some drug resistance and virulence factors such as DNA molecules can be transmitted between different pathogens. FDA scientists are conducting a study to better understand these molecules so that methods can be developed to prevent the spread of these enhanced-virulence pathogens, like salmonella, through the human food supply. A second project aims to identify an antimicrobial-resistance marker for *Staphylococcus aureus* that is known to grow on antimicrobial-coated medical devices and provide data to help FDA design management

⁸ FDA Susceptibility Test Interpretive Criteria webpage at <https://www.fda.gov/STIC>

⁹ <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM588747.pdf>

¹⁰ <https://www.regulations.gov/document?D=FDA-2017-N-5925-0012>

¹¹ <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm593952.htm>

practices for pathogen control in these devices. Patients who have an inserted medical device are at greater risk of infection with this pathogen because once *S. aureus* colonizes on the medical device, it is highly resistant to treatment with antibiotics.

Additionally, FDA is conducting research that aims to evaluate the potential for antimicrobial-resistance development in human intestinal microbiota following long-term exposure to residual concentrations of antimicrobial drugs in foods. Within this project, researchers are also exploring the effects of tetracycline on intestinal bacteria and the potential for transfer of tetracycline-resistance genes to other bacteria and pathogens. Understanding the mechanisms of this horizontal transfer of genes may help FDA better combat multi-drug resistance, including resistance to critically important human antimicrobial drugs.

RMAT Designation Process

The Committee:

When reviewing an RMAT submission, the FDA evaluates three main criteria: 1) whether the therapy is a regenerative medicine; 2) does it involve a serious disease; and 3) does it have the potential of addressing an unmet medical need. The FDA appears to be inconsistent in its evaluation of the third criterion, specifically the definition of potential for a particular therapy and, if this inconsistency continues, the result would undermine the goal of the 21st Centuries Cures Act to facilitate medical innovation.

26. How does FDA evaluate the potential for a particular therapy when reviewing an RMAT submission? Is the same standard applied consistently across all RMAT submissions in different indications?

Response: Under section 506(g) of the FD&C Act, as added by the 21st Century Cures Act, a drug is eligible for RMAT designation if:

- It meets the definition of regenerative medicine therapy,
- It is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
- Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

Regarding the preliminary clinical evidence to demonstrate the potential of a regenerative medicine therapy to address unmet medical needs, FDA generally expects that such evidence would be obtained from clinical investigations specifically conducted to assess the effects of the therapy on a serious or life-threatening disease or condition. Such clinical investigations, particularly at the initial stages of product development, may not always be prospective clinical trials with a concurrent control. In some cases, clinical evidence obtained from clinical investigations with appropriately chosen historical controls may provide sufficient preliminary clinical evidence of the potential to address an unmet medical need. In other cases, preliminary clinical evidence could come from well-designed retrospective studies or clinical case series that provide data systematically collected by treating physicians. Such clinical evidence may be from studies conducted outside of the United States. In any case, it is essential that the preliminary clinical evidence be generated using the product that the sponsor intends to use for clinical development.

When determining whether the preliminary clinical evidence is sufficient to support RMAT designation, FDA intends to consider factors, including but not limited to: the rigor of data collection; the consistency and persuasiveness of the outcomes; the number of patients or subjects, and the number of sites contributing to the data; and the severity, rarity, or prevalence of the disease or condition. In addition, FDA intends to consider the potential that bias (e.g., bias in the study design, treatment assignment, or outcome assessment) may be a factor in the evidence provided in support of RMAT designation.

The process and standard for RMAT designation is described in *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Guidance for Industry* published February 2019. FDA will make designation decisions on a case-by-case basis, but, in doing so, will always review designation requests against the criteria for designation set forth in section 506(g) of the FD&C Act, that is, reviewing whether the drug meets the definition of a regenerative medicine therapy, if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and whether the preliminary clinical evidence in the designation request indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

Buprenorphine

The Committee:

Recently, FDA published a final guidance called “Opioid Use Disorder: Developing Depot Buprenorphine Products for Treatment” to spur development and coverage of injectable buprenorphine products.¹² Specifically, according to Commissioner Gottlieb, the goal of this guidance is to “advance the development of new and better ways of treating opioid use disorder to help more Americans access successful treatments.”¹³

Yet, in December of 2018, FDA refused to give marketing authority to a weekly and monthly buprenorphine injection even though the product met all the efficacy and safety standards and is distinct in many ways from the only currently approved buprenorphine injection product. Currently, FDA’s exclusivity decision regarding depot buprenorphine injections is so broad that no other injectable depot products, even those with indications and formulations that are distinct from the currently approved product, can be marketed until November 2020.

27. How does FDA’s broad application of exclusivity enhance or chill innovation and development of other depot buprenorphine products?

Response: Congress intended exclusivity to provide incentives for new drug innovation. The Hatch-Waxman Amendments of 1984 (which introduced the exclusivity provisions at issue) aim to promote a balance between providing such incentives and greater public access to drugs that result from generic drug competition. Three-year exclusivity prevents the approval of ANDAs or applications described in section 505(b)(2) of the Federal Food, Drug, & Cosmetic Act if they share certain exclusivity-protected “conditions of approval” as the drug product which is

¹² <https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm605227.pdf>

¹³ <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm630847.htm>

protected by such exclusivity. In assessing the scope of exclusivity for any new drug product, the Agency applies a considered, fact specific approach consistently across all therapeutic areas.

Under this approach, 3-year exclusivity generally provides limited protection to an approved NDA by delaying the approval of certain new drugs for the exclusivity-protected “conditions of approval.” FDA interprets the applicable provisions such that the protected conditions of approval are the innovation represented by the new clinical investigations which were essential to the approval, and the exclusivity, of the protected drug.

The Agency believes that its considered, fact-specific approach to assessing the scope of such exclusivity balances incentives for innovation, while ensuring continued access to drugs. For example, in this case, any buprenorphine drug products that do not share any of the exclusivity-protected conditions of approval as a previously approved buprenorphine drug product with 3-year exclusivity would not be blocked by such exclusivity.

The Committee:

28. Doesn't FDA's exclusivity decision to block approval of an innovative depot drug for treatment of OUD seriously undercut the Agency's assertions in the guidance that it wants to spur development of innovative OUD treatments?

Response: The Agency recognizes that the crisis of opioid addiction is an issue of great concern, and addressing it remains a public health priority for the FDA. The outcome of FDA's exclusivity decisions often benefit sponsors whose drugs qualify for such exclusivity by delaying the market entry of certain competing products, which is consistent with Congress's intent that exclusivity provide an incentive for the development of innovative treatments. Opioid use disorder treatments receive the same rigorous scientific and legal exclusivity analysis the Agency applies to all therapeutic areas.

The Committee:

29. What message do you think FDA's exclusivity decision gives to companies considering investing in the development of a new OUD treatment?

Response: The Agency believes that companies considering investing in the development of a new OUD treatment benefit from the consistency provided by the Agency's well-established, fact-specific approach to determining the scope of exclusivity, and the legal and scientific rigor of the Agency's approach.

Economic Incentives

The Committee:

Over the last decade there has been a growing recognition domestically and internationally that antibiotic resistance poses a serious and growing threat to public health. Without effective antibiotics, important medical advances such as chemotherapy and common surgeries like hip replacements may become too risky. However, there is a mounting problem in the antibiotics drug development space. Recently, the antibiotics field has seen exits by large pharmaceutical companies to focus more on highly profitable therapeutic areas, such as oncology. Furthermore, biotech companies are shuttering their antibiotics research and development (R&D) divisions

shortly after receiving FDA approval for their respective antibiotic drugs. The common thread for these departures is insufficient financial returns-on-investment (ROI) from antibiotics R&D investments.

30. Commissioner, is the Agency currently evaluating alternative reimbursement models as a way to potentially incentivize industry's re-engagement in antibiotics field? If so, can you elaborate on Agency's activities and why you feel this approach could have an impact?

Response: Developing new drugs is a costly endeavor. The current reimbursement model, where drugs are reimbursed based on each episode of their use, presents incentives that run contrary to responsible stewardship over new antibiotics in order to prevent pathogens from becoming over-exposed to a new mechanism of attack and developing resistance to it.

FDA is working with the Centers for Medicare and Medicaid Services (CMS) to explore innovative approaches for reimbursement of certain new antibacterial drugs that meet critical patient and public health needs. These concepts are still being developed.

The Committee:

31. Commissioner, what challenges, if any, do you foresee with some of the recently proposed economic incentives, particularly 'pull' incentives?

Response: Since the Commissioner's announcement last year that FDA would work with other agencies to explore "pull" incentives to create a predictable market for antimicrobial drugs, the Agency has held several meetings with staff at CMS (including the Center for Medicare and Medicaid Innovation) and HHS about whether such incentives might be feasible and appropriate under current authorities and appropriations. At this point, the Agency has not announced a recommended approach.

FDA is exploring several possible incentive designs, including a licensing model to provide a predictable return on investment for antimicrobials that would meet a narrow set of critical, public health criteria. FDA and its sister agencies have identified the following important issues to consider in the design of such incentives:

- a) incentive value relative to existing market-based incentives,
- b) timing of incentive receipt relative to development, e.g., in phase 2 or 3 of development or post approval, and
- c) targeting, i.e., whether the incentive could be somehow limited (targeted) to a specific new antimicrobial product that might plausibly be brought to market.

FDA is also working with others to evaluate the authorities necessary to implement new "pull" incentives in the form of reimbursement reforms that allow innovators to capture more of the long-run social and economic value generated from the development of new antimicrobial products.

These concepts are still being developed and the Agency looks forward to greater public engagement around these ideas.

FDA Exclusivity Board

The Committee:

In a 2015 memo to three amphetamine manufacturers, FDA's Exclusivity Board stated that the 3-year exclusivity granted to an approved extended-release amphetamine product did not block the approval of a new extended-release amphetamine product because, even though the drugs had the same active moiety, they had "different formulation[s] with a different drug release profile."¹⁴ Similarly, the currently approved monthly buprenorphine injection has a different formulation and release profile than the weekly/monthly product. For example, the currently approved monthly product cannot be used to initiate therapy (i.e., patients must be stabilized on an oral formulation for 7 days before starting treatment with the injection) whereas the weekly and monthly injection can be used from the first day of treatment and offers flexible weekly and monthly dosing.

32. Why is this decision inconsistent with the Board's previous decision, which had similar facts?

Response: FDA believes that the question is referring to a Center for Drug Evaluation and Research (CDER) Exclusivity Board (Board) memorandum dated September 15, 2017, in which the Board, in consultation with the reviewing division in CDER, recommended that the 3-year exclusivities recognized for two extended-release amphetamine products (Dynavel XR and Mydayis ER) should not block approval of a new extended-release amphetamine product (Adzenys ER) because all of the conditions of approval sought in the Adzenys ER application were outside the scope of the exclusivities recognized for the two extended-release amphetamine products. The recommendation by the Board for the referenced amphetamine products is not inconsistent with its recommendation regarding the buprenorphine products. Instead, it reflects the principles of a well-established approach in determining the scope of exclusivity.

The Committee:

33. What are the likely consequences of inconsistent precedent established by the Board?

Response: As noted in the response to the prior question, the Board's recommendation for the buprenorphine products is not inconsistent with the 2015 recommendation but reflects FDA's longstanding interpretation of the scope of 3-year exclusivity.

The Committee:

34. What are the steps FDA is taking to rectify this decision given that it limits access to new treatments in the midst of an opioid overdose epidemic?

Response: The Agency recognizes that opioid addiction and the resulting overdoses and deaths have created a national crisis. Reducing the scope of this crisis continues to be one of FDA's highest public health priorities. Against this backdrop, the Agency must apply the same consistent legal and scientific analysis to decisions affecting relevant new treatments for opioid overdose as it applies to all exclusivity decisions.

¹⁴ https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/204325Orig1s000Admincorres.pdf

The Committee:

Decisions regarding exclusivity are conducted by CDER's Exclusivity Board. The CDER Exclusivity Board was established in 2012 to "oversee certain exclusivity determinations, including whether and what type of exclusivity should be granted and the appropriate scope of exclusivity grants," and to ensure consistency and accuracy among exclusivity determinations.¹⁵ From publicly available information, we can find that "the Exclusivity Board consists of Office of Chief Counsel, the Office of New Drugs, the Office of Regulatory Policy, and the Office of Generic Drugs."¹⁶

35. Who specifically is on the board?

Response: The Board is comprised of representatives from the CDER Offices of New Drugs, Regulatory Policy, Medical Policy, Pharmaceutical Quality, and Generic Drugs, and the Office of the Chief Counsel. These representatives include scientists, lawyers, and regulatory professionals who work closely with relevant scientific and medical experts from the reviewing office and respective division within CDER, and other offices as appropriate, when making exclusivity recommendations.

The Committee:

36. Why does FDA refuse to discuss the composition of the CDER Exclusivity Board?

Response: The composition of the CDER Exclusivity Board is provided in the response to the prior question.

The Committee:

37. What is FDA's process for determining who serves on the board and how does it determine whether board members have any potential conflicts of interest that could affect their independent judgement (e.g., familial relationships, prior employment, or ownership of stock in a company that manufactures a drug subject to an exclusivity decision)?

Response: The participating offices identify staff that will serve as Exclusivity Board representatives. These offices may employ several factors in determining who serves on the Board, including relevant legal, regulatory, and scientific expertise. All Board members are regular government employees and, as such, are subject to government ethics laws and regulations restricting participation in certain matters on behalf of the government in which they or others whose interests are imputed to them, such as a spouse or minor child, have a financial interest. Moreover, Board members, who are required to make certain financial disclosures, are also generally prohibited from holding financial interests in a wide range of business entities deemed to be significantly regulated organizations, including a broad range of companies in the drug, biologics, medical device, food, and tobacco industries, among others. Other applicable government ethics rules may restrict Board members from, among other things, participating in

¹⁵ <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm323412.htm>; <https://www.policy.med.com/2013/01/fda-center-for-drug-and-evaluation-research-exclusivity-board-data-partnership-and-neoadjuvant-thera.html>;

¹⁶ <https://www.policy.med.com/2013/01/fda-center-for-drug-and-evaluation-research-exclusivity-board-data-partnership-and-neoadjuvant-thera.html>

matters before the Board in which an entity with which they have recently had a business relationship are a party or represent a party.

The Committee:

38. Why doesn't the CDER Exclusivity Board provide its decisions to companies who are adversely affected by those decisions?

Response: Board recommendation memos are subject to disclosure policies that comply with the Freedom of Information Act (FOIA), other relevant disclosure statutes, and FDA's information disclosure regulations. The Agency makes Board recommendations available to parties who submit requests under FOIA after redacting information that is nonpublic under applicable laws, including confidential commercial information (CCI) and trade secrets.

The Committee:

39. Why doesn't the CDER Exclusivity Board make its decisions publicly available as a routine matter?

Response: The Agency has in the past made some Board recommendations from approved applications publicly available on its "Electronic Reading Room" site.¹⁷ The Agency continues to explore how best to make available other Board recommendations, subject to resource and other limitations.

The Committee:

40. Why is the process cloaked in so much secrecy, even from the applicants who are directly affected by it?

Response: Board recommendations are subject to disclosure policies that must comply with certain statutory and regulatory requirements, including those that restrict the disclosure of certain confidential information, such as confidential commercial information and trade secret information. In general, such information must be redacted before disclosure to applicants affected by the Board's exclusivity analysis, recommendation, and the Agency's decision. The Agency has generally acted as expeditiously as possible to provide its analyses to affected parties. When requested, members of the Board and representatives from reviewing divisions have also met with affected parties to discuss the Agency's exclusivity decisions.

Questions for the Record from Chairman Sanford Bishop of Georgia
Drug Prices

Chairman Bishop:

Commissioner – In response to a question from the subcommittee regarding drug prices, you said that in Medicare Part B "the government is largely a 'price taker' and those drugs aren't competitively bid[.]" As you know, Medicare Part B reimburses physicians for drugs based on the Average Sales Price (ASP) plus a percentage add-on fee. The ASP is calculated based on the

¹⁷ For example:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/UCM540646.pdf>

entire sales of a drug, including sale to commercial and government payors. As such, the ASP reflects all of the negotiated discounts and rebates provided to all payors by manufacturers.

41. Given that ASP includes all these market factors, can you please elaborate on why you think Medicare is simply a “price taker” and that drugs provided through the Part B program aren’t competitively bid?

Response: As noted, the prices paid by Medicare Part B are determined by ASP plus the add-on fee and as a factual matter are not set through an auction or a bidding process. Since ASP is intended to reflect the average price of the product considering sales to commercial and government payors, it seems fair to characterize the government’s role as a price taker.

Rare Cancers

Chairman Bishop:

There are over 396 distinct forms of cancer and 374 of those are considered rare. In 2019, an estimated 1,762,450 people will be diagnosed with cancer and more than 500,000 of those Americans will be diagnosed with a rare form of cancer. Unfortunately, most rare cancers do not receive sufficient development for targeted therapies. Further, 83% of all patients who lack an FDA-approved targeted therapy are rare cancer patients.

42. What is the FDA doing to solve this crisis and help spur the development and trials for rare cancer therapies. Additionally, please describe the FDA’s efforts in addressing other rare diseases, including VCP? What more can Congress do to help the FDA in this effort?

Response:

Rare Cancers

The Office of Orphan Products Development (OPPD) oversees several incentive and grant programs that aim to spur development of medical products for rare diseases and conditions, including many rare cancers. In 2018, OPPD granted 337 orphan-drug designations, of which approximately one-third were for oncology products. In addition, the Orphan Product Clinical Trial Grants Program has fostered and encouraged the development of safe and effective medical products. The program has facilitated the marketing approval of more than 60 products.

Currently, approximately 30% of ongoing OPPD grants are for rare cancers. To address the lack of treatments for the majority of rare diseases, including rare cancers, FDA encourages innovative clinical trial methods, such as adaptive and seamless trial designs, modeling and simulations, and basket and umbrella trials. In addition to clinical trials funding, FDA funds rare disease natural history studies through the Orphan Products Natural History Grants Program. Natural history data can help guide the design of successful clinical trials. FDA recently published a draft guidance titled Rare Diseases: Natural History Studies for Drug Development.

To spur the development of drugs for rare diseases, the Agency published three guidances that can be used to develop drugs and biological products using the following types of trial designs:

- *Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics Guidance for Industry - Draft Guidance, September 2018*

- *Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry - Draft Guidance, August 2018*
- *Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development Guidance for Industry - Draft Guidance, August 2018*

Many treatments for rare cancers include cellular therapies, such as chimeric antigen receptor T-cell products, considered regenerative medicine therapies. These products may qualify for FDA's programs to help expedite the development and review of drugs and biological products intended to address unmet medical needs in serious or life-threatening diseases or conditions. In February 2019, the Agency published the final guidance, *Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*, which provides information on the new Regenerative Medicine Advanced Therapy (RMAT) designation established under the 21st Century Cures Act, as well as other expedited programs that may be available to sponsors of regenerative medicine therapies, such as Breakthrough Therapy designation, Priority Review, Accelerated Approval, and Fast Track designation. In addition, building on the benefits FDA has seen from the earlier and more frequent interactions with sponsors associated with several of the expedited programs, CBER recently launched the Initial Targeted Engagement for Regulatory Advice on CBER products (INTERACT) meeting program,¹⁸ which can be used to discuss issues such as a product's early preclinical, CMC (Chemistry, Manufacturing and Controls), or clinical development programs.

FDA's National Center for Toxicological Research (NCTR) is developing bioinformatics approaches to systematically examine marketed drugs and their potential use in the treatment of rare diseases including rare cancers. Drug repositioning as a drug discovery paradigm provides a potential solution to this challenge and aims to provide safer and affordable drugs in a fast development cycle. NCTR has comprehensively evaluated the computational drug repurposing approaches and proposed critical steps for implementing in silico drug repositioning into different domain applications. The results and database generated in this research may be used to enhance the currently established Continuing Umbrella of Research Experiences (CURE) program initiated by FDA and NIH/NCATS.

Other Rare Diseases

FDA has a long history in regulating and facilitating the development of drug and biological products intended for use in rare diseases and conditions, and for assuring their continued safety and effectiveness once on the market. CDER has the Rare Diseases Program in the Office of New Drugs which advises the individual review divisions on both drugs in development and under review for marketing. CBER has a rare disease coordinating committee. Both groups meet regularly to provide training to reviewers on special considerations associated with products for rare diseases, including, for example, considerations that are involved in rare disease drug development for human gene therapy products for rare diseases.

Also, sponsors of products for rare diseases may be eligible for multiple expedited programs (such as Accelerated Approval as well as Fast Track, Breakthrough Therapy, Priority Review,

¹⁸ For additional information on INTERACT meetings, please see the following website:
<https://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Industry/ucm611501.htm>.

and Regenerative Medicine Advanced Therapy designations) that are intended to help expedite drug and biological product development and review for products that address unmet needs in serious diseases or conditions. Because rare diseases are often serious conditions with significant unmet need, these programs are heavily utilized by sponsors of products for rare diseases; the increased attention and interactions with the Agency can often help innovative, safe, and effective products get to the market sooner.

The Agency also supports drug development through the issuance of grants, which are frequently utilized in the rare disease space, as well as in advising drug developers on conducting natural history studies, biomarker development, endpoint development, and innovative trial designs, either through guidance or individualized advice. FDA also conducts critical research to supplement scientific gaps for unmet needs where there is a low likelihood of pharmaceutical investment due to low financial returns. FDA conducts cluster meetings with international regulatory bodies, discussing rare disease drug development programs to assist in the alignment of scientific advice. Most pediatric protocols, many of which are for rare pediatric cancers, are discussed in these cluster meetings.

As mentioned in the response to the prior question, the Office of Orphan Products Development (OOPD) administers rare disease drug development incentive and grants programs, including the Orphan-Drug Designation Program and the Orphan Products Clinical Trials Grants Program. OOPD also works collaboratively with the Office of Pediatric Therapeutics and the CDER Rare Diseases Program, among others, to administer the rare pediatric disease priority review voucher program.

Regarding your reference to “VCP,” FDA assumes this refers to VCP Disease, which primarily manifests as Inclusion Body Myopathy Disorder, which identifies the three primary disorders originally associated with the disease: Inclusion Body Myopathy, Paget's Disease of Bone, and Frontotemporal Dementia. A drug for the prevention or treatment of inclusion body myopathy may be eligible for the incentive and grants programs described above, if it meets the criteria for those programs.

Congressional Support

The Agency appreciates Congress' recent FY 2019 appropriation of \$10 million towards FDA's rare disease efforts and is happy to continue to work with Congress in this space.

To spur the development of treatments for rare disease, Congress can continue to support the mission of the Orphan Drug Act (ODA). Specifically, Congress can clarify that the demonstration of clinical superiority standard added to the ODA in the FDA Reauthorization Act of 2017 (FDARA) applies to every drug approval after FDARA, regardless of when the drug was designated as an orphan. Otherwise, sponsors of any of the 4,000 drugs designated before FDARA may seek serial periods of orphan-drug exclusivity by making small changes to their existing drugs.

In addition, Congress can continue to support the Orphan Product Clinical Trial Grants Program and the Pediatric Device Consortia Grants program. Due to the rising costs of clinical trials, OOPD has prioritized which meritorious applications are reviewed through the program. The

budget for the Orphan Products Grants Program has been flat for the last 4 years at \$16.5 million and prior to that had been at \$14 million since 2005.

Over the Counter Pain Relief

Chairman Bishop:

During testimony before the subcommittee the Commissioner discussed significant efforts by the FDA to invest in research into non-addictive pain relief alternatives as part of a collective effort address the opioid crisis in the US. The HHS Pain Management Best Practices Inter-Agency Task Force recognized one source of non-addictive alternatives to opioids is over the counter (OTC) pain relievers. However, in a press release dated January 14, 2014, FDA announced it intended to take regulatory action to restrict access to OTC acetaminophen over 325 mg citing examples of consumer behaviors that conflict with the recommended dosage and led to unintentional overdose. The Committee is concerned regulatory action limiting access to acetaminophen may run counter to the efforts to respond to the opioid crisis and limit access to OTC pain relief for nearly half of the American public that is limited to taking acetaminophen to manage pain due to contraindications with non-steroidal treatments due to kidney, heart and blood disorders. Given the need to respond to the opioid crisis with non-addictive pain relief treatment options for patients;

43. Does FDA still intend to take regulatory action limiting access to OTC acetaminophen?

Response: Although FDA plans several actions to address safety issues related to acetaminophen, none of these actions will remove acetaminophen as an active ingredient under the OTC Drug Review or prevent consumers from accessing acetaminophen over the counter.

Chairman Bishop:

44. How has FDA partnered with the public health community to address behaviors that may lead to acetaminophen unintentional overdose?

Response: FDA has partnered with the public health community to address behaviors that may lead to acetaminophen unintentional overdose. FDA is an advisor to the Acetaminophen Awareness Coalition (AAC), which is made up of leading health, healthcare provider and consumer organizations.¹⁹ The goal of AAC is to educate consumers and patients on the importance of knowing the ingredients in their medicines and following labeling directions to prevent unintentional acetaminophen overdose. AAC is the official sponsor of the Know Your Dose campaign.²⁰ Know Your Dose educates individuals about the medicine label and which common medicines contain acetaminophen, provides advice on managing chronic pain and cold/flu, encourages safe use and proper disposal, and provides additional resources for consumers and healthcare providers.

In 2009, FDA issued the Organ-Specific Warnings Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products for Over-the-Counter Human Use Final Rule, which

¹⁹ The Acetaminophen Awareness Coalition is available at <https://www.knowyourdose.org/the-acetaminophen-awareness-coalition/>

²⁰ <https://www.knowyourdose.org/>

required the Drug Facts label of acetaminophen products warn that severe liver damage may occur.²¹ In addition to disseminating safety-related information in medicine labels, FDA also provides the following free resources on its website for public health use:

- Drug Safety Communication: Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure²²
- Acetaminophen: Avoiding Liver Injury²³
- Safe Use of Over-the-Counter Pain Relievers and Fever Reducers²⁴
- Using Acetaminophen and Nonsteroidal Anti-inflammatory Drugs Safely²⁵
- Don't Overdo It with Acetaminophen video²⁶
- Acetaminophen Information²⁷

Chairman Bishop:

45. Have the efforts of FDA and the public health community led to a decrease in acetaminophen unintentional overdoses?

Response: Despite issuing the 2009 Organ-Specific Warnings Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products for Over-the-Counter Human Use Final Rule (which required the Drug Facts label warn of severe liver damage) and FDA's partnership with the public health community (specifically, the Acetaminophen Awareness Coalition, Know Your Dose Campaign, and public communication on the FDA website), FDA continues to receive reports related to acetaminophen and liver toxicity, including liver failure.

The number of reports of liver toxicity and failure received by the FDA Adverse Event Reporting System (FAERS) fluctuates over time. FDA observed a steady increase in reports from 2009 to 2013, a downward trend in 2014, an increase in 2015, and a downward trend in 2016. The steady influx of reports starting in 2009 may have resulted from changes made to the reporting requirements for serious adverse events associated with nonprescription drugs, effective December 22, 2007 (under Public Law 109-462). However, FDA did not identify any

²¹ Guidance for Industry *Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use – Labeling for Products That Contain Acetaminophen* is available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm310477.pdf>

²² Drug Safety Communication *Prescription Acetaminophen Products to be Limited to 325 mg Per Dosage Unit; Boxed Warning Will Highlight Potential for Severe Liver Failure* is available at

<https://www.fda.gov/drugs/drugsafety/ucm239821.htm>

²³ *Acetaminophen: Avoiding Liver Injury* is available at

<https://www.fda.gov/forconsumers/consumerupdates/ucm168830.htm>

²⁴ *Safe Use of Over-the-Counter Pain Relievers and Fever Reducers* is available at

<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/SafeUseofOver-the-CounterPainRelieversandFeverReducers/default.htm>

²⁵ *Using Acetaminophen and Nonsteroidal Anti-inflammatory Drugs Safely* is available at

<https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/SafeUseofOver-the-CounterPainRelieversandFeverReducers/ucm164977.htm>

²⁶ *Don't Overdo It with Acetaminophen* is available at <https://www.youtube.com/watch?v=hX7e3rrwyO8>

²⁷ *Acetaminophen Information* is available at

<https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm165107.htm>

major reporting changes around the time period of the acetaminophen Final Rule (2009)²⁸ and publication of a Drug Safety Communication (2011)²⁹.

FDA is currently working on a proposed rule to update the conditions of use for OTC acetaminophen. One of the Agency's goals is to optimize safety while maintaining effectiveness and consumer access.

Questions for the Record from Rep. Chellie Pingree of Maine
E-labeling for Prescribing

Rep. Pingree:

46. Given that the provider community opposes a transition to e-labeling for prescribing information, why has FDA continued to pursue proposed rules that would replace the prescribing information with an electronic copy of the same information? Is FDA considering the high number of Americans living areas without strong access to broadband and thus may be unable to access the information when necessary?

Response: The proposed rule on electronic prescribing information (79 FR 75506, Dec. 18, 2014) pertained only to distribution of labeling intended for prescribers. The proposal requested comments regarding prescribers who are routinely unable to access electronic prescribing information due to lack of internet access and whether the alternatives proposed in the rule would be sufficient to serve their needs (see, e.g., 79 FR 75510). That said, upon passage of the appropriations rider in the 2016 appropriations bill, enacted December 18, 2015, and identical riders in subsequent appropriations bills which directed FDA to suspend work on finalizing the proposed rule on electronic prescribing information (79 FR 75506, Dec. 18, 2014), FDA suspended all work on the rulemaking.

Citizen Petitions

Rep. Pingree:

47. What is FDA's timeline for finalizing its October 2018 guidance on the citizen petition process? Does FDA need additional authorities to ensure that the process is not used to further anticompetitive abuses?

Response: FDA is currently in the process of reviewing comments submitted to the guidance docket and, at this time, does not have a set timeline for publication of the final guidance for industry on *Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act*.

FDA believes that additional authorities would help to ensure that the citizen petition process addressed in section 505(q) of the Federal Food, Drug, and Cosmetic Act is not used to further anticompetitive abuses. To that end, as part of the budget for fiscal year 2020, the Department of Health and Human Services included a proposal to amend section 505(q) to provide FDA with greater flexibility to summarily deny citizen petitions submitted with the primary purpose of delaying approval of abbreviated applications submitted pursuant to section 505(b)(2) or (j) of the Federal Food, Drug, and Cosmetic Act or section 351(k) of the Public Health Service Act.

²⁸ <https://www.govinfo.gov/content/pkg/FR-2009-04-29/pdf/E9-9684.pdf>

²⁹ <https://www.fda.gov/Drugs/DrugSafety/ucm239821.htm>

Question for the Record from Rep. Mark Pocan of Wisconsin
Priority Renewal for Abbreviated New Drug Applications (ANDAs)

Rep. Pocan:

As the Commissioner stated in our recent hearing, the FDA provides priority renewal for ANDAs and, at times, limited re-importations during times of drug shortages based upon the running shortage list maintained by your agency.

To that point, I am interested in learning if the remainder of the FDA renewal process is considered priority after the ANDA is designated as a priority renewal.

48. Are there existing guidelines in effect that direct the FDA review staff to continue to prioritize the review beyond the initial priority designation stage in order to shorten review timelines and reach approval in a more expeditious manner? If there are, does FDA have any steps in mind that will be taken to expedite the process? If so, when can we expect those steps to be taken?

Response: FDA takes great efforts, within its legal authority, to address and prevent drug shortages, which can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Currently, review of ANDA submissions related to drug shortages is prioritized under FDA's Manual of Policies and Procedures (MAPP) *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* (Prioritization MAPP), which describes how the review of original ANDAs, ANDA amendments, and ANDA supplements will be prioritized for review within the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ). Specifically, the Prioritization MAPP states that ANDA submissions that could help mitigate or resolve a drug shortage and prevent future shortages, including submissions related to products that are listed on FDA's Current Drug Shortages Index at the time of the submission, may receive a priority review. In addition, under the Generic Drug User Fee Amendments, as amended by the FDA Reauthorization Act of 2017 (FDARA), ANDAs for products that are on the drug shortage list are now eligible for a shorter review goal date if the applicant submits facility information (i.e., pre-submission facility correspondence) at least 60 days prior to submitting the ANDA. FDA recently issued a draft Guidance for Industry, *ANDAs: Pre-Submission Facility Information Related to Prioritized Generic Drug Applications*, to aid ANDA applicants in submitting this pre-submission facility correspondence.

To help mitigate or resolve a drug shortage, FDA proactively identifies situations where priority review is warranted. For example, FDA will prioritize the review of an ANDA after making the determination that the ANDA is for a drug product listed on FDA's Current Drug Shortages Index. This practice supports faster reviews, in particular when an ANDA applicant has not identified any of its products as drug shortage products. Once a complete review of the initial submission has concluded, the Agency will issue an approval, tentative approval, or complete response letter. A complete response letter describes deficiencies the Agency has identified that must be satisfactorily addressed before approval. The ANDA applicant may address the deficiencies through the submission of an amendment(s) to the ANDA. Until the drug shortage is resolved, amendments will be prioritized.

These combined steps (to include potential eligibility for a shorter review goal date) went into effect under FDARA.

Paper Prescribing Information

Rep. Pocan:

In a notice of proposed rulemaking, the FDA called for policy changes that would eliminate paper prescribing information and replace it with an electronic – and less accessible – copy of the same information. Why has FDA continued to place this proposal on the unified agenda when Congress has been clear that the change should not be made?

Response: The Agency receives frequent stakeholder inquiries regarding the status of the final rule. The item is listed as a long-term action on the *Unified Agenda*, which reflects that the rule has never been finalized. It includes no proposed date for finalization, consistent with the fact that the Agency has ceased all activity on the rule since the adoption of the appropriations riders directing the Agency to suspend work on finalizing the proposed rule on electronic prescribing information.

Rep. Pocan:

49. Given the fact that a 2013 study by the Government Accountability Office found that relying on electronic labeling for pharmaceutical literature as a substitute for paper labeling could adversely impact public health, why has FDA continued to place a proposal on the unified agenda that would replace paper with electronic labeling?

Response: The 2013 GAO Report, *Electronic Drug Labeling: No Consensus on the Advantages and Disadvantages of Its Exclusive Use*, identified some situations where electronic prescribing information could present access challenges, such as during public health emergencies or natural disasters, or could interfere with pharmacists' workflow. The proposed rule on electronic distribution of professional prescribing information, published in December 2014, discussed these issues and requested public comment on them. The rule also proposed to address concerns raised in the report, in part by providing means by which individual health care providers, pharmacists, or patients could receive paper copies of professional prescribing information upon request.

Printed Paper Medication Guides and Patient Medication Information

Rep. Pocan:

In the recent notice of proposed rulemaking (NPRM) (HHS/FDA; RIN 0910-AH68), FDA is proposing to amend FDA medication guide regulations, including requirements for Patient Medication Information development and distribution.

50. Under this proposed rule, is the FDA proposing to change the current distribution requirement for printed paper medication guides/patient medication information, if so what distribution method is being contemplated?

Response: As published in the *Unified Agenda*, the proposed rule would amend FDA medication guide regulations to require a new form of patient labeling, Patient Medication Information, for submission to and review by FDA for human prescription drug products and certain blood

products used, dispensed, or administered on an outpatient basis. The proposed rule would require clear and concisely written prescription drug product information presented in consistent and easily understood format to help patients use their prescription drug products safely and effectively. The proposed rule would also include requirements for Patient Medication Information development and distribution. However, at this time, the Agency has not determined what will be proposed regarding the manner in which Patient Medication Information should be disseminated to patients. If published, the public would be given the opportunity to comment on the proposed rule for a specified timeframe.

Question for the Record from Rep. Betty McCollum of Minnesota
Over-the-Counter Monographs

Rep. McCollum:

Congress has been working to reform the over-the-counter (OTC) monograph process and provide FDA with adequate resources to effectively administer a more streamlined process for OTC ingredients.

Over the course of this process an issue has come to my attention regarding ingredient data generation and collection.

The current monograph process and the one in legislation that passed the House earlier this year allows for companies to access and utilize a newly finalized monograph that required additional support data - regardless of whether those companies participated in the very costly data generation process.

This creates an unlevel playing field and disadvantages companies that spend the resources to generate new and up to date data to support the safe use of ingredients.

I believe it is absolutely critical to help FDA obtain the data it needs to ensure these products are safe and effective.

51. Could you explain the agency's current authority to ensure that all market players participate in the costly, but necessary data generation process to demonstrate the safety of ingredients used in OTC products?

Response: The Over-the-counter (OTC) Drug Review was created by FDA in 1972 to facilitate the efficient review of hundreds of thousands of OTC medicines. Rather than approve each product, as typically is done for prescription drugs and certain OTC drugs, the OTC Drug Review develops monographs for various therapeutic categories (e.g. internal analgesics, cough/cold products). The monographs establish conditions, such as active ingredients, indications, dosage forms and labeled directions, under which an OTC drug is generally recognized as safe and effective (GRASE) for use. Any manufacturer may market a product that meets the conditions in the monograph, without seeking FDA approval. To establish the monographs, FDA reviews publicly-available data submitted by industry and other parties. Before FDA finalizes a monograph, industry and other interested parties have the opportunity to submit data to demonstrate the safety and efficacy of an ingredient for particular conditions of use.

Because marketing under the OTC drug monograph is open to all manufacturers with products that fulfill the criteria of the monograph and as a result do not require individual drug product approval prior to marketing, any manufacturer may benefit from the lower regulatory burden to enter the marketplace, creating wide consumer access. Under the current system, FDA has no authority to ensure that all market players who may potentially benefit from a final monograph determination participate in generation of data to support the GRASE status of their marketed products. However, FDA is committed to working with manufacturers, either singly or in self-determined groups, to support submission of necessary data.

Rep. McCollum:

52. What resources or additional authority might be necessary to ensure that all companies that participate in data generation are treated fairly under the OTC monograph system?

We want to ensure that companies are appropriately motivated to respond to data call-ins to promote better data and scientific conclusions that ultimately leads to safer products in the marketplace and I look forward to working with you on this issue.

Response: The current regulatory system for OTC monograph drugs no longer functions as originally intended. FDA faces significant challenges in completing monographs, addressing safety issues, and supporting innovation in the OTC marketplace. Reforms of the existing system are urgently needed to promote innovation and choice for consumers while also improving FDA's ability to address urgent safety issues in a timely fashion and ensure the safety and effectiveness of OTC products. The Agency continues to look forward to working with Congress in this space.

One legislative approach to improving the OTC process could have OTC manufacturers pay an annual facility fee and then an additional fee each time a sponsor submitted an application for an innovation (OTC Monograph Order Request or OMOR). Such a system could help ensure equitable distribution of costs among manufacturers benefitting from it. Further, in such approach, manufacturers submitting an OMOR could be made eligible for confidential meetings with FDA early on and might be incentivized to provide data to support the request through a period of marketing exclusivity for the innovation.

In order to preserve the public nature of the monograph and the low regulatory burden to enter the marketplace by not requiring FDA approval of individual drug products, such an approach would likely not require that every manufacturer who might benefit from a final determination that a drug is generally recognized as safe and effective (GRASE) participate in data generation to support that determination. However, because drugs would first have to be found to be GRASE before such a new innovation pathway could be used, manufacturers wishing to innovate might be incentivized to contribute data to the underlying GRASE determination.

Question for the Record from Rep. Henry Cuellar of Texas
Naloxone

Rep. Cuellar:

53. Synthetic opioids appear to stay in a patient's system for much longer than naloxone as a reversal agent. What are the agencies plans to address this problem?

Response: Recent data show a marked increase in the number of opioid-related overdose deaths driven by heroin and synthetic opioids. The currently approved formulations of naloxone are indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. However, keep in mind that although naloxone is intended for immediate administration as emergency therapy in settings where opioids may be present, naloxone is not a substitute for emergency medical care.

Rest assured that the Agency is doing what it can to facilitate the development and approval of new innovative opioid reversal products for use in the community. "Promoting use of overdose-reversing drugs" is one of the five priorities to combat the opioid crisis by Department of Health and Human Services, and the Agency is focused on increasing the use and access to potentially life-saving naloxone.

FDA has been concerned about the differences in the duration of action of naloxone and the length of time opioids affect a person's ability to breathe throughout the work to facilitate development of naloxone products intended for use in the community. This is of particular concern in situations where access to emergency services may take longer than ideal, such as rural areas where emergency services may need to travel long distances to reach patients, but also in some urban settings where available emergency services may be under-resourced. One way the Agency has addressed this is to require that companies package two dosage units for both nasal spray and autoinjector products. This serves two purposes. First, when there is a delay in the arrival of emergency services, a second dose can be administered if the patient starts to have worsened breathing after initially responding. The second dose also permits adding more naloxone on top of the first dose if the patient's breathing does not improve with the first dose. The Agency is also working with commercial sponsors and staff from NIDA to facilitate the development of treatments that may work for longer periods of time.

Furthermore, FDA has held several public meetings to discuss the development of naloxone products for use in the community, including most recently a two-day advisory committee meeting on December 17-18, 2018 to discuss naloxone products intended for use in the community. The Agency asked external advisors from the FDA's Anesthetic and Analgesic Drug Products and the Drug Safety and Risk Management Advisory Committees to consider various options for increasing access to naloxone. Moving forward, the Agency is considering the Committees' recommendations carefully as it determines the directions FDA will take to address this critical issue.

Rep. Cuellar:

54. Does allowing an Over the Counter (OTC) Naloxone discourage development of longer-acting naloxone product?

Response: There is a pressing public health need for increased availability and accessibility of naloxone. Nonprescription availability would be one way of addressing this need.

It is unlikely that nonprescription availability of naloxone would discourage development of longer-acting opioid overdose reversing agents. It is well known that the duration of action of opioids often exceeds the duration of action of naloxone. Additionally, synthetic long-acting opioids such as fentanyl now account for a large and increasing percentage of opioid overdoses and deaths. Opioid overdose, and death from opioid overdose, has been increasing year by year. FDA is working hard to support the development of all types of opioid reversal agents, including new agents with longer durations of action.

Rep. Cuellar:

55. How can you encourage companies to continue investing in a better formulation of Naloxone if the product goes over-the-counter?

Response: Due to the high and increasing incidence of opioid overdose and opioid overdose death, there is high market demand for opioid reversal agents, including naloxone. While FDA does not know the precise impact of making a nonprescription product available, providing an additional option in this public health crisis could help.

FDA has been active, both on the prescription side and on the nonprescription side, in providing advice and encouragement to sponsors interested in developing new formulations of naloxone. Additionally, on the prescription side, FDA has been providing advice to sponsors interested in developing longer-acting opioid overdose reversing agents. FDA will continue to provide this support and give high priority to review of innovative opioid overdose reversing agents. The Agency is also working to support the development of generic naloxone products.

Historically, after nonprescription availability of a drug product, brisk innovation in a given therapeutic area continues, with product improvements and entry of competitors into the nonprescription market. FDA expects that this would also be the case if a nonprescription naloxone product is approved.

Rep. Cuellar:

56. Would the agency consider accelerating approval for naloxone products that work better and for a longer period to counteract longer-acting synthetic Opioids?

Response: Section 901 of FDASIA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to allow FDA to base accelerated approval for drugs for serious conditions that fill an unmet medical need on whether the drug has an effect on a surrogate or an intermediate clinical endpoint.

Speeding the availability of drugs that treat serious diseases is in everyone's interest, especially when the drugs are the first available treatment or if the drug has advantages over existing treatments. The first two naloxone products approved for use in the community, Evzio auto-injector and Narcan nasal spray, were granted priority review timelines. However, because of

the importance of these new products, the reviews were completed and the products approved earlier than the 6 month PDUFA timeline.

FDA will continue to review the information for each specific product on a case-by-case basis and apply an expedited program for any new naloxone product that meets the appropriate requirements.

Rep. Cuellar:

57. If Naloxone is made readily available through OTC purchasing, there is a fear that if insurers force their covered patients to buy Naloxone over-the-counter it will cost significantly more than the patient \$5-20 copay for their prescriptions. It's not a leap to see patients deciding not to pay out of pocket for OTC naloxone and that they would potentially go without this life saving product. Please tell me how your agency will work to ensure that this does not happen.

Response: Data support that switching from prescription to nonprescription status does not result in decreased use of a medication; instead, increased use is observed. This increase in use has been observed across multiple therapeutic classes.^{30,31} Additionally, both healthcare system costs and individual consumer costs have been observed to decrease once a drug becomes available as a nonprescription product. The cost of an insurance copay is not the only cost to a medication consumer. The cost of a physician visit, emergency room visit, delay in relief of symptoms, lost pay due to taking off work, parking, and other costs are important to individual consumers and can often be avoided or decreased due to the availability of a nonprescription medication option.^{31,32}

With specific respect to naloxone, a recently published economic analysis predicted that the total quantity of naloxone sold in pharmacies would increase 15-179% following conversion to nonprescription status.³¹

At present, despite state programs to make naloxone more available through standing prescription orders, consumers often report difficulty obtaining naloxone citing unwillingness of pharmacists to dispense it or lack of stocking of the prescription product.³³ Wider access to naloxone is needed, and nonprescription status is one means of increasing access.

In summary, based on prior experience with prescription to nonprescription switch, and on current economic analysis, it seems unlikely that access to or use of naloxone by consumers

³⁰Mahecha L 2006. Rx-to-OTC switches: trends and factors underlying success. *Nature Reviews Drug Discov.* 5(5) 380-5

³¹ Murphy S et al 2019. Will converting naloxone to over-the-counter status increase pharmacy sales? *Health Serv Res.* ePub PMID 30790269. DOI 10.1111/1475-6773.13125.

³² Chang D et al 2017. Time trends in physician visits for gastroesophageal reflux disease before and after the Rx-to-OTC switch of proton pump inhibitors. *J Clin Pharmacol* 57(4) 452-8

³³ Rapaport L 2018. Many US drugstores fail to provide naloxone for opioid overdoses. *Reuters Health News*, Nov 13, 2018. Accessed 2019 03 27 at <https://www.reuters.com/article/us-health-overdose-antidote/many-u-s-drugstores-fail-to-provide-naloxone-for-opioid-overdoses-idUSKCN1NI2RB>

would decrease with nonprescription status. Rather, access would increase and sales and use would likely increase.

Rep. Cuellar:

58. There are by most estimates 53 million patients that are considered at high risk of overdose due to the opioid's dosage prescribed for their condition or due to the combination of an opioid and other respiratory depressing agents like benzodiazepines that the patient is taking. On December 17-18, 2018: Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee met and the committee recommended label changes for opioids that included co-prescribing of Naloxone. At a minimum why wouldn't we require co-prescribing Naloxone for those high-risk patients? Do you agree that this would be a reasonable approach to start? What is the status of this recommendation?

Response: Prevention and treatment of opioid overdose is an urgent public health priority, and FDA recognizes the need to improve access to naloxone for the emergency treatment of known or suspected overdoses until emergency medical help arrives. The Agency is focusing on: (1) expanding the utilization of naloxone; (2) accelerating the development and availability of new naloxone formulations and user-friendly products; and (3) identifying and disseminating the best practice naloxone delivery models and strategies.

At the December 17-18, 2018 Advisory Committee meeting, FDA sought the advisory committees' feedback regarding naloxone co-prescribing for high risk groups that have been prescribed opioid analgesics. Moving forward in this opioid crisis, the Agency is actively discussing the committees' recommendations and exploring feasible labeling changes as it determines the best directions to take in addressing naloxone co-prescribing for high-risk populations.

The Committees supported labeling changes that recommend naloxone co-prescribing for all or targeted high-risk patients, suggesting that it can effectively expand access to naloxone and improve public health. However, the Committees also commented that changing labeling to recommend co-prescribing may not be the most effective or efficient strategy to reach individuals who may need naloxone the most. They commented on the lack of evidence available on the impact of co-prescribing on harm reduction, as compared to the evidence presented on the considerable impact of community-based provision of naloxone to people who inject drugs. The Committees were concerned about potential diversion of limited supplies of naloxone away from these successful community-based programs.

Another strategy that the Agency is pursuing to expand access to naloxone is through switching it from prescription to over-the-counter (OTC). Having naloxone widely available, for example as an approved OTC product, is an important public health advance and a need that the Agency has been working on. To encourage drug companies to enter the OTC market and increase access to naloxone, FDA took an unprecedented step by developing a consumer-friendly model Drug Facts Label with easy-to-understand pictograms on how to use the drug. FDA has also conducted label comprehension testing to ensure the instructions were simple to follow. This action was part of the Agency's broader commitment to addressing the opioid crisis.

Rep. Cuellar:

59. Would patients be able to pay for over-the-counter naloxone by using their Flexible Spending or Healthcare Spending dollars that they save through payroll deductions?

Response: The Agency is unable to provide comment, as this falls outside of FDA's purview.

Cannabidiol (CBD):

Rep. Cuellar:

In December we passed the 2018 Farm Bill, an important piece of legislation that contained specific language around cannabidiol (CBD). The law provides for the removal of "hemp," a variety of the *Cannabis sativa* plant species, from the Federal Controlled Substances Act ("CSA") and legalizes hemp cultivation as an agricultural commodity like grain, meat, and dairy. The new Farm Bill defines "hemp" as "the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." In September 2018 the DEA rescheduled a pharmaceutical product made with high concentrations of CBD active ingredient to a schedule 5 from a schedule 1 because of its low abuse potential, however, all other CBD derivatives remain scheduled as schedule 1. Even those with a fraction of CBD and no THC remain schedule

60. Aren't there plenty of cough and cold products that are schedule 5?

Response: Per the enactment of the 2018 Farm Bill, *Cannabis sativa* L. and constituents with less than 0.3% THC by dry weight were exempted from the Controlled Substances Act (CSA). Prior to the Farm Bill's passage, the DEA placed the drug product Epidiolex in Schedule V due to international treaty obligations and also provided for the streamlined scheduling of future FDA-approved drugs with less than 0.1% THC into Schedule V. The DEA is in the process of removing the current regulatory listing for CBD products and any future scheduling actions will be based on a recommendation from the Department of Health and Human Services and the drug review and approval process. As per the Bill, the DEA does not treat cannabis constituents, referenced as "CBD derivatives", as controlled substances when they contain less than 0.3% THC by dry weight. FDA would refer the Committee to DEA for other questions regarding the scheduling of Epidiolex and other CBD products in light of the 2018 Farm Bill.

Rep. Cuellar:

61. Weren't both actions taken because the medical benefits of CBD outweighed the risks or lack of any psychoactive effects associated with CBD?

Response: FDA has approved only one specific cannabidiol (CBD) medication, Epidiolex, for the treatment of two rare and severe forms of pediatric epilepsy disorders. FDA's approval was based on well-controlled clinical trials evaluating the use of this compound in the treatment of specific conditions. Epidiolex is a purified form of CBD, a chemical constituent of the cannabis plant. It is being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits. While it has some psychoactive effects, CBD does not have the same psychoactive effects as delta-9-

tetrahydrocannabinol (known as THC, the main psychoactive substance in products derived from cannabis). The approval of Epidiolex means that patients can be prescribed Epidiolex by their health care practitioner as part of a course of treatment for two rare and severe forms of epilepsy. The decision by FDA to approve Epidiolex was made following a rigorous process of research into its potential medical benefits. The ultimate decision regarding the scheduling of Epidiolex was made by the Drug Enforcement Administration (DEA) based on considerations under the Controlled Substances Act that are broader than the factors FDA considers when making an approval decision.

Rep. Cuellar:

62. Can you see where the position by FDA, the stance by DEA and the newly passed Farm Bill are very confusing for consumers and companies looking to develop new consumer products?

Response: While the 2018 Farm Bill removed hemp from the definition of marijuana (marijuana) in the Controlled Substances Act, Congress explicitly preserved FDA's current authority to regulate products containing cannabis or cannabis-derived compounds. This allows FDA to continue to regulate drugs, foods, dietary supplements, and other products containing cannabis and cannabis-derived compounds. Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, the Agency intends to hold a public hearing on May 31, 2019, for stakeholders to share their experiences and challenges with these products, including information and views related to their safety. This information will be used in part to further explore whether and how to develop additional lawful regulatory pathways for new consumer products. In the interim, FDA will update its website to provide information to stakeholders on the impact of the 2018 Farm Bill. In addition, the Agency will continue to work with its federal partners in the U.S. Drug Enforcement Administration and the U.S. Department of Agriculture to help ensure consistent and clear communication.

Rep. Cuellar:

63. We can easily verify through laboratory and scientific assessment that any CBD raw material meets the 2018 Farm Bill requirements (<0.3% THC), so then why would we not allow consumers broader access to CBD for over-the-counter use?

Response: The Farm Bill explicitly preserved FDA's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act. As a result, cannabis and cannabis-derived products are subject to the same authorities and requirements as FDA-regulated products containing any other substance. In preserving FDA's authorities, Congress recognized FDA's public health role with respect to all the products the Agency regulates. While FDA understands the desire for broader access to CBD in those products, the Agency has an obligation as a public health agency to ensure the safety and, in the case of medical products, the efficacy of the products we regulate. The Agency intends to hold a public hearing in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to safety. This information will be used in part to further explore whether and

how to develop additional lawful regulatory pathways for new consumer products. FDA plans to move ahead as efficiently as possible.

With respect to the ability to verify that any CBD raw materials meet the Farm Bill requirements we cannot comment at this time. FDA is still in discussions with DEA on this issue.

Rep. Cuellar:

64. What steps can you and your agency take to expedite access for U.S. consumers to CBD?
How fast can you act on opening greater access?

Response: While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. These pathways include ways for companies to seek approval from the FDA to market CBD products with therapeutic claims as human or animal drugs. It is also worth noting that the 2018 Farm Bill's removal of hemp from the definition of marihuana (marijuana) in the Controlled Substances Act may streamline the process for researchers to study hemp and hemp derivatives, including some CBD, as defined by the Farm Bill.

In addition, pathways remain available for the FDA to consider whether CBD might be permitted in a food or dietary supplement. Although food and dietary supplement products with CBD are generally prohibited by statute from entering interstate commerce because CBD is an ingredient in an approved drug and was the subject of substantial clinical investigations before it was marketed as a dietary supplement or in a food, FDA has authority to issue a regulation allowing CBD in these products and would consider doing so if the Agency determines that other safety requirements in the Federal Food, Drug, and Cosmetic Act can be met. FDA is taking steps to evaluate whether such a process should be pursued.

FDA intends to hold a public hearing on May 31, 2019, to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds, including CBD, can be marketed, and how FDA can make these legal pathways more predictable and efficient.

Medical Gases Regulations

Rep. Cuellar:

Congress has passed two laws directing the FDA to draft new regulations governing medical gases – including the Consolidated Appropriations Act for Fiscal Year 2017. This is an issue that has been going on for several years now, predating your tenure at the FDA.

65. Can you assure us that the FDA is working full steam ahead to finalize medical gas regulations?

This has been dragging on now since 2012, and we would really like to see it get done.

Response: FDA is actively working to revise Federal drug regulations with respect to medical gases. FDA has held three comprehensive public workshops on medical gas regulation, covering

several areas of FDA's regulation of medical gases, including labeling, current good manufacturing practices, post market safety reporting, certification and deemed approval of designated medical gases, and drug registration and listing. Overall, the public workshops were highly productive, and are informing the Agency's efforts to provide greater regulatory clarity and reduce burdens on the regulated industry without compromising the quality, safety, and effectiveness of these products. The Agency also is considering proposed regulatory changes submitted to public dockets FDA-2017-N-0001 and FDA-2018-N-1214 by stakeholders as it works to issue a proposed rule. FDA understands the need for drug regulations to be better tailored to medical gases and is aiming to issue a proposed rule this year.

Center for Food Safety and Applied Nutrition
Questions for the Record from Chairman Sanford Bishop of Georgia
 Food Safety Modernization Act Implementation

Chairman Bishop:

66. Please provide an update on where the FDA is on FSMA implementation?

Response: FDA continues to devote considerable resources to FSMA implementation. In support of the seven foundational FSMA rules which FDA has finalized, the Agency is focusing on inspection programs, training, and outreach. To assist industry, FDA has also issued numerous guidance documents and other materials to facilitate implementation of and compliance with the requirements by regulated industry.

FDA has implemented inspection programs to evaluate compliance with the Preventive Controls for Human and Animal Food rules; Sanitary Transportation rule; the Foreign Supplier Verification Program (FSVP) rule; and the sprouts farm requirements of the Produce Safety rule. Inspections of large produce farms other than sprouts operations will begin in Spring 2019. Compliance dates for the Intentional Adulteration rule begin July 2019; FDA is currently developing its inspection program. From FY17 to FY18, FDA and state staff accomplished approximately 780 inspections for Preventive Controls for Human Food and approximately 800 animal food good manufacturing practice (GMP) inspections; and FDA accomplished approximately 1,120 FSVP inspections, 120 Sanitary Transportation inspections, and 47 sprouts farm inspections.

Training is an important part of implementation for both FDA and industry. FDA has developed and presented training programs for both FDA and state staff to support the inspection programs. FDA has also partnered with three alliances to provide training to industry.

In addition to FSVP, two other FSMA programs within the imports program are the accredited third-party certification program (TPP) and the voluntary qualified importer program (VQIP). Under the TPP program, FDA has recognized four accreditation bodies. The accreditation bodies are in the process of accrediting certification bodies, three of which have been accredited. FDA is currently accepting applications for VQIP, which is supported by TPP. Importers participating in VQIP can gain expedited entry for their imported foods.

Chairman Bishop:

67. Please provide the Committee with updates on the actions the FDA has taken towards monitoring compliance and overall measurement of specific food safety outcomes.

Response: FDA has continued to monitor compliance with FSMA using facility inspections and sampling and has worked with its regulatory partners to carry out inspections and other compliance monitoring in the risk-based, prevention-oriented manner envisioned by FSMA. As it has increased the number of inspections, FDA has also trained more investigators and increased the adoption of new information technology systems for more comprehensive, structured reporting of the regulatory requirements covered during inspections and compliance deficiencies observed. This year, FDA is piloting and evaluating a two-tier inspection approach for certain businesses subject to the Preventive Controls (PC) for Human Food rule. The potential benefits of the two-tier inspection approach are: decreased inspection time in facilities, improved public health protection by addressing food safety issues across multiple facilities, and greater opportunities for education, outreach, and communication between FDA food safety staff and industry.

Regarding food safety outcomes, FDA is coordinating with CDC to track the number of outbreaks and outbreak-associated illnesses attributable to foods subject to specific FSMA rules. In particular, separate efforts are underway for the PC for Human Food rule, the Produce Safety rule, sprouts, and imported foods. In addition to tracking these metrics on an annual basis, CDC and FDA plan to collaborate to evaluate these data for trends over time.

While there are robust surveillance systems for human disease, a similar surveillance system does not exist to track either pet or production animal diseases. As a result, FDA will track recalls of animal food produced at facilities subject to the Preventive Controls for Animal Food rule instead of outbreaks or illnesses in animals.

Chairman Bishop:

68. What does the early data indicate on improvements to food safety?

Response: For public health outcomes, early data are currently being analyzed as part of the FDA and Centers for Disease Control and Prevention joint effort to track the number of outbreaks and outbreak-associated illnesses attributable to human foods subject to specific FSMA rules. Early data are being used to establish a baseline by which future years of data on the number of outbreaks and illnesses may be evaluated for trends. Outbreak data reflects significant year-to-year variability due to randomness and uncertainties throughout outbreak investigation and reporting. An additional factor to consider is the use of new, rapid diagnostic tests, such as whole genome sequencing. Use of such tests has increased the ability to detect illness and outbreaks and attribute those to a contaminated food more rapidly, including the ability to link sporadic cases of foodborne illness to contaminated food. As a result, the numbers of detected foodborne illnesses and outbreaks may rise even as the actual risk of foodborne illness decreases.

Data from inspections and recalls will be analyzed to assess the impact of the FSMA regulations on food safety. The first performance measures to be implemented will be for the Preventive

Controls (PC) for Human Food and PC for Animal Food rules, which had the earliest compliance dates. A set of these measures will be published via FDA's Agency-wide performance management system in 2019.

As the staggered compliance dates pass and inspections start up, FDA has begun monitoring compliance for facilities subject to the current good manufacturing practice (CGMP) and PC requirements for human food and facilities subject to the CGMP requirements for animal food. Very preliminary data indicate that both human and animal food manufacturers are successfully implementing the relevant requirements (CGMPs and PCs for human food and CGMPs for animal food). With the final compliance date for very small PC human food facilities passing in September 2018 and PC for animal food inspections starting in October 2018, it is too early to establish trends, but FDA will continue this monitoring to ascertain compliance baselines.

In general, retrospective analyses of policy require extended time periods before and after implementation to quantify impact. Evaluation of FSMA-based food safety trends are likely to be complicated due in part to staggered FSMA compliance dates, changing risk profiles of firms targeted for inspection each year under the frequency mandates, and FDA's "educate before and while we regulate" approach to inspections, which focuses enforcement on food safety problems that pose an imminent public health risk. These factors introduce bias into the sample set complicating the analysis of early FSMA data trends.

Sodium

Chairman Bishop:

69. The National Academy of Science Study on Dietary Reference Intakes for Sodium and Potassium was recently released, does the Food and Drug Administration have any plans to update or provide guidance on sodium targets?

Response: FDA plans to finalize the short-term voluntary sodium reduction targets outlined in the draft guidance *Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods* in 2019. The National Academies of Sciences, Engineering, and Medicine's report "Review of the Dietary Reference Intakes for Sodium and Potassium" concluded that "[T]here is sufficient evidence for the causal and intake-response relationships between sodium intake and chronic disease risk; therefore, the committee has established a sodium Chronic Disease Risk Reduction Intake (CDRR)." The CDRR for sodium is 2,300 mg/day, which reaffirms the need for sodium reduction in the U.S. population as current intakes are substantially higher than the CDRR. FDA is now considering the next steps regarding long-term sodium reduction targets.

Dietary Supplements

Chairman Bishop:

A few weeks ago, FDA made an important announcement about the future of dietary supplement oversight. In the announcement, the FDA called for "implementing one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years." The dietary supplement industry has grown significantly since the enactment of the Dietary Supplement Health and Education Act of 1994, when Congress found that an estimated 600 dietary supplement manufacturers in the US produced approximately 4,000 products with total

annual sales of at least \$4 billion. Today, nearly 25 years later, the dietary supplement market is worth in excess of \$40 billion, with current estimates ranging from 50,000 to 80,000 different products on the market.

70. What is the total budget at FDA to regulate dietary supplements and do feel the budget has grown proportionally to that of this growing industry? If not, how can this committee be helpful in ensuring you have the necessary resources and authorities to provide effective oversight to the dietary supplements industry?

Response: FDA's Office of Dietary Supplement Programs (ODSP) in the Center for Food Safety and Applied Nutrition (CFSAN) is the programmatic lead on dietary supplement regulation. FDA created ODSP in December 2015, elevating the program from its previous status as a division, reflecting the Agency's recognition that the industry's growth requires a higher priority for dietary supplement regulation if FDA is to effectively fulfill its public health mission. The planned total budget for ODSP in FY 2019 is \$8,000,000 and 26 FTE, which includes all payroll and operating expenses. CFSAN has reached its maximum capacity to realign resources from other program areas.

In addition to ODSP staff, other CFSAN employees outside of ODSP work on dietary supplement matters, including compliance and research work. The Office of Regulatory Affairs (ORA) also performs functions at the heart of dietary supplement regulation including domestic and foreign facility inspections, border activities, laboratory testing, and online surveillance. The National Center for Toxicological Research (NCTR) also conducts research on dietary supplement issues.

Dietary Supplement Resources FY 2018 (Dollars in millions)	
CFSAN	\$10.9
ORA	\$5.4
NCTR	\$1.1
Total	\$17.4

FDA appreciates the Committee's continued interest in the oversight of dietary supplements. In the FY 2020 President's Budget, FDA has proposed new legislative authority to strengthen FDA's implementation and enforcement of Dietary Supplement Health and Education Act (DSHEA). Under current law, FDA is not clearly authorized to require listing of individual dietary supplement products on the market, and the Agency has no convenient mechanism for compiling basic information about those products.

This proposal would require all products marketed as "dietary supplements" to be listed with FDA and give FDA authority to act against non-compliant products and the manufacturers and/or distributors of such products. This would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products, improve transparency and promote risk-based regulation. FDA looks forward to working with Congress on this proposal.

Chairman Bishop:

71. Additionally, the announcement states that stakeholders are raising the idea of product listing as a tool for the Agency. Is this something that the FDA has explored before and why is this needed at this time? How does FDA get a sense of what is on the market? If there is a problematic supplement, how do you know if there are similar products being sold?

Response: Yes, this concept is suggested in FDA's FY2020 budget. FDA does not currently have this explicit authority – though it has been raised among stakeholders and some in Congress as a means to quickly identify and act against dangerous or otherwise illegal products, improve transparency, and promote risk-based regulation. FDA looks forward to working with the Committee as it considers this concept.

As you know, the dietary supplements marketplace has changed significantly in the past 25 years. For example, while the Dietary Supplement Health and Education Act's (DSHEA's) findings spoke about domestic manufacturers, today's supply chain is much more global. In 1994, few people envisioned the role that the internet plays today both as a channel of commerce and as a source of information (and misinformation). The universe of products available as dietary supplements has exploded from well-recognized ingredients such as vitamins, minerals, and herbs intended to promote long-term good health, to include a diverse range of novel compounds, often marketed as quick fixes with short-term effects.

Currently, FDA knowledge about what is on the market is severely limited due to a lack of product listing authority. The Agency learns about what is on the market through *ad hoc* and resource-intensive means such as observation during facility inspections; a variety of surveillance activities; adverse event reporting; and complaints and inquiries from consumers, the media, and other stakeholders.

FDA is limited in the ability to identify "similar" dangerous or otherwise illegal products. For example, if concerns with the product relate to unlawful claims, like claims to treat serious diseases such as Alzheimer's, or to unlawful ingredients, like tianeptine, then FDA relies primarily on market surveys that include internet searches and searches of prominent online retailers. But in a case where FDA detects high levels of a toxic element (such as lead) in a specific product, the Agency may need to engage in a more resource-intensive effort, including facility inspections, to trace the problem back to its source and then trace it forward again to determine the scope of affected products.

Chairman Bishop:

Commissioner, you also mention that at present, the key to ensuring a flexible regulatory framework is through the new dietary ingredient (NDI) notification process. I have heard some concerns that there are some in the industry who bypass the NDI process and sell products with new ingredients that the FDA does not know about.

72. Please discuss any updates to the NDI process the FDA may be considering?

Response: The new dietary ingredient (NDI) notification process is critically important because it represents FDA's only opportunity to evaluate the safety of a new dietary ingredient before it becomes available to consumers.

The Agency cannot quantify products with new ingredients that have been introduced to the market without complying with the NDI notification requirement. FDA estimates, though, that the number of products on the dietary supplement market has increased from 4,000 in 1994 to somewhere between 50,000 and 80,000 products today. Based on this estimate, at least 46,000 new products have been introduced to market in the last 25 years. FDA has received only approximately 1,100 NDI notifications in that time. Not every new product is subject to the notification requirement, but the Agency suspects that thousands of these products should have been notified.

FDA has an obligation to protect the public from unsafe and otherwise unlawful products. At the same time, the Agency is mindful of Dietary Supplement Health and Education Act's (DSHEA's) finding that FDA should not "impose unreasonable regulatory barriers limiting or slowing the flow of safe products" to consumers. FDA's goal is to conduct a meaningful evaluation of the products for which notification is required. FDA wants to ensure that well-prepared notifications containing the necessary information are submitted for the right products. The Agency is committed to working with stakeholders to achieve this goal, and FDA has observed that notifications tend to have a higher success rate when the submitter has met with Agency staff before submitting a notification. FDA is working to make sure that stakeholders are aware of this option.

Chairman Bishop:

73. The statement also references incentives for establishing dietary supplement exclusivity what do you all mean by this and how would it work?

Response: FDA has heard from stakeholders about the importance of ensuring that the new dietary ingredient (NDI) notification requirement exists within the context of a strong regulatory framework. While the need to comply with legal requirements should be self-evident, FDA also recognizes that developments in the NDI notification space over time have created a disconnect between regulatory goals and requirements and economic incentives. The Agency wants to make sure that it is doing its part so stakeholders are motivated to comply with these requirements.

One side of this equation is making sure that the consequences of non-compliance are predictable and appropriate. In many cases this will mean enforcement, but enforcement in this space can be challenging for a number of reasons, including that it is time- and resource-intensive and that the outcome is far from guaranteed. For example, FDA might investigate an ingredient that appears from the surface not to have complied with the notification requirement, only to eventually determine that its presence in the food supply has exempted the ingredient from the notification requirement. FDA is reviewing its compliance policies to be sure that the Agency is using its tools effectively.

The other side of the equation relates to incentives, and the Commissioner's statement used the word "exclusivity" as a reference to exploring whether any structural incentives such as a marketing advantage might be available to motivate compliance with the NDI notification requirement. FDA has not yet given extensive thought to this issue, but the Agency wants to hear stakeholders' ideas about what kinds of incentives might be effective and, equally importantly, whether any of those incentives are feasible within existing authorities. FDA expects a robust discussion of these topics and others at the public meeting the Agency is planning for this spring 2019 on responsible innovation in the dietary supplement industry.

Chairman Bishop:

74. What are the next steps after this announcement?—immediate and longer term?

Response: The February 11 statement mentioned a number of new initiatives that are part of our effort to modernize and reform FDA oversight. FDA established a Dietary Supplement Working Group to take a close look at the Agency's organizational structures, processes, procedures, resources, and practices. This Working Group has already begun its internal review. FDA has also created the Botanical Safety Consortium, a public-private partnership that aims to gather the leading scientific minds from industry, academia, and government to promote the use of cutting-edge toxicology tools in evaluating the safety of botanical ingredients and mixtures in dietary supplements. The organizational structure for this group is still being finalized, but its scientific work is underway.

Additionally, the Agency has reaffirmed its commitment to taking enforcement action when appropriate, such as action against products that claimed to treat Alzheimer's and related diseases. Finally, FDA is planning a public meeting this spring to discuss issues related to responsible innovation in dietary supplements. FDA recognizes the growing stakeholder discussion regarding a need for a product listing requirement, and the Agency looks forward to joining that dialogue.

It is also important to note that the work that FDA does every day must continue. This includes, among other things, reviewing adverse event reports; reviewing new dietary ingredient (NDI) and structure/function notifications; conducting inspections and providing expert input on issues related to compliance with the current good manufacturing practice (CGMP) and labeling requirements; and taking and supporting advisory and enforcement actions, as appropriate.

Chairman Bishop:

Speaking of dietary supplements, earlier this year Nature's Rx issued a voluntary recall of their Silver Bullet 10x supplements illegally spiked with active pharmaceutical ingredients. This follows a similar voluntary manufacturer-instituted recall just a few weeks before when Rhino 5k supplements were also spiked with drugs.

75. Is the FDA seeing an increase in incidents of these types of products on the market?

Response: It is difficult to determine whether there has been an increase in products on the market that contain undeclared active pharmaceutical ingredients. While FDA is unable to test and identify all products marketed as dietary supplements that have potentially harmful hidden

ingredients, hidden active pharmaceutical ingredients continue to be identified in products that are misrepresented as dietary supplements and promoted for sexual enhancement, weight loss, bodybuilding and/or pain relief. When FDA becomes aware of a product purporting to be a dietary supplement that contains a hidden drug ingredient, the agency warns the public through an immediate public notification (IPN). Over the past decade, the FDA has posted on its website hundreds of public warnings and recall announcements related to these types of fraudulent products. FDA's tainted products database can help consumers identify some of these potentially harmful products.³⁴

FDA issued an IPN for The Silver Bullet in January 2019, and advised consumers not to purchase the product, which contained the hidden active ingredients sildenafil and tadalafil. These undeclared ingredients may interact with nitrates found in some prescription drugs, such as nitroglycerin, and may lower blood pressure to dangerous levels.

In November 2018, the FDA warned consumers not to purchase or use Rhino male enhancement products, due to a recent rise in reported health issues. Since 2007, the FDA has identified more than 25 products marketed with variations of the name "Rhino" that contained hidden drug ingredient(s).

Even if a product is not included in FDA's tainted products database, consumers should be cautious about using certain products, especially those promoted for sexual enhancement, weight loss, bodybuilding and/or pain relief. Consumers should also be on alert for products that offer immediate or quick results and that sound too good to be true.

Chairman Bishop:

76. It is my understanding that the FDA, if needed, has mandatory recall authority over foods—of which dietary supplements are classified—but not mandatory recall authority over drugs. How would the agency respond to products like Silver Bullet and Rhino if a mandatory recall were warranted—does the agency have the authority to recall dietary supplements tainted with pharmaceutical ingredients?

Response: Although tainted products like The Silver Bullet and Rhino purport to be dietary supplements, products such as these that contain active pharmaceutical ingredients are often excluded from the definition of a dietary supplement under section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. § 321(ff)(3)(B)]. Under that definition, a dietary supplement cannot include an article that is approved as a new drug under section 505 of the FD&C Act [21 U.S.C. § 355] or an article authorized for investigation as a new drug for which substantial clinical investigations have been instituted and made public, unless the article was marketed as a dietary supplement or food before it was approved or authorized for investigation as a new drug. In many cases, tainted products purporting to be dietary supplements are actually drugs; FDA does not have mandatory recall authority for most drugs.

FDA's authority to mandate drug product recalls is limited to controlled substances, pursuant to the authority granted to FDA in October 24, 2018, with the enactment of the SUPPORT Act. This limited scope means that FDA's mandatory recall authority may not be available in many of

³⁴ https://www.accessdata.fda.gov/scripts/sda/sdNavigation.cfm?sd=tainted_supplements_cder

the situations described above involving products that contain certain active pharmaceutical ingredients. A manufacturer may choose to voluntarily recall its products for any reason. While it is true that drug companies typically issue a recall voluntarily when requested by FDA, absent clear authority for the Agency to require a company to issue a recall, we often lose critical time negotiating the terms of the recall. In the meantime, patients continue to be exposed to dangerous or ineffective products. Under the current system, a company may disagree with FDA as to the need for a recall or the scope of a recall. While we work out those matters collaboratively, patients are left vulnerable to potentially dangerous products.

FDA continues to take actions within its authority to protect public health and develop new enforcement strategies, as a key element of our approach to protecting consumers as the risks evolve. The Agency has already made its internal processes more efficient for taking enforcement action when products claiming to be supplements contain unlawful ingredients, including unlawful drug ingredients. For example, last April FDA took strong action to protect consumers from the dangers of dietary supplement products marketed in bulk and containing pure and highly concentrated caffeine. The Agency also warned consumers in November to not purchase Rhino male enhancement products because they were unapproved new drugs that contained sildenafil and/or tadalafil, which are active ingredients in the FDA-approved prescription drugs Viagra and Cialis, respectively. During the same month, FDA issued warnings to companies for unlawfully marketing as dietary supplement products that contained a compound called tianeptine; these products were unapproved new drugs that bore unproven claims that the products could treat opioid addiction. FDA has also been active with compliance and enforcement efforts against firms that have shown persistent inability to comply with the current good manufacturing practice requirements for dietary supplements and taking action to protect the public against unsafe imports and recalled products.

Agricultural Water Rule

Chairman Bishop:

Last year, 210 people across 36 states became infected with a deadly strain of E. coli after eating romaine lettuce —this includes 96 people who were hospitalized, 27 people who developed a type of kidney failure, and 5 people who died. FDA released its environment assessment in late 2018 and reaffirmed its initial finding that the outbreak strain was found in canal water used to irrigate produce fields and apply pesticides.

The finding underscores the urgent need for FDA to finalize an agricultural water standard. The FDA Food Safety Modernization Act directs FDA to establish safety standards for possible sources of contamination of produce, including water. To date, and more than 7 years after the law was enacted, the water requirements have not yet been put into place.

77. Could you please update us on the status of that rule and whether, in light of the recent outbreaks, you are considering adjusting the compliance dates so that we don't have to wait until 2024 for the standards to be in effect?

Response: FDA continues to consider questions that have been raised about the agricultural water standards for produce covered by the Produce Safety rule (other than sprouts, which were required to meet compliance dates that have passed). Recent outbreaks have highlighted just

how diverse agricultural production is and have stressed the importance of ensuring that the agricultural water standards are workable across the diversity of farms, water sources, and uses. The Agency is incorporating lessons learned from these recent outbreaks and using the best science available to help minimize the risk that produce can become contaminated.

FDA is extending compliance dates for agricultural water requirements for large farms to January 2022, small farms to January 2023, and very small farms to January 2024. This allows additional time to engage with stakeholders and to apply best thinking around the standards for pre-harvest microbial water quality. FDA is firmly committed to finding a solution as expeditiously as possible that is workable for growers and protective of public health.

During the extension, FDA is strongly encouraging growers to ensure that water is suitable for its intended use and to use good agricultural practices to maintain and protect the quality of their water sources. Growers are responsible for ensuring that the food they produce is not adulterated under the Federal Food, Drug, and Cosmetic Act.

Food Traceability

Chairman Bishop:

78. Please discuss actions or steps the FDA has taken in addressing gaps in our ability to trace food products from farm to fork to ensuring that there is an effective food traceability system?

Response: The ability to trace food products is very important to public health. Efficiently tracking and tracing FDA-regulated food products will enable FDA to work with stakeholders, including industry producers, to quickly remove harmful products or ingredients from the supply chain. FDA is committed to pursuing a tracking and tracing initiative with stakeholders. This initiative is a top priority of the FDA Foods Program and it will be led by FDA's new Deputy Commissioner for Food Policy and Response, who comes to the Agency with extensive experience in this area. Improving food traceability is part of an overall focus on creating a smarter food safety system, which will utilize emerging technologies to better respond to food safety events and to better incorporate risk information into new prevention efforts. In the near term, FDA's priority is the traceability rulemaking for high-risk foods, required by Section 204 of the FDA Food Safety Modernization Act (FSMA), to which the Agency is devoting considerable resources.

Chairman Bishop:

79. What other steps is FDA going to take to reach the goal and what could the Committee do to assist the agency in meeting that goal?

Response: With additional resources, FDA could enhance its ability to leverage new technologies that make it easier to track and trace products throughout the product lifecycle. Efficiently tracking and tracing regulated products will enable FDA to work with stakeholders, including industry producers, to more quickly remove harmful products or ingredients from the supply chain. Over the last year alone, FDA faced challenges dealing with the complexities of supply chain tracking and management related to two outbreaks of E. coli O157:H7 in romaine lettuce, for which records were being kept mostly on paper. In the wake of these two incidents,

FDA worked with industry on common sense changes, like providing greater clarity on package labeling by including harvest date and location and calling for industry to better improve traceability.

In recent years, track and trace technologies have emerged that can assist response efforts to allow the Agency to intervene in time to alert consumers, implement recalls, and avoid human illnesses. These include technologies like blockchain, which uses a decentralized, secure ledger that is shared by all parties in the supply chain to provide transparency on a product's origins. FDA is already exploring what new technologies might mean to the Agency with the announcement of new pilots with pharmaceutical products. The Agency is also interested in exploring how new and enabling technologies might facilitate food traceability both for industry and regulators.

Such technologies can reduce the time it takes to find a food source from days or weeks to minutes or even seconds, in certain cases. It can greatly assist in warning consumers about risks with specific foods and in implementing more targeted and efficient recalls. While FDA's primary goal in enhancing track and trace is protecting public health, this new technology will also assist industry by minimizing the number of products implicated in outbreaks of foodborne illness and other product problems that could result in the loss of millions of dollars in profits.

When the lack of transparency in supply chains delays the identification of contamination sources and the root causes of product problems, the economic and public health costs can be considerable. An enhanced ability to trace foods to their source during an outbreak will also allow FDA to conduct better and more real-time root-cause analysis to prevent similar reoccurrences.

Animal Cell Culture Technology

Chairman Bishop:

80. With the recent announcement of a formal agreement between the Food and Drug Administration and the U.S. Department of Agriculture where in the process and what is the timeline on where the agencies stand in further developing standard operating procedures towards facilitating coordination of the shared regulatory oversight?

Response: FDA and the U.S. Department of Agriculture (USDA) met the 60-day deadline directed in the FY 2019 omnibus by finalizing the formal agreement on March 7, 2019, to address regulatory oversight roles and responsibilities for both agencies. FDA and USDA are developing more detailed procedures to facilitate coordination of the shared regulatory oversight of foods incorporating cultured livestock and poultry cells. Further work is needed to coordinate the transfer of oversight at the cell harvest stage and develop processes for coordinated investigation of any food safety issues that might arise. Workgroups have been formed to develop this and other processes. Such groups were identified as a key requirement during development of the formal agreement.

Chairman Bishop:

81. What has FDA and USDA completed on the development of product labeling to ensure labels are consistent and transparent?

Response: FDA and the U.S. Department of Agriculture will work to develop more detailed procedures to facilitate coordination of the shared regulatory oversight of foods incorporating cultured livestock and poultry cells. Further work is needed to develop joint principles for product labeling and claims to ensure that all foods incorporating cultured animal cells from any source are labeled consistently and transparently. Workgroups have been formed to develop this and other processes. Such groups were identified as a key requirement during development of the formal agreement.

Small Format Packaging

Chairman Bishop:

82. The food industry has been waiting on guidance on how to proceed on small format packaging as the new format requirements are bigger than small packages can fit. Since this information was not included in the March 1 guidance, when will this guidance be issued?

Response: FDA published draft guidance in November 2018 that addressed the labeling of small packages. The Agency has reviewed the comments received on the draft and is working to finalize the guidance as soon as possible.

Pecan Imports

Chairman Bishop:

It is our understanding that Mexican pecan growers use a plant growth hormone, paclobutrazol, on their pecan trees. This chemical cannot be used on any edible crop in the U.S. This chemical reduces tree size and causes the tree to develop more fruiting shoots, both of which can increase pecan production. This gives Mexican growers an advantage over U.S. growers in addition to raising food safety concerns. If this chemical is prohibited in its use on edible crops in the U.S., imported products should be subject to the same rules for our consumers.

83. Are there inspection tools available to FDA regarding increasing inspections of imported pecans relative to chemicals, not approved for use in the U.S. on edible crops at the point of entry?

Response: Under FDA's pesticide residue monitoring program, FDA samples individual lots of domestically produced and imported foods and analyzes them to determine whether they contain pesticide chemical residues that are "unsafe" within the meaning of the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA enforces tolerances established by the Environmental Protection Agency (see tolerances for pesticide residues in food 40 CFR part 180). When a pesticide chemical residue is not assigned a tolerance or exemption from the requirement for a tolerance, a food that bears or contains the pesticide chemical residue is deemed to be adulterated under section 402(a)(2)(B) of the FFDCA. A shipment of imported food with violative residues may be refused entry into U.S. commerce and may result in a firm being placed on an import alert that includes "Detention Without Physical Examination" for future shipments of that firm's commodity.

In general, when planning sampling for the pesticide residue monitoring program FDA experts consider such factors as violation history, data from other agencies, and food consumption patterns. FDA uses the PREDICT (Predictive Risk-based Evaluation for Dynamic Import

Compliance Targeting) screening tool to target foods that may warrant increased inspections. PREDICT is a risk-based analytics program that electronically screens all regulated shipments imported or offered for import. To guide screening, PREDICT uses automated data mining, pattern discovery, automated queries of FDA databases, information on the inherent risk of a product, and information about previous firm history.

Regarding the use of paclobutrazol on pecan trees by Mexican pecan growers, there is no tolerance for paclobutrazol on pecans in the U.S. and findings of paclobutrazol in pecans would be considered a violation. FDA currently tests for paclobutrazol (along with 700 other pesticide chemical residues) in samples of domestic and imported pecans, and pecans are well represented in FDA pesticide sampling.

Question for the Record from Rep. Barbara Lee of California
Cell-based meat and the regulatory process

Rep. Lee:

As you know, Commissioner, we face the ongoing challenge of feeding a growing global population with increased risks of climate change and food production. Meeting that demand in a sustainable way presents us with significant challenges, and the emerging field of cellular agriculture has the potential to be part of the solution to those challenges. I have four cell-based meat start-ups in my district. I know that you and Secretary Perdue announced an agreement last November to share oversight of this emerging industry when it involves cells from livestock and poultry.

84. What is FDA doing, in partnership with USDA, to ensure that cell-based meat is safe and properly labeled?

Response: FDA and the U.S. Department of Agriculture (USDA) met the 60-day deadline directed in the FY 2019 omnibus by finalizing the formal agreement on March 7, 2019 to address regulatory oversight roles and responsibilities for both agencies. FDA and USDA are developing more detailed procedures to facilitate coordination of the shared regulatory oversight and are also developing joint principles for product labeling and claims to ensure that products incorporating cultured animal cells from any source (e.g., meat, seafood) are labeled consistently and transparently. In addition, FDA plans to develop and document processes for conducting premarket consultations to evaluate production materials/processes and manufacturing controls to include oversight of tissue collection, cell lines, cell banks, and all components and inputs for any animal cell culture process. Workgroups have been formed to develop this and other processes. Such groups were identified as a key requirement during development of the formal agreement.

Questions for the Record from Rep. Chellie Pingree of Maine
Nutrition Innovation Strategy

Rep. Pingree:

85. In 2018, FDA announced a multi-year Nutrition Innovation Strategy, which aims to reduce preventable death and disease related to poor nutrition. Please provide an update on the Strategy and a timeline for actions that FDA intends to take as part of the Strategy.

Response: FDA has taken several steps to develop and inform its Nutrition Innovation Strategy. The Nutrition Innovation Strategy will use FDA's tools and authorities to both empower consumers with information and facilitate industry innovation toward producing healthier foods by modernizing the Agency's approaches to claims and standards of identity, advancing efforts to develop voluntary sodium targets, and fully implementing the updated Nutrition Facts label and menu labeling.

FDA hosted a public meeting in July 2018 and opened a corresponding docket to receive input from stakeholders on the Strategy. The approximately 5,000 comments that were received are currently being reviewed. The public meeting addressed a standard icon or symbol for the claim "healthy;" a more efficient review strategy for evaluating qualified health claims; labeling statements or claims that could facilitate innovation to promote healthful eating patterns; approaches for modernizing standards of identity; changes that could make ingredient statements on food labels more consumer friendly; and FDA's educational campaign for consumers about the updated Nutrition Facts label that consumers will see in the marketplace. Over 900 people attended the public meeting in-person or via webcast.

FDA issued a request for information in September 2018 to solicit comments and feedback from the public to gain more insight into how consumers use plant-based dairy alternatives and how they understand terms like "milk" or "cheese" when used on the labels of these products made, for example, from soy, peas, or nuts. The comment period closed in January 2019, and FDA is now reviewing the approximately 13,000 comments received. Additionally, FDA indicated in its Fall 2018 Unified Agenda the Agency's intent to re-open the comment period on a proposed rule, issued jointly with the U.S. Department of Agriculture's Food Safety and Inspection Service in 2005, that proposed to establish general principles that would be the first step in modernizing and updating standards of identity.

FDA also intends to publish a proposed rule in the near future to update the regulatory definition of "healthy" as part of the Agency's efforts to modernize the approach to claims, as well as finalize short-term voluntary sodium reduction targets in 2019. In addition, FDA plans to finalize two remaining guidance documents on the Nutrition Facts label very shortly, including final guidance on the labeling of added sugars on single-ingredient sugars and syrup products as well as certain cranberry products, so that industry has clarity needed to implement the updated Nutrition Facts label.

Food Additives

Rep. Pingree:

86. How did the shutdown disrupt the agency's handling of petitions and notices by its Office of Food Additive Safety? Has the office missed or does it anticipate missing any statutory or regulatory deadlines as a result of the shutdown or backlog from catching up from the shutdown?

Response: When the shutdown started, the reviews of food additive petitions, color additive petitions, GRAS notices, food contact notifications, and consultations for foods derived from new plant varieties were suspended for the duration of the shutdown. When the shutdown ended, the reviews were restarted. During the shutdown period, new submissions were sent to FDA

creating a backlog (food contact notifications: 25 under review at shutdown, 17 received during shutdown; GRAS notices: 35 under review at shutdown, 16 received during shutdown). When work resumed, the normal load plus the backlog required CFSAN's Office of Food Additive Safety to triage submissions and suspend many non-review-related activities such as pre-filing consultations and industry and stakeholder meetings.

The shutdown has resulted in a strain on personnel resources due to the accumulated backlog of submissions that are on concurrent review clocks. The Office of Food Additive Safety is focusing its resources on not missing any statutory deadlines in our mandatory programs (food additive petitions, color additive petitions, food contact notifications). However, the deadlines for review of GRAS ingredient submissions under the voluntary notification program may not be met. Additionally, voluntary consultations with industry (pre-submission consultations) have been impacted until the backlog of reviews in the mandatory programs are cleared. Assuming no new stressors on the program, recovery to normal operating conditions is estimated by the end of fiscal year 2019.

FSMA Agricultural Water Requirements

Rep. Pingree:

87. In September of 2017, FDA issued a proposed rule to extend the compliance dates for the agricultural water requirements within the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. When the proposed rule is finalized, FDA will not begin to enforce the agricultural water requirements for covered produce, with the exception of sprouts, until January 2022. However, there are a number of questions and concerns about when and how FDA will implement the agricultural water rule. Produce farmers need an ample amount of time to learn about and comply with any potential changes to the agricultural water requirements. What is FDA's plan and timeline for considering any changes to the agricultural water requirements? What does FDA hope to accomplish around the agricultural water requirements within the next three years?

Response: FDA is extending compliance dates for agricultural water requirements for large farms to January 2022, small farms to January 2023, and very small farms to January 2024 (except for sprout operations, which are subject to compliance dates that have passed). This allows additional time to engage with stakeholders and to apply best thinking around the standards for pre-harvest microbial water quality. FDA will work with the Produce Safety Alliance and other partners on outreach and educational activities to help growers prepare for compliance with the agricultural water requirements, taking into consideration that, if changes are made, growers will need time to understand the changes and how to implement them.

FDA continues to work to ensure that the agricultural water standards will be practical to implement across the diversity of farms, water sources, and uses. The Agency is incorporating information learned through significant outreach to the produce community, including a February 2018 agricultural water summit that FDA helped organize. The summit brought together growers, regulatory personal, industry representatives, educators, and researchers to increase understanding and work collaboratively to develop ideas that support risk reduction related to water. FDA will continue working closely with produce farmers on sensible approaches to protect consumers. While the produce industry has adopted many measures to

promote the safety of agricultural water, FDA's goal is to make sure that federal requirements reflect the most modern, robust, and practical measures.

FSMA Risk-Based Approach

Rep. Pingree:

88. FDA's risk assessment and research efforts to establish application intervals for untreated biological soil amendments of animal origin is a methodical, science and risk-based approach. Is FDA taking the same approach with the agricultural water standard? If not, why? Are there any additional resources or support FDA needs to ensure a science and risk-based approach is taken to inform potential changes to the agricultural water requirements?

Response: Yes, FDA is taking a methodical, scientific, and risk-based approach to the agricultural water standards. Among other things, FDA is reviewing the outcomes from the February 2018 agricultural water summit, which brought together growers, regulatory personnel, industry representatives, educators, and researchers to increase understanding and work collaboratively to develop ideas that support risk reduction related to water. Additionally, FDA subject matter experts have consulted with academics and continue to monitor scientific developments in this area. The Agency is also reviewing relevant portions of our Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce, as well as lessons learned from recent produce outbreaks. In addition, FDA is working closely with state partners and growers in addressing the challenges associated with the diversity of water sources and uses in a science- and risk-based manner. FDA does not need additional resources or support to accomplish these objectives.

FSMA Coordination with USDA

Rep. Pingree:

89. How is FDA coordinating with USDA on food safety efforts to ensure trainings and audits provide farmers with the knowledge they need to comply with the Produce Safety Rule?

Response: FDA developed and is implementing a robust multi-pronged approach to coordinate with the U.S. Department of Agriculture (USDA) on training activity and audits so that farmers have the knowledge necessary to comply with the Produce Safety Rule (PSR). The approach includes the following activities:

1. FDA and USDA Cooperation & Coordination Agreement Workgroup with leadership at senior levels at each agency (Office of the Commissioner at FDA and Office of the Secretary at USDA). Focus areas for this workgroup, thus far, have been: (a) announcing the alignment of USDA's market access harmonized Good Agricultural Practices (GAP) audit program to the PSR; (b) training for Cooperative Extension and other personnel in the PSR standards and the nature of regulatory inspections; and (c) outreach to the international community utilizing USDA's Foreign Agricultural Service personnel expertise.
2. Collaborative Training Forum that FDA and USDA representatives co-chair and which involves coordinating individual efforts of the Produce Safety Alliance (cooperative agreement with Cornell University), the Local Food Producers cooperative agreement (with National Farmers Union), and the Native American Tribes cooperative agreement

(with Indigenous Food and Agriculture Initiative at University of Arkansas) to address training needs around the PSR.

3. FDA and USDA worked cooperatively to align USDA's market access harmonized GAP audit program to the requirements of the PSR. The resulting revised harmonized GAP audit has been utilized since the 2018 growing season.
4. FDA and USDA are providing opportunities for each other's staff to cross train in each other's training classes. For example, FDA has provided training slots for USDA GAP audit staff in its FD226, "Produce Inspections for Regulators," course. In turn, these USDA GAP audit staff are creating a module for its larger auditor staff in the FDA technical aspects of on-farm inspections. Likewise, USDA has provided training slots for FDA staff in its GAP Auditor Training course.
5. FDA provides majority support for a full-time USDA position that focuses on FSMA and, specifically, the PSR. The incumbent, a USDA Agricultural Marketing Service (AMS) Specialty Crops Program (SCP) employee formerly worked in a variety of USDA AMS SCP initiatives and programs including USDA GAP program, shipping point (origin) and terminal market grading and inspection, training of both staff and industry, and outreach; and is now dedicated to FDA- and FDA-USDA-assigned projects that impact farmers, educators, staff, and other stakeholders. The incumbent maintains an office at FDA CFSAN within the Division of Produce Safety.

Indirect Food Additives

Rep. Pingree:

90. Does FDA rely on modern science to assess the safety of indirect food additives, including consideration of all vulnerable populations, a full range of health endpoints, assessment of aggregate and cumulative risks, and the latest recommendations of the National Academies of Science on risk assessment?

Response: FDA's safety assessment of indirect food additives, now referred to as food contact substances (FCS), relies on evaluating probable consumer exposure to an FCS, including all impurities, as a result of the proposed use and ensuring that probable consumer exposures are safe consistent with available toxicological information. FDA utilizes a tiered approach in its safety testing recommendations, i.e., higher exposure for a substance leads to increased toxicity testing recommendations. FDA considers the available high-quality scientific information from all sources (e.g., published literature, FDA research, manufacturer's studies contained in the submission, etc.), as well as the structure of the molecule and information on similar substances. Safety is evaluated for the general population, as well as any subpopulation that might have special sensitivities (e.g., infants, women of child-bearing age) as appropriate. FDA provides information on its website describing the Agency's process in evaluating indirect food additives, guidance on technical recommendations for submissions to the Agency, as well as draft guidance for indirect additives used in products in contact with infant formula and/or human milk that, once finalized, will represent FDA's thinking on the topic.

Chemicals in Food

Rep. Pingree:

91. I understand that FDA evaluates petitions seeking to add or expand uses of chemicals in food or food contact substances, as well as petitions to remove or limit uses approved for food or

food contact substances based on safety concerns. Please provide a summary showing FDA's timelines from initial filing to a final decision for each of the two types of evaluations for the last year.

Response: FDA reviews food additive petitions according to the procedures described in Title 21 of the Code of Federal Register (CFR) Part 171. FDA reviews color additive petitions, including color additives intended for use in food, according to the procedures described in 21 CFR Part 71. The statutory and regulatory requirements for a food additive petition and a color additive petition are similar but not identical.

Some key similarities are summarized as follows. FDA has 15 days after receiving a petition to decide whether it is suitable for filing; this decision is published in the Federal Register. After filing, FDA has 90 days to complete its review. This period may be extended by an additional 90 days, for a total of 180 days. If the petition has missing data or analytical flaws, a notice of such is sent to the petitioner, and the review clock is stopped until the requested data are received. When the petition review is complete, and if the food additive or color additive is judged to be safe under the proposed conditions of use, a regulation specifying the conditions of use is published in the Federal Register and a listing is created in Title 21 of the CFR. If the petition is for revoking the authorization of a food additive or color additive and FDA determines that this authorization should be revoked, the decision is published in the Federal Register and the authorizing regulation for the additive in the CFR is removed. In the case of color additives, under the statute, FDA's final rule (one either creating or removing a listing) is stayed if FDA receives objections and a request for a hearing within 30 days until FDA takes final action on the objections and request for a hearing.

FDA provides performance data on a quarterly basis through FDA-TRACK, the agency-wide performance management program available on the agency's website.

Below is a table outlining the duration of review for the food additive and color additive (for use in food) petitions that were completed in calendar year 2018. The table contains information on when the petition was filed and when the Agency's final response was published in the Federal Register.

Petition # and Substance	Requested by the petition		Approve Based on Safety	Filing Date	Final Rule Date
	Revocation Based on Abandonment	Safety			
5A4810 (7 Flavoring Agents)		X		August 17, 2015	October 9, 2018
5A4811 (PHOs)			X	October 1, 2015	May 21, 2018 (Denial Notice)
6A4817 (Styrene)	X			May 16, 2016	October 9, 2018
7A4818 (Vitamin D)			X	June 1, 2017	September 20, 2018
7C0308 (Iron Oxide)			X	October 3, 2017	November 1, 2018

Healthy Labeling on Bottled Water

Rep. Pingree:

92. What is FDA's timeline for providing guidance on the use of the term "healthy" on the labels of bottled water?

Response: FDA is prioritizing its limited resources to develop a proposed rule to update the regulatory definition of "healthy" as an implied nutrient content claim for use in food labeling across products. The Agency published a request for information (RFI) on the use of the claim "healthy" in September 2016 and is considering all the comments received to the RFI, including those related to the use of the term "healthy" on bottled water, while developing the updated criteria. The proposed rule will consider the issues raised regarding bottled water and other beverages, and FDA expects to receive broad stakeholder input as part of the public comment process. As outlined in FDA's Fall 2018 *Unified Agenda*, the Agency intends to publish the proposed rule for "healthy" in the near future.

Food Allergens

Rep. Pingree:

93. If a food allergy patient is affected by an undeclared allergen or by a mistake, they must use epinephrine, which is subject to persistent shortages. The current clinical trials system only approves one allergen at a time, despite patients often being allergic to multiple allergens. What impact does the current system have on the development and approval of new, innovative treatments?

Response: FDA recognizes the need for innovative products to treat food allergies. The Agency does not have a policy limiting sponsors to the clinical development of single allergens for the treatment of food allergies. Sponsors interested in developing allergenic products to treat multiple food allergies can conduct clinical studies to demonstrate safety and effectiveness of these products. FDA would approve (license) these products based on data demonstrating that the products are safe, pure, and potent and the facility in which the products will be manufactured, processed, packed, or held meets standards designed to assure that the products continue to be safe, pure, and potent. The Agency encourages all sponsors to engage in ongoing communication with the Agency about their clinical development programs. Please note that FDA has approved allergenic products for the treatment of multiple aeroallergens (e.g. Oralair) in recent years.

Food Standards of Identity

Rep. Pingree:

94. Please provide an update on FDA's effort to undertake a holistic approach to modernizing food standards of identity. Additionally, please provide an update on FDA's efforts to finalize the yogurt standard of identity. When will FDA finalize the yogurt standard of identity?

Response: FDA hosted a public meeting in July 2018 and opened a corresponding docket to receive input from stakeholders on the Nutrition Innovation Strategy, including approaches to modernizing standards of identity. Additionally, FDA indicated in the Fall 2018 *Unified Agenda* its intent to re-open the comment period on a proposed rule, issued jointly with the U.S.

Department of Agriculture's Food Safety and Inspection Service in 2005, that proposed to establish general principles that would be the first step in modernizing and updating standards of identity. FDA is also addressing other important areas to modernize standards of identity, including updating individual standards and removing standards of identity that are no longer necessary.

FDA intends to issue a final rule to update the standard of identity for yogurt soon; this is work that was underway prior to FDA examining the broader approach to modernizing standards of identity under the Nutrition Innovation Strategy and is being prioritized for completion.

Question for the Record from Rep. Mark Pocan of Wisconsin
Food Allergies

Rep. Pocan:

95. Under the current state of affairs, food allergy patients only choice for management of their disease is avoidance. If something happens with either an undeclared allergen or a mistake, they have to use epinephrine. With persistent shortages of epinephrine, it is more vital than ever to push curative and life changing therapies into marketplace as fast as possible. When people are allergic to 9 allergens, as many often are, why are we pushing a clinical trials system that only approves one allergen at a time, and slows the general development and approval of these new innovative treatments?

Response: FDA recognizes the need for innovative products to treat food allergies. The Agency does not have a policy limiting sponsors to the clinical development of single allergens for the treatment of food allergies. Sponsors interested in developing allergenic products to treat multiple food allergies can conduct clinical studies to demonstrate safety and effectiveness of these products. FDA would approve (license) these products based on data demonstrating that the products are safe, pure, and potent and the facility in which the products will be manufactured, processed, packed, or held meets standards designed to assure that the products continue to be safe, pure, and potent. The Agency encourages all sponsors to engage in ongoing communication with the Agency about their clinical development programs. Please note that FDA has approved allergenic products for the treatment of multiple aeroallergens (e.g. Oralair) in recent years.

Question for the Record from Rep. Andy Harris of Maryland
Dietary Supplement Working Group

Rep. Harris:

96. FDA has indicated publicly that an internal working group was formed to examine the agency's regulation of dietary supplements. Can you describe the scope of that work, and when FDA will provide its recommendations?

Response: The Dietary Supplement Working Group is being led out of the Commissioner's Office and is comprised of representatives from multiple centers and offices across the Agency. The group has been tasked with taking a close look at FDA's organizational structures, processes, procedures, resources, and practices in order to identify opportunities to modernize and help support the Agency's oversight of dietary supplements. FDA takes very seriously the

obligation to use the resources and authorities that the Agency has as efficiently and effectively as possible, and this group's charge is to ensure that this is happening.

The working group has a broad mandate, but there are examples of the types of issues it will examine. In some cases, products that are sold as dietary supplements do not meet the legal definition of "dietary supplement"—for example, if they contain drug ingredients that cause the product to be excluded from the "dietary supplement" definition, or if they do not contain any ingredients that qualify as dietary ingredients. Depending on the intended use of such products, they may instead be subject to regulation as drugs. Under internal FDA procedures established many years ago, the circumstances of a specific product will determine whether that product is handled by the Agency's Center for Food Safety and Applied Nutrition (CFSAN) or by the Center for Drug Evaluation and Research (CDER). Although this division made sense early in the implementation of the Dietary Supplement Health and Education Act (DSHEA), in some cases, it can lead to absurd results today. In one instance, FDA determined that tianeptine is not a dietary ingredient, but it is not an "excluded" ingredient. As a result, products labeled as dietary supplements that contain only tianeptine are within CDER's jurisdiction (assuming the labeling bears a claim that subjects the product to regulation as a drug), while products labeled as dietary supplements that contain tianeptine and at least one dietary ingredient (for example, Vitamin C) are within CFSAN's jurisdiction.

The Working Group aims to provide recommendations later this year.

Rep. Harris:

97. What is the status of FDA's effort to finalize the draft New Dietary Ingredient notification guidance?

Response: FDA recognizes the importance to stakeholders of providing clarity around the new dietary ingredient (NDI) notification process. FDA has received hundreds of substantive comments on the revised draft guidance that was published in 2016, and the Agency is considering those comments. Many of the issues surrounding the revised draft guidance are complicated issues that do not lend themselves to easy solutions. Other issues, especially issues that are more procedural in nature, are more straightforward.

FDA's approach has been to try to make progress on discrete topics where there seems to be some consensus, while the Agency continues to grapple with the difficult issues. For example, in October 2017, FDA held a public meeting to discuss development of an authoritative list of pre-Dietary Supplement Health and Education Act (DSHEA) dietary ingredients. This was a productive meeting where the Agency heard suggestions about how a list that is broader in scope might be more valuable, along with questions about whether the benefits of a list would justify the resources needed to compile it. FDA is considering the opinions shared at the meeting and reviewing the written comments that were submitted, and the Agency is committed to being transparent in deciding how to move forward on this issue.

FDA has also worked on the issue of NDI master files, another suggestion raised in the comments on the draft guidance. FDA has held discussions on this subject with a number of stakeholders to gain a better understanding of how a master file system could be useful. The

Agency remains committed to finding new ways, and to highlighting existing ways, to reduce the burden of submitting and reviewing notifications without compromising FDA's ability to fulfill our public health mission.

FDA expects that the public meeting planned for this spring will also touch on some issues related to the NDI guidance.

Center for Veterinary Medicine
Questions for the Record from Chairman Sanford Bishop of Georgia
 Antibiotics Five Year Agenda

Chairman Bishop:

FDA has announced an ambitious five-year agenda to advance antibiotic stewardship in animal agriculture and to continue to reduce the unnecessary use of medically important antibiotics in production agriculture.

98. Following your agency's work implementing Guidance 209 and 213 and the Veterinary Feed Directive (VFD), it's a laudable goal – can you update the subcommittee on your progress so far and what milestones we can expect to see over the remainder of the year?

Response: Following the successful implementation of Guidances for Industry (GFI) #209 and #213 and the Veterinary Feed Directive final rule, in December 2018 FDA's Center for Veterinary Medicine (CVM) announced that domestic sales and distribution of all medically important antimicrobials intended for use in food-producing animals decreased by 33 percent between 2016 and 2017.³⁵ While sales data do not necessarily reflect antimicrobial use, the reduction in sales volume is an important indicator that ongoing efforts to support antimicrobial stewardship are having a significant impact.

CVM is progressing under the framework of a five-year plan to support antimicrobial stewardship in veterinary settings, which was released in September 2018.³⁶ One group of actions relates to establishing durations of use for medically important antimicrobials administered in the feed or drinking water of food-producing animals that are approved for indications that lack a defined duration of use.³⁷ CVM has developed a Request for Applications (RFA) for studies that can help establish more targeted or defined durations of use for approved medically important antimicrobial drugs used in the feed of food-producing animals. This funding opportunity is intended to generate publicly available data that sponsor(s) can use to support updates to product dosage regimens that reflect more targeted or defined durations of

³⁵ FDA Center for Veterinary Medicine, "2017 Summary Report on Antimicrobial Drugs Sold or Distributed for Use in Food-Producing Animals," December 2018, available at <https://www.fda.gov/downloads/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/UCM628538.pdf>.

³⁶ FDA Center for Veterinary Medicine, "Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019-2023," September 2018, available at <https://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/UCM620420.pdf>.

³⁷ Action 1.1.1: Publish a list of medically important antimicrobial drugs administered in the feed or drinking water of food-producing animals that are approved for indications that lack a defined duration of use; Action 1.1.2: Issue a draft strategy (e.g., guidance for industry) to ensure that all medically important antimicrobial drugs used in the feed or drinking water of food-producing animals have an appropriately targeted duration of use.

use. CVM expects to publish this RFA, along with a list of the antimicrobial drug products affected by the duration of use issue, in early April 2019.

FDA is also making progress to bring remaining dosage forms of medically important antimicrobials under veterinary oversight.³⁸ To fulfil these actions, CVM plans to issue a strategy, in the form of draft GFI, prior to September 30, 2019. This GFI will provide the framework, including proposed timelines, for transitioning from over-the-counter to prescription marketing status for all approved medically important antimicrobial drugs that are not yet subject to veterinary oversight. In conjunction with issuing this draft strategy, CVM intends to publish a list of affected new animal drug applications.

Additionally, as part of the five-year plan³⁹ and supported by the FDA Science Board, the National Antimicrobial Resistance Monitoring System has taken steps to expand the scope of its antimicrobial resistance testing by initiating a pilot study that samples farm-raised seafood products sold at retail.

Chairman Bishop:

I am particularly encouraged that you're planning to tackle the issue of injudicious antibiotic drug labels. As you know, research suggests that, even after the full implementation of GFI 213, as many as 1 in 3 medically important animal antibiotic labels doesn't meet FDA's own judicious use standards – and this means that we're allowing drugs important to human medicine to be used for very long durations, much longer than clinically appropriate. I hope you agree with me that this is an especially important area of focus, and I hope you'll prioritize the agency's work to update these labels.

99. Can you tell me more about your plans for updating antibiotic drug labels?

Response: FDA has already taken a critical step to update the labeling of all medically important antimicrobial drugs used in the feed or water of food-producing animals to require their use be under the oversight of licensed veterinarians. Moving forward, FDA plans to bring the remaining dosage forms (e.g., injectables, intramammary) of medically important antimicrobial drugs used in animals under veterinary oversight and update the product labeling, as well. To initiate this, FDA plans to issue a strategy on the remaining dosage forms in the form of a draft guidance for industry prior to September 30, 2019.

FDA also intends to implement a strategy to ensure that all medically important antimicrobial drugs used in the feed or water of food-producing animals are labeled with an appropriately targeted duration of use. Establishing durations of use for these drugs is a continuation of FDA's antimicrobial stewardship efforts. However, given the significant scientific and technical

³⁸ Action 1.1.3: Issue a draft strategy (e.g., guidance for industry) to bring all dosage forms (including injectable, intramammary, etc.) of medically important antimicrobial drugs approved for use in food-producing animals under the oversight of a licensed veterinarian; Action 1.2.2: Ensure that all dosage forms of medically important antimicrobials for use in companion animals are under the oversight of a licensed veterinarian.

³⁹ Action 3.2.1: Expand the National Antimicrobial Resistance Monitoring System to characterize resistance in bacteria from additional animal species and commodities where medically important antimicrobials are used.

challenges, including the potential need to generate appropriate supporting information and data, FDA anticipates that this initiative will require substantial time to fully complete.

By the end of September 2020, FDA intends to publish an additional draft strategy, also likely in the form of a draft guidance, that will address establishing defined durations of use for the affected new animal drug applications. The agency expects this draft guidance to outline a proposed process for sponsors to revise the approved conditions of use, including proposed time frames for implementation.

FDA's primary objective is to update product dosage regimens to better target when and for how long the drug may be used. Defining more targeted durations of use supports the FDA's ongoing efforts to slow the development of antimicrobial resistance by fostering the judicious use of medically important antimicrobial drugs in animals.

Chairman Bishop:

I'm concerned that your action plan stages the work through as late as 2023 – delaying four or five years to issue a final strategy to tackle this problem is too long to wait.

100. Acknowledging the few weeks of delay you've experienced as a consequence of the shutdown, will you commit to accelerating your work updating these labels to ensure that all medically important antibiotics are used judiciously as soon as possible?

Response: Even though FDA lost valuable time this fiscal year, the agency is still on track to achieve milestones related to defining durations of use and updating the label for those medically important antimicrobial applications.

FDA is committed to advancing this initiative as quickly as possible. Labeling updates need to be based on sound scientific data and information. Understanding that such data and information are currently limited, FDA has moved forward with developing a Request for Applications (RFA) for studies that can help establish more targeted or defined durations of use for approved medically important antimicrobial drugs used in the feed of food-producing animals. This funding opportunity is intended to generate publicly available data that drug sponsor(s) can use to support updates to product dosage regimens that reflect more targeted or defined durations of use. FDA expects to publish this RFA, along with a list of the antimicrobial drug products affected by the duration of use issue, in early April 2019.

It is important to note that a critical step has already taken place to update the labeling of all medically important antimicrobials used in the feed or water of food-producing animals to require their use be under the oversight of licensed veterinarians. Moving forward, FDA plans to initiate a process to bring the remaining dosage forms, such as injectables, of medically important antimicrobial drugs used in animals under veterinary oversight and update the product labeling, as well. To accomplish this, FDA plans to issue a strategy on the remaining dosage forms in the form of draft guidance for industry prior to September 30, 2019.

Chairman Bishop:

I'm also encouraged by your proposal to finalize a biomass denominator to better contextualize antibiotic use and sales data.

101. Can you tell me more about your plans to advance this objective, and when we can expect to see a final methodology?

Response: As you are aware, FDA solicited public comment on a proposed method for applying a food animal biomass denominator to annual data on antimicrobials sold and distributed for use in food-producing animals in the United States. That comment period closed on November 13, 2017, and the agency received valuable feedback on the proposed U.S.-specific biomass denominator method. While many comments were not in favor of additional analysis of estimated species-specific sales data, FDA believes applying a denominator (e.g., FDA's proposed biomass method) to these data provides important context. Applying such an approach would enable FDA to adjust antimicrobial sales data to take into account the size of the animal populations potentially being treated with such drugs and would allow for a more nuanced interpretation of animal drug sales over time in a manner that is specific to U.S. animal production.

FDA's Center for Veterinary Medicine (CVM) currently expects to see the first application of a biomass denominator included in a more comprehensive report on antimicrobial stewardship that integrates and analyzes available information about antimicrobial use and resistance in animal agriculture to help assess the progress of efforts to foster antimicrobial stewardship and reduce the development of antimicrobial resistance.

As part of FDA's five-year plan to support antimicrobial stewardship in veterinary settings, the agency intends to publish such a report by the end of calendar year 2019.

Center for Tobacco Products
New Tobacco User Fees

Chairman Bishop:

102. Commissioner, FDA's FY 2020 budget request includes a proposal to collect an additional \$100 million in user fees from producers of electronic nicotine delivery systems (ENDS). How did FDA determine that \$100 million was the right level for the program? Will this number increase in future years?

Response: FDA believes that \$100 million represents an appropriate increase in resources to ensure comprehensive regulation of the changing tobacco product marketplace. \$100 million will enable FDA to expand much-needed activities for the newly regulated products in the critical areas of public education, enforcement, and research. These are programmatic areas that historically have required a significant investment by FDA and for which less than \$100 million was felt to be less impactful given what these programmatic costs have been in the past. This additional funding will support actions FDA is taking to combat youth use of tobacco products, including the epidemic of youth use of e-cigarettes, through our Youth Tobacco Prevention Plan. Overall, the Agency believes that \$100M will allow FDA to strengthen our regulatory activities

for tobacco given the new challenges we are facing, especially with the increase in youth use of e-cigarettes.

The existing tobacco user fees (\$712M) are not currently subject to inflation. FDA is requesting an inflation adjustment for all tobacco user fees to ensure that the resources can keep up with the marketplace of tobacco products.

Chairman Bishop:

103. What tools do you currently have at your disposal or can this Subcommittee provide to prevent and deter youth from accessing ENDS and other new tobacco products that are sweeping our nation? Will user fees from ENDS be utilized the same way as other tobacco product user fees? Please describe the differences, if any.

Response: FDA has numerous tools to prevent and deter youth from accessing ENDS and other new tobacco products. These include:

- Compliance and Enforcement,
- Public Education Campaigns,
- Product Review and Evaluation, and
- Issuing Regulations and Guidance.

FDA has a comprehensive compliance and enforcement program to monitor industry compliance with regulatory requirements, and to restrict access and marketing of tobacco products, including e-cigarettes, to youth. FDA ensures industry compliance by enforcing warning label and advertising requirements, and restricting sales and marketing of tobacco products to underage youth through the use of compliance inspections, warning letters, civil money penalties, and no-tobacco-sale-orders. For example, in March 2019, FDA sent warning letters to several companies for, among other violations, selling ENDS products with labeling and/or advertising that failed to include the required nicotine warning statement. Also, in March 2019, FDA requested a meeting with the corporate management of Walgreen Co. to discuss the company's track record of illegally selling tobacco products, including ENDS, to kids.

FDA's public education campaigns help educate the public—especially youth—about the dangers of regulated tobacco products. Achieving the FDA's mission to reduce tobacco-related death and disease requires a comprehensive, scientific, and innovative approach. FDA's tobacco use prevention campaigns focus on changing knowledge, attitudes and beliefs that lead to tobacco use, by following an evidence-based process to develop messages and tactics. For example, in September 2018, FDA launched “The Real Cost” Youth E-cigarette Prevention Campaign. The campaign ads run on age-verified digital platforms such as Hulu, Facebook, and Spotify, as well as “The Real Cost” campaign website.

FDA reviews new tobacco products to determine if their marketing is appropriate for the protection of the public health, or if they are substantially equivalent to existing products. Tobacco products are inherently dangerous. FDA's responsibility is to review new tobacco products to determine if they meet the appropriate statutory standard for marketing. For example, as part of the Agency's evaluation of premarket tobacco applications, FDA considers

the product's risks on the population as a whole, including tobacco product users as well as non-users.

FDA's Tobacco Program is accomplished by issuing regulations and guidance that explain FDA's expectations to regulated industry and the public. For example, FDA is considering a potential tobacco product standard regulation that would address the appeal to youth of flavors in tobacco products.

The new user fees collected for ENDS products will be used to fund FDA's tobacco regulatory activities, including the regulatory structure for these products. While each class of tobacco products is unique, all tobacco products are subject to the regulatory requirements in the Federal Food, Drug, and Cosmetic Act (FD&C), such as product listing, ingredient listing, and the adulteration and misbranding provisions of the statute. FDA is considering product-specific standards for ENDS to protect against known public health risks, such as ENDS battery issues and children's exposure to liquid nicotine. FDA also is considering a product standard for establishing limits on the level of toxicants and impurities found in certain ENDS ingredients.

Chairman Bishop:

104. How can we help to ensure that small and medium sized-businesses that provide harm reducing alternatives to adult smokers are able to cope with the regulatory costs associated with FDA regulations for these new products- specifically would some form of product standards, a risk-based approach to the Pre-market Tobacco Approval process for new tobacco products, or a small business exemption and limitation for regulatory costs be a viable solution? Will the user fees from ENDS be used to develop a different regulatory structure for these producers?

Response: FDA understands that regulated entities, especially entities that are small and/or new to regulation, need assistance in understanding how to comply with the FD&C Act and FDA regulations. The Agency is committed to providing this assistance and issuing foundational rules to make the science-based regulatory review process more efficient, predictable, transparent, and less costly for manufacturers, while upholding the agency's public health mission.

FDA has a system to assist small businesses in navigating the regulatory requirements for tobacco products. For example, FDA has a call center that triages all calls received from regulated tobacco industry. The Center's Office of Small Business Assistance (OSBA) responds to hundreds of calls, emails and correspondence from small businesses every year to assist them in answering their specific questions on how to comply with the law.

When finalizing the tobacco deeming rule, FDA recognized that small businesses would need additional time to comply with certain new regulatory requirements. Under a compliance policy announced with the final deeming rule, small-scale tobacco manufacturers, defined as those manufacturers with 150 employees or fewer and \$5,000,000 or less in annual revenues, were given additional time to comply with requirements related to tobacco health document and ingredient listing submissions, and harmful and potentially harmful constituent (HPHC) reporting.

To help streamline and simplify the tobacco product application process and potentially reduce the associated costs, FDA is encouraging the creation and use of tobacco product master files (TPMFs). For example, a flavor supplier might voluntarily submit a TPMF to FDA that contains the full listing of ingredients and composition information of different flavors. The flavor supplier could then grant a customer, for example, an e-cigarette manufacturer, the right to reference the TPMF to support the customer's premarket application for an e-cigarette that uses the supplier's flavors. When reviewing the premarket application for the e-cigarette, FDA would also review confidential ingredient and composition information in the TPMF, without that information being shared with the e-cigarette manufacturer. FDA has published a final guidance to provide information for manufacturers on how to establish and reference a TPMF.

Another way FDA has worked to streamline the product review process is to allow bundling of premarket applications for new tobacco products. For example, when groups of SE reports have identical content, they may be bundled. It is expected to take less time to prepare and submit a bundled group of similar reports, than multiple individual submissions.

FDA often grants requests from prospective modified risk tobacco product application (MRTPA) and premarket tobacco product application (PMTA) applicants for pre-submission meetings to help resolve questions about application content and organization and welcomes the opportunity to engage a manufacturer on the filing of an application for one of these e-cigarette products. FDA published "Guidance for Industry and Investigators - Meetings with Industry and Investigators on the Research and Development of Tobacco Products" that describes the process to ensure these meetings are useful and productive for industry.

FDA continues to make progress toward putting into place the scientific and regulatory foundation to efficiently and effectively implement the Family Smoking Prevention and Tobacco Control Act, including updating some of our product application review processes, gathering input from stakeholders on that process and taking steps to provide additional information about FDA's science-based review and decisions to manufacturers.

On April 2, 2019, a proposed rule that would establish requirements for the content and format of reports manufacturers must send to the Agency to demonstrate the substantial equivalence (SE) of a new tobacco product published in the Federal Register. The proposed rule also provides information as to how the agency intends to evaluate these submissions. The proposed regulation, which will be open for public comment for 75 days, would further clarify the rules of the road for what information FDA needs in order to review and potentially allow new tobacco products to come to market.

Additional information and resources for industry, including small businesses, are available on FDA's website regarding several improvements to the tobacco product application process. Specifically, FDA recently posted six appendices⁴⁰ on our website to assist manufacturers

⁴⁰<https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/default.htm>
<https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/SubstantialEquivalence/default.htm>

preparing SE Reports. These appendices, which are broken down by product type, highlight common deficiencies that may result in an unfavorable SE decision.

FDA is actively working on proposed rules regarding PMTAs and MRTPAs, which would provide further detail on the information that should be included in these applications.

FDA is taking a number of actions to provide more information to industry while work on these rules continues. In October 2018, FDA held a two-day public meeting to address common issues in applications, including PMTAs and MRTPAs, and responded to questions by industry. FDA has also made its application review decision letters public, except for information that is trade secret or otherwise confidential commercial information.

FDA published “Modified Risk Tobacco Product Applications: Draft Guidance for Industry” discussing how to organize and submit an MRTPA, what scientific studies and analyses should be submitted, and what information should be collected through post market surveillance and studies. The Agency also published “Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products” discussing who may submit a new tobacco product application under section 910 of the FD&C Act, how the review process works and what information FDA would recommend be included in the application. And finally, FDA also issued “Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems” draft guidance, which, when final, will assist persons submitting PMTAs specifically for ENDS products. It explains, among other things, products to which the guidance applies, when a PMTA is required, general procedures for review of an ENDS PMTA, information the FD&C Act requires applicants to submit in a PMTA, and what information FDA would recommend applicants submit to show whether permitting new ENDS tobacco product to be marketed is appropriate for the protection of the public health.

The new user fees collected for ENDS products would be used to fund FDA’s tobacco regulatory activities, including the regulatory structure for these products. While each class of tobacco products is unique, all tobacco products, except for accessories of newly deemed products, are subject to the regulatory requirements in the Federal Food, Drug, and Cosmetic Act (FD&C) such as product listing, ingredient listing, the adulteration and misbranding provisions of the statute. FDA is working on product-specific standards and other regulations for ENDS to protect against known public health risks such as ENDS battery issues and concerns about children’s exposure to liquid nicotine. FDA also is pursuing a product standard for establishing limits on the level of toxicants and impurities found in certain ENDS ingredients.

Tobacco Compliance and Enforcement

Chairman Bishop:

105. What factors are determined in allocating resources by state for Tobacco Retailer Inspections?

Response: In accordance with the Federal Food, Drug, and Cosmetic Act, FDA contracts, where feasible, with the States and territories to carry out inspections of retailers within that State.

Each year, FDA issues a Request for Proposals (RFP) for the Tobacco Retail Compliance Check Inspection contracts to which the states and territories submit proposals that detail their respective program structure, inspection plan, and cost. These proposals generally account for the cost of living, organizational structure of the program, resources available to dedicate to the program such as number and type of contractor staff dedicated to the program, distribution of retailers and inspectors within the state, number of inspections the state proposes to complete within the period of performance, travel costs, and other circumstances unique to each state program. FDA reviews the proposal packages to determine whether the business and technical plans fulfill the requirements in the RFP.

Chairman Bishop:

106. Please provide a table for FY 2017 and FY 2018 showing the number of inspectors (FTE) by state, the amount of funding for each state, the number of retail inspections performed by state, the number of warning letters by state, the number of civil money penalties by state, and the number of No-Tobacco-Sale-Orders by state in rank from greatest to least based upon the number of inspectors in each state.

Response: In FY 2018, OCE continued its implementation of the Tobacco Retail Inspection Program. This work includes re-awarding contracts to conduct FDA compliance check inspections of retail establishments in the U.S. States, Territories, and Tribal jurisdictions that sell regulated tobacco products. Where FDA is unable to contract with a state or territorial government agency for compliance check inspections, FDA utilizes alternative options, such as contracting with other entities to coordinate inspections or using FDA staff to conduct inspections. Please note that the table below includes funding for contracts to States, Territories, and other entities to conduct or coordinate retail inspections.

FDA commissions inspectors working under these contracts to conduct tobacco compliance check inspections using the processes and procedures outlined through nationwide inspector training. Currently, there are more than 800 active inspectors. The number of inspectors and whether they are full-time or part-time, varies from state-to-state based on the way each state has proposed to structure the inspections under the contract. That makes providing the FTE data you requested more difficult to provide in such a format.

Many States are under a cost-reimbursement structured contract in which inspector time is reported and reimbursed based on the actual time spent working on the contract. There are factors that can impact the FTE's utilized under a contract for a given year or time of year. Examples of these include recent and past natural disasters within the states and U.S. territories which can hinder inspections, increased inspections when the minors have greater availability (i.e., during the summer and school holidays) or when seasonal businesses are open (such as beach or ski resorts), and decreased inspections when travel is extremely limited in some states during certain times of the year. Although state programs may estimate yearly time/salary for each inspector, these factors can contribute to that time varying throughout the year.

The tables below contain the rest of the retail inspection contract data requested.

FDA Tobacco Retailer Inspection Contracts Annual Funding by State

State/Territory	Fiscal Year 2017	Fiscal Year 2018
Alabama	\$1,263,693.00	\$1,326,880.00
Alaska	\$260,499.17	\$265,707.80
Arizona	\$561,113.39	\$561,113.39
Arkansas	\$861,310.36	\$889,338.45
California	\$5,052,268.00	\$5,134,174.00
Colorado	\$1,494,056.36	\$1,498,516.46
Connecticut	\$1,144,192.00	\$1,198,424.00
Delaware	\$474,964.02	\$499,641.92
Florida	\$899,948.16	\$917,927.04
Georgia	\$643,818.86	\$618,743.37
Hawaii	\$501,754.00	\$523,741.00
Idaho	\$1,137,164.00	\$208,761.00
Illinois	\$1,455,309.00	\$1,533,575.00
Indiana	\$904,659.66	\$931,802.61
Iowa	\$546,698.27	\$561,508.74
Kansas	\$336,844.83	\$346,538.18
Kentucky	\$631,406.95	\$642,219.95
Louisiana	\$485,358.48	\$495,048.12
Maine	\$612,016.00	\$634,066.00
Maryland	\$1,044,523.00	\$1,098,366.00
Massachusetts	\$1,002,860.00	\$1,042,768.44
Michigan	\$1,380,364.00	\$1,537,557.00
Minnesota	\$906,818.00	\$927,216.00
Mississippi	\$833,806.24	\$833,809.24
Missouri	\$637,182.00	\$646,638.00
Montana	\$184,185.00	\$250,388.00
Nebraska	\$250,191.78	\$255,194.04
Nevada	\$0.00 ⁴¹	\$262,258.00
New Hampshire	\$211,157.12	\$215,163.92
New Jersey	\$1,762,978.48	\$2,259,732.35
New Mexico	\$516,399.21	\$518,206.25
New York	\$735,937.48	\$750,616.68
North Carolina	\$1,218,417.00	\$1,162,878.00
North Dakota	\$220,636.62	\$225,047.38
Ohio	\$2,836,153.26	\$2,899,614.86
Oklahoma	\$328,275.18	\$334,836.57

⁴¹ In FY 2017, FDA did not have a Tobacco Retail Inspection contract for tobacco retail inspections to be conducted in Nevada. In FY 2017, FDA inspectors conducted retail inspections in Nevada.

State/Territory	Fiscal Year 2017	Fiscal Year 2018
Oregon	\$0 ⁴²	\$339,149.80
Pennsylvania	\$976,020.00	\$999,840.00
Rhode Island	\$528,368.00	\$532,605.00
South Carolina	\$2,302,783.10	\$380,008.15
South Dakota	\$206,168.04	\$210,292.82
Tennessee	\$389,231.12	\$397,008.88
Texas	\$1,665,667.00	\$1,711,056.00
Utah	\$198,663.80	\$202,639.16
Vermont	\$332,484.82	\$174,002.84
Virginia	\$1,152,089.92	No Award
Washington	\$1,324,224.37	\$1,339,444.00
West Virginia	\$863,139.38	\$863,484.10
Wisconsin	\$1,387,685.00	\$1,432,937.00
Wyoming	\$206,390.15	\$210,517.56
American Samoa	\$147,387.00	\$147,405.00
Northern Mariana Islands	\$0.00	No award
Guam	\$249,860.91	\$250,168.71
Puerto Rico	\$895,881.43	No Award
U.S. Virgin Islands	\$179,068.00	\$181,800.00
Washington, DC	\$225,791.24	\$197,200.20

⁴² In FY 2017, FDA did not have a Tobacco Retail Inspection contract for tobacco retail inspections to be conducted in Oregon.

FDA Tobacco Retailer Inspection Program
Total Inspections and Enforcement Actions by State⁴³

Fiscal Year	State/Territory	Warning Letter	CMP	NTSO	Total Inspections
FY17	Alabama	245	23		4433
FY17	Alaska	19	20		511
FY17	American Samoa	6	5		265
FY17	Arizona	252	109		1675
FY17	Arkansas	188	53		3607
FY17	California	135	32		4423
FY17	Colorado	363	141	1	4220
FY17	Connecticut	317	118	5	3866
FY17	Delaware	113	8		817
FY17	District of Columbia	96	56		604
FY17	Florida	1486	980	3	14972
FY17	Georgia	118	13		2710
FY17	Guam	28	5	1	330
FY17	Hawaii	14	2		240
FY17	Idaho	112	25	1	2216
FY17	Illinois	489	166	1	3786
FY17	Indiana	470	239	5	4855
FY17	Iowa	131	24		2450
FY17	Kansas	167	28		2268
FY17	Kentucky	178	58		3243
FY17	Louisiana	369	133		4759
FY17	Maine	75	10		2510
FY17	Maryland	143	103	3	2253
FY17	Massachusetts	383	148	1	6303
FY17	Michigan	582	542	18	5117
FY17	Minnesota	266	117	1	6012
FY17	Mississippi	193	65		4081
FY17	Missouri	508	369	3	4528
FY17	Montana	49	2		1182
FY17	Nebraska	174	93	1	2356
FY17	Nevada	18	6		160 ⁴⁴
FY17	New Hampshire	69	52		539
FY17	New Jersey	526	222	4	4879
FY17	New Mexico	110	2		393
FY17	New York	746	232		8060

⁴³ Inspections conducted on tribal land are included in the data for the state within which the tribal land is located.

⁴⁴ FY17 inspections in Nevada were conducted by FDA Inspectors.

Fiscal Year	State/Territory	Warning Letter	CMP	NTSO	Total Inspections
FY17	North Carolina	339	98		3186
FY17	North Dakota	40	36		335
FY17	Northern Mariana Islands				1
FY17	Ohio	878	17		3210
FY17	Oklahoma	193	152	2	1020
FY17	Oregon				0
FY17	Pennsylvania	547	223	3	5266
FY17	Puerto Rico	942	356		3741
FY17	Rhode Island	57	46	1	1115
FY17	South Carolina	624	291	3	8604
FY17	South Dakota	104	110		951
FY17	Tennessee	168	39		1992
FY17	Texas	293	131	1	5496
FY17	Utah	30	6		1079
FY17	Vermont	54	16		941
FY17	Virgin Islands	2	1		130
FY17	Virginia	202	65		2768
FY17	Washington	529	303	2	8659
FY17	West Virginia	191	109	1	2665
FY17	Wisconsin	331	141		2234
FY17	Wyoming	69	57		743
FY18	Alabama	261	28		2780
FY18	Alaska	12	3		271
FY18	American Samoa	36	1		174
FY18	Arizona	245	52		1780
FY18	Arkansas	186	21		4019
FY18	California	84	9		2206
FY18	Colorado	298	35	4	3733
FY18	Connecticut	287	62	6	3035
FY18	Delaware	173	35		1053
FY18	District of Columbia	60	9		447
FY18	Florida	1384	548	6	10069
FY18	Georgia	63	3		2740
FY18	Guam	5	2		298
FY18	Hawaii	9	1		304
FY18	Idaho	148	23		2728
FY18	Illinois	361	71		2549
FY18	Indiana	333	164	8	5164
FY18	Iowa	143	12		2476

Fiscal Year	State/Territory	Warning Letter	CMP	NTSO	Total Inspections
FY18	Kansas	118	15		2026
FY18	Kentucky	172	14	1	3176
FY18	Louisiana	404	110		4046
FY18	Maine	84	7		1732
FY18	Maryland	276	88	4	2000
FY18	Massachusetts	383	90	1	6657
FY18	Michigan	696	316	3	4479
FY18	Minnesota	291	53		4490
FY18	Mississippi	208	33		3314
FY18	Missouri	521	182	5	4236
FY18	Montana	28	6		1193
FY18	Nebraska	78	26	1	996
FY18	Nevada	15	4		83
FY18	New Hampshire	52	19	2	601
FY18	New Jersey	278	79	3	4281
FY18	New Mexico	56	4		794
FY18	New York	359	86		5753
FY18	North Carolina	525	104	1	3008
FY18	North Dakota	60	14		329
FY18	Northern Mariana Islands				0
FY18	Ohio	1569	431		8729
FY18	Oklahoma	124	17		1161
FY18	Oregon	123	1		1239
FY18	Pennsylvania	310	108		3637
FY18	Puerto Rico				145
FY18	Rhode Island	68	13	1	1036
FY18	South Carolina	769	215	1	7989
FY18	South Dakota	58	31		460
FY18	Tennessee	330	22		1995
FY18	Texas	514	71	1	6262
FY18	Utah	24	4		446
FY18	Vermont	54	9		846
FY18	Virgin Islands				2
FY18	Virginia	334	26		2707
FY18	Washington	515	117	2	5493
FY18	West Virginia	169	45	4	2521
FY18	Wisconsin	344	76		2286
FY18	Wyoming	27	6		405

Chairman Bishop:

107. Please describe the tobacco enforcement actions FDA has taken in FY 2018 with regards to the electronic vapor market and the “secondary” market for these products, specifically with regards to online retailers?

Response: FDA conducts surveillance of websites, social media, magazines and other publications that sell and/or advertise regulated tobacco products in the U.S. market. In FY 2016, FDA began surveillance of websites that sell deemed tobacco products, including electronic nicotine delivery system (ENDS) products and took compliance actions when violations were found. As of September 30, 2018, FDA has issued over 680 warning letters as a result of these surveillance activities. In FY 2018 alone, more than 115 warning letters were issued.

In FY 2018, as part of the Youth Tobacco Prevention Plan, FDA took multiple actions to stop youth use of, and access to, JUUL and other e-cigarette products. For example, FDA conducted a nationwide blitz to crack down on the sale of e-cigarettes to minors at both brick-and-mortar and online retailers, and subsequently issued more than 1,300 warning letters and civil money penalty complaints to retailers who illegally sold e-cigarette products to minors. FDA also partnered with the Federal Trade Commission (FTC) to issue warning letters to manufacturers, distributors, and retailers for selling e-liquids used in e-cigarettes with labeling and/or advertising that cause the products to imitate food products, particularly ones that are marketed toward, and/or appealing to children such as juice boxes, candy, or cookies—some of them with cartoon-like imagery. Further, FDA requested that certain e-cigarette manufacturers submit documents to help the Agency better understand the reportedly high rates of youth use and youth appeal of e-cigarette products, and also issued letters to the manufacturers of five top-selling vape product brands asking each company to submit plans addressing youth access and use of their products. The Agency also investigated e-cigarette companies that may have been illegally marketing their products to youth. Finally, FDA contacted eBay to raise concerns over several listings of JUUL products listed for sale on their website, which appeared to be inconsistent with eBay’s policy on tobacco products. As a result, eBay removed the listings and voluntarily implemented measures to prevent future listings from being posted on their website.

Throughout FY 2018, FDA took many more similar actions against retailers for selling e-cigarettes and other tobacco products to minors. In total, FDA conducted 146,377 inspections of retail establishments that sell tobacco products, issued 14,024 warning letters to retailers for violating the law, and initiated about 3,522 civil money penalty cases. FDA also issued more than 50 No-Tobacco-Sale Orders, which results in retailers being prohibited from even selling tobacco products for specified periods of time.

Menthol Cigarettes

Chairman Bishop:

108. Commissioner, what considerations has FDA made with respect to the potential black market effects of banning menthols cigarettes? It is your believe that menthol smokers will just quit? Assuming they won’t, has there been any research by FDA to better determine the black market implications of an outright ban?

Response to questions 108 - 112: Menthol-flavored products represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes. The menthol serves to mask some of the unattractive features of smoking that might otherwise discourage a kid from smoking. Moreover, menthol products disproportionately and adversely affect underserved communities. As a matter of public health, menthol products exacerbate troubling disparities in health related to race and socioeconomic status that are of major concern to the Agency.

According to the National Youth Tobacco Survey (NYTS), in 2018, 46.1 percent of current high school cigarette smokers reported smoking menthol cigarettes. Among middle school students, 42.0 percent of current smokers in 2018 reported smoking menthol cigarettes. Of note, there are large differences in menthol cigarette smoking by race/ethnicity. In 2018, among middle and high school students who are current cigarette smokers, 51.4 percent of non-Hispanic Blacks report smoking menthol cigarettes, compared to 42.8 percent of non-Hispanic Whites, and 50.6 percent of Hispanics. These differences by race/ethnicity have remained steady since at least 2011. While declines in menthol cigarette use have been observed among non-Hispanic White youth, those declines have not been observed among non-Hispanic Black youth or Hispanic youth.

In November, FDA announced its intention to advance a notice of proposed rulemaking that would prohibit menthol in cigarettes and a notice of proposed rulemaking that would prohibit characterizing flavors (including menthol) in cigars. FDA continues to gather evidence and data on an ongoing basis regarding tobacco products, including tobacco products with menthol additives. FDA is focused on implementing a science-based, comprehensive approach to tobacco and nicotine regulation.

Chairman Bishop:

109. Do you agree that a ban on menthol cigarettes could stretch an already overburdened law enforcement system? Enforcing laws against tobacco contraband is expensive. Black market tobacco products are already a serious problem for law enforcement, and a ban on menthol cigarettes would add to the issue. Many urban communities are already dealing with the devastating effects of unemployment, poverty, failing schools, and the “war on drugs.” They do not need a “war on menthol” on top of these problems.

Response: Please see response to question 108.

Chairman Bishop:

110. You cite youth usage as a main reason for the menthol ban, but have you considered that a ban on menthol could actually exacerbate the problem? Contraband cigarettes on a black market would be cheap and readily available without proof of age. In addition, we need to think about those products being manufactured without federal regulation. There will be no guarantee on what will actually constitute the counterfeit menthol cigarettes sold.

Response: Please see response to question 108.

Chairman Bishop:

111. Have you considered the effects a ban on menthol would have on state revenues, state economies, and local businesses? Banning menthol cigarettes would drive sales underground and greatly harm the states' ability to tax a substantial portion of the cigarette market. The loss of state and local taxes will mean even more restricted budgets for our local and state governments. To add to that, local businesses and state economies also would suffer. Tobacco products are top-selling items for convenience stores and draw purchasers who end up buying other items, like home goods, snacks, coffee and other items. Further, because of menthol cigarettes' large market share, many tobacco employees would lose their jobs.

Response: Please see response to question 108.

Chairman Bishop:

112. Have you considered that because the majority of adult African-American smokers smoke menthol cigarettes, a ban likely would engender resentment within the African-American community over attitudes that led to (inadvertently or not) the targeting of their tastes in the interests of "health?" A ban also would disproportionately impact businesses in African-American communities dependent on sales of menthol cigarettes.

Response: Please see response to question 108.

Question for the Record from Rep. Barbara Lee of California
Menthol use in African Americans

Rep. Lee:

Commissioner, you announced in November that FDA would issue a proposed rule that would remove both menthol cigarettes and flavored cigars from the marketplace. This is something I strongly support and it is long overdue.

As you know, menthol cigarettes disproportionately harm communities of color. 85% of African Americans use menthol cigarettes compared to 29% of white smokers. In fact, the FDA's own Scientific Advisory Committee found that African American menthol smokers were significantly less likely to quit smoking than white non-menthol smokers. And most recently, your own research with the NIH shows that African Americans have a genetic vulnerability to menthol cigarette use.

It's been 3 months has the FDA announced it would issue a notice of proposed rulemaking to prohibit menthol. By what date can we expect FDA to publish a rule in the Federal Register?

113. Could you also please speak to the evidence and the science FDA has that led to your November announcement? Why will the public health – and African Americans and other racial and ethnic minorities in particular – benefit from these products being removed from the marketplace?

Response: Menthol-flavored products represent one of the most common and pernicious routes by which kids initiate on combustible cigarettes. The menthol serves to mask some of the unattractive features of smoking that might otherwise discourage a kid from smoking.

Moreover, menthol products disproportionately and adversely affect underserved communities. As a matter of public health, menthol products exacerbate troubling disparities in health related to race and socioeconomic status that are of major concern to the Agency.

According to the National Youth Tobacco Survey (NYTS), in 2018, 46.1 percent of current high school cigarette smokers reported smoking menthol cigarettes. Among middle school students, 42.0 percent of current smokers in 2018 reported smoking menthol cigarettes. Of note, we see large differences in menthol cigarette smoking by race/ethnicity. In 2018, among middle and high school students who are current cigarette smokers, 51.4 percent of non-Hispanic Blacks report smoking menthol cigarettes, compared to 42.8 percent of non-Hispanic Whites, and 50.6 percent of Hispanics. These differences by race/ethnicity have remained steady since at least 2011. While declines in menthol cigarette use have been observed among non-Hispanic White youth, those declines have not been observed among non-Hispanic Black youth or Hispanic youth.

On March 21, 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) to seek data, research, and information from all stakeholders to inform the Agency's process for examining the role that flavors, including menthol, play in the initiation, use, and cessation of tobacco products. This built on the Agency's past efforts to examine the use of menthol in cigarettes.

In November, FDA announced its intention to advance a notice of proposed rulemaking that would prohibit menthol in cigarettes and a notice of proposed rulemaking that would prohibit characterizing flavors (including menthol) in cigars. The proposed rules are currently in development at FDA. FDA continues to gather evidence and data on an ongoing basis regarding tobacco products, including tobacco products with menthol additives. FDA is focused on implementing a science-based, comprehensive approach to tobacco and nicotine regulation.

Question for the Record from Rep. Henry Cuellar of Texas
Premium Cigar Industry

Rep. Cuellar:

I would like to first commend the work you and the Center for Tobacco Products have and continue to do to address e-cigarettes and cheap, flavored tobacco products that studies have repeatedly found are utilized by America's youth. I am concerned, however, that the broad nature of the deeming rule regulations are crippling businesses that manufacture and sell hand-made premium cigars. San Antonio is home to one of America's oldest cigar shops, Finck's Cigars, which began in 1893. In 2014, after 121 years manufacturing hand-made cigars, Finck's San Antonio manufacturing closed due to the looming regulations. Without modification to the scope of the deeming rule provisions applicable to hand-made premium cigars, I fear more manufacturing and retailing operations will similarly be unable to remain in business serving their adult customers. I am aware FDA sought and received public comments from industry and other interested parties on this subject last year.

114. How can modifications be made to ensure the deeming rule addresses youth-oriented products but does not unfairly burden small adult-oriented businesses?

Response: As part of the Agency's comprehensive plan for regulation of nicotine and tobacco, in March 2018, FDA issued an advance notice of proposed rulemaking (ANPRM) to provide an opportunity for the public to provide new information for the Agency to consider in the regulation of "premium" cigars. In particular, the Agency sought comments and scientific data related to how to define a "premium" cigar and the patterns of use and resulting public health impacts from these products. The Agency is currently considering over 32,000 comments received in response to the ANPRM.

In addition, FDA has provided and will continue to provide assistance to regulated entities, including small businesses. FDA's Center for Tobacco Products has a dedicated Office of Small Business Assistance, which has responded to hundreds of questions since the deeming regulation published and continues to respond to questions from industry, including small businesses.

TUESDAY, MARCH 12, 2019.

OFFICE OF THE INSPECTOR GENERAL

WITNESSES

PHYLLIS K. FONG, INSPECTOR GENERAL, USDA

**GIL H. HARDEN, ASSISTANT INSPECTOR GENERAL FOR AUDIT, USDA
OFFICE OF INSPECTOR GENERAL**

**ANN COFFEY, ASSISTANT INSPECTOR GENERAL FOR INVESTIGA-
TIONS, USDA OFFICE OF INSPECTOR GENERAL**

OPENING STATEMENT BY MR. BISHOP

Mr. BISHOP. The subcommittee will come to order. Let me say good afternoon and let me apologize for my delay. There was a moment of silence in remembrance of the 23 people who lost their lives in the tornado in Alabama on March 3. That tornado, of course, killed 23 people in Lee County, Alabama, which is adjacent to my district, but the tornado also came across from Alabama, the west side in Alabama, the Chattahoochee River over into Harris County and into Talbot County, which is in my congressional district.

And I was standing with my colleagues from Alabama as we remembered and had our thoughts and prayers going out to those people impacted. So I apologize for keeping you waiting, but I think it was for a worthy cause, and I appreciate your patience.

Let me just welcome everyone to today's hearing, especially our witnesses. Ms. Fong, Mr. Harden, Ms. Coffey, thank you for appearing before us again. I have an abiding interest in your work and in what you do. We have to do everything that we can possibly do to eliminate fraud, waste, and abuse and mismanagement. And we have to do all we can to assure that USDA programs, over which our subcommittee has oversight, are operated with the best possible efficiencies in order to create the best possible outcome for those who use the agency.

I was particularly pleased to see your annual plan for fiscal year 2019 focuses on many of the concerns that the subcommittee has, from enforcement of the Animal Welfare Act to food safety threats to oversight of disaster assistance programs. We rely on you to conduct audits and investigations to ensure that the programs we fund are run efficiently and that issues are addressed in a timely manner.

While I am glad that you have an active oversight profile, I do have some concerns about the number of recommendations that remain open and the agency's efforts to close them out. Based on your last semiannual report, there are recommendations pending final agency actions going back to 2005. We would like to hear your thoughts on how to incentivize the agency to act.

So today I would like to hear more about your plans to conduct adequate oversight of USDA programs as well as the challenges that you face in ensuring agreed-upon recommendations are implemented. In addition, I want to ensure that civil rights issues are getting thoughtful and appropriate attention throughout USDA. I look forward to discussing that with you as well as other important issues, and I thank you again to you and to all of the OIG staff for all that you do.

Now let me ask our distinguished ranking member, Mr. Fortenberry, if he has any opening remarks, and I would like to recognize him at this time.

OPENING STATEMENT BY MR. FORTENBERRY

Mr. FORTENBERRY. Yes, sir. Thank you, Mr. Bishop, Chairman Bishop.

And we appreciate all of your willingness to appear before us today. Ms. Fong, nice to see you again. I think the last time we had direct interaction was on the Agriculture Subcommittee on Nutrition, but I really do appreciate your intensive work and the entire team here, am very grateful.

You have a very experienced team, and obviously we are looking forward to your testimony today to understand the progress that you have made to correct any problems, policies, or practices that may be of concern. So that is the primary intent that I have to learn more about what you are doing today.

On the one hand, you are our police force out there, making sure that billions are spent legally and effectively. On the other hand, you must audit the programs managed by 29 agencies to ensure that they are operating as designed, everything from commodity to conservation to school meal programs to rural development loans. You have a big portfolio.

I would like to delve a little bit deeper into a couple major areas of your work, particularly the investigative work involving fraud and waste and any abuse of taxpayer funds as well as the audit work which helps determine if USDA programs are operating as designed and if you think we need to be in more robust partnership with you in that regard.

While certainly the vast, vast majority of farmers and ranchers and participants in Nutrition Assistance Programs are honest people, someone out there will always try to game the system, which makes your work all the more important. And, frankly, sometimes I am amazed at the amount of scheming that certain people will do to commit fraud, as in your testimony you point out one Detroit store defrauded the WIC program alone by \$2 million.

Someone else stole \$174.7 million from the Rural Business-Cooperative Service, as I understand it, Business Industry Loan Program. So I will be very interested to hear what tools you have in place to identify and act upon these types of fraud and abuse situations sooner. It is not just about improper use of taxpayer dollars. When this type of activity happens, it actually takes money away from those in need who we are actually trying to help. That is what is so deeply abusive and scandalous here.

One program in particular, I want to talk about food safety and bring this to your attention, and why a producer was able to break

the law and put millions of pounds of meat and poultry into the marketplace without safety inspection and not be caught for years. I think this would be a good thing to delve deeper into, and maybe we can revisit that after your testimony.

So it is my understanding that for the year the budget request is \$98.2 million, the same level of funding you received last year. Of course, we will decide if your agency deserves or—and you can point out if you desire more resources to oversee such a massive portfolio, although there are \$200 billion in assets.

So, again, Ms. Fong, your real dedication to public service speaks for itself, and we are grateful to have you and your impressive team here.

Thank you so much, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you, Mr. Fortenberry.

And before Ms. Fong begins, a reminder to members that, as is customary with our subcommittee, members will be recognized by seniority for those who were here when I gaveled the hearing to order and then in the order of arrival after that. I will alternate majority/minority members and we will adhere to the 5-minute rule.

Ms. Fong, without objection, your entire written testimony will be included for the record. And I recognize you now for your statement, and then we will proceed with questions. You may summarize or you may give the entire statement. It is completely up to you.

OPENING STATEMENT BY MS. FONG

Ms. FONG. Thank you very much, Mr. Chairman and Ranking Member Fortenberry and members of the committee. It is a real pleasure to be here again this year to talk with you about our work at USDA, and we appreciate your invitation.

I want to start out by thanking this subcommittee for the support that you have given us over the years. In addition to our fiscal year 2019 funding level, which is very helpful to us, you also included the OIG in the disaster recovery supplemental last year, and that has been very, very helpful to us in terms of planning oversight of the Department's disaster work. So we appreciate that ongoing support.

And as you all know—you have referenced it—our job within USDA OIG is to help the Department deliver its programs more effectively and with integrity. And we do that through a number of different products, and I think today we may be able to highlight some of the new approaches that we are taking in addition to audit and investigation. But in the end, as you mention, we make recommendations, and it is up to the Department officials to implement those recommendations that they see fit to implement. And I think that is where the rubber really hits the road.

As you have my written statement, you see the range of things that we are working on. So I just want to mention a few highlights that struck me as we were preparing for this hearing. I want to emphasize that the safety of USDA employees is a very significant and top priority for our office. We recently issued an audit report on sexual misconduct and harassment concerns in Region 5 of the Forest Service and what the Forest Service is doing to address

those issues. But I want to highlight the fact that these issues and our work extend beyond the Forest Service.

Within USDA as a whole, we want to send the message that we take very seriously any allegation or complaint of sexual misconduct. Our investigators can and do respond immediately in many instances to allegations of sexual assault and other criminal misconduct, and we have had some very good results, very quick results working with Federal prosecutors in some of these cases.

Turning to another part of USDA, as has been mentioned, we do focus significant resources on oversight of SNAP and the Nutrition Programs. And we are in the middle of issuing a series of reports on the summer food summer feeding program, which provides meals to students during the summer when school is not in session. We have a series of audit reports in this area as well as very significant investigative results due to bad actors in this program.

Finally, I want to note we have summarized a number of reports in the farm Program, Conservation Program, and Rural Development, as well as Crop Insurance, and we also focus quite bit of attention on management issues affecting the Department as a whole, namely financial management, financial statements, cybersecurity and improper payments. Progress in these areas requires continued attention by all of us.

So, in closing, I want to thank the subcommittee for your support, your ongoing interest in our work, and we look forward to responding to your questions.

[The information follows:]

**Statement by
Phyllis K. Fong
USDA Inspector General
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

Introduction

Good afternoon, Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee. Thank you for the opportunity to testify regarding the Office of Inspector General's (OIG) budget for fiscal year (FY) 2020. My statement will highlight OIG's recent audit and investigative work that demonstrates our commitment to promoting the economy, efficiency, effectiveness, and integrity of the Department of Agriculture's (USDA) programs and operations.

OIG conducts audits and investigations to detect and prevent fraud and abuse in USDA's programs and operations. We also make recommendations to improve how USDA's programs operate. During FY 2018, our audit and investigative work resulted in potential monetary results totaling more than \$368 million.

OIG conducts audits to determine if programs functioned as anticipated, if program payments reached intended recipients, and if programs achieved their intended purposes. For FY 2018, we issued 42 final audit reports and made 203 recommendations to strengthen and improve USDA programs and operations. Overall, our audit work during this period has produced more than \$42 million in potential efficiencies. OIG also planned and completed investigations of individuals and entities suspected of USDA program abuse, as well as other criminal activities such as significant thefts of Government property or funds, bribery, extortion, smuggling, and assaults on employees. In some of these investigations, we partnered with Federal, State, and local law enforcement agencies to achieve maximum results in identifying and prosecuting illegal activity. Our investigations have resulted in fines and imprisonment for those convicted of wrongdoing, disqualification from USDA-administered and other Federal programs, and administrative action against USDA employees engaged in misconduct.

During this period, OIG's investigations led to 541 convictions, with potential results totaling more than \$326 million.

OIG also utilizes advanced data analytics to support and enhance our audits and investigations. During FY 2018, our Office of Data Sciences (ODS) has participated in a total of 52 audits and investigations.

Strategic Goal 1—Safety, Security, and Public Health

OIG's first priority is to help strengthen USDA's ability to protect safety, security, and public health. Our work reflects these endeavors and focuses on issues such as employee safety, national security, cybersecurity, and food safety inspection activities.

Safety

We regard the safety of USDA employees as one of our most important responsibilities. In response to a request from Members of Congress, OIG provided oversight for the Forest Service's (FS) Pacific Southwest Region as it addressed concerns about sexual harassment or retaliation against employees who alleged mistreatment. In February 2019, we issued our final report, which evaluated whether the actions FS took in response to complaints of sexual misconduct and sexual harassment were:

(1) effectively implemented as outlined in the joint agreement with USDA and (2) sufficiently addressed workplace concerns. We reviewed 11 cases of substantiated allegations of sexual harassment and sexual misconduct from FYs 2013–2017 and found at least 2 cases in which former supervisors did not inform FS hiring officials about employees' prior histories of misconduct. These employees were later selected for supervisory positions in other regions. We also reviewed intake forms for 125 complaints of sexual harassment or sexual misconduct for FYs 2014–2017, and found that 18 of these cases were not reported by FS managers or supervisors within the required 24-hour timeframe. In addition, we found that in 13 of these 18 cases, FS took no action against the management officials who failed to timely report these allegations. Lastly, we found that, for 4 of the 11 cases we reviewed where the allegations of sexual harassment and sexual misconduct were substantiated, the decided action was less than the corresponding penalty listed in the *USDA Guide for Disciplinary Penalties*.¹ Though deviating from recommended penalties is allowed, in three of the cases FS officials did not adequately document their

¹ USDA, *Department Personnel Manual*, Chapter 751, Appendix A, "USDA Guide for Disciplinary Penalties" (June 29, 1994).

justification for deviating from the penalty outlined in the Guide. We recommended that FS improve its training and guidance for handling these types of allegations and any subsequent disciplinary action. FS officials generally agreed with our recommendations.

Security

OIG has recently evaluated USDA's prevention, detection, and response concerning agroterrorism. Specifically, we reviewed steps that three USDA agencies—the Animal and Plant Health Inspection Service (APHIS), the Agricultural Research Service (ARS), and the Food Safety and Inspection Service (FSIS)—took to prepare for threats to national security that could result in human illness and death, destruction of crops and livestock, or economic loss to farmers and ranchers. We found that, while these agencies developed plans and initiated actions to prevent, detect, and respond to agroterrorism threats or attacks, they did not have information readily available to respond to the USDA Office of Homeland Security's (OHS) requests for information. OIG identified improvements these three USDA agencies can make to further their emergency preparedness, including tracking and implementing corrective actions from emergency response exercises or actual incidents. All three agencies generally agreed with our recommendations and OHS stated that our recommendations should bolster its efforts to oversee USDA's agroterrorism preparedness.

OIG has also evaluated USDA's 2018 compliance with the Federal Information Security Modernization Act of 2014 (FISMA).² As required by law, we reviewed USDA's ongoing efforts to improve its information technology (IT) security program and practices. We found that while USDA continues to take positive steps to improve its IT security posture, many longstanding weaknesses remain. In FYs 2009–2017, we made 67 recommendations for improving the overall security of USDA's systems—47 recommendations were completed and 20 open recommendations are overdue, which is an improvement over 27 open recommendations in FY 2017. Our testing showed that weaknesses still exist in six of the closed recommendations, and we have issued eight new recommendations based on security weaknesses identified in FY 2018. Due to these existing security weaknesses, we continue to report a material weakness in USDA's IT security that should be included in the Department's Federal

² Federal Information Security Modernization Act of 2014, Pub. L. No. 113-283, 128 Stat. 3073.

Financial Integrity Act (FMFIA) report. The Department generally agreed with our findings and stated it has developed corrective actions and project plans to address prior year recommendations.

Public Health

Oversight of USDA's food safety programs is a top priority for OIG. We recently completed an extensive criminal investigation after the massive recall of more than 1 million pounds of meat and poultry. The case revealed that the California facility in question had been processing millions of pounds of meat that bypassed required safety inspections for years. In addition, the facility mislabeled products at a second location, which enabled uninspected products to be sold to the public as if they had passed inspection. The corporation and its owners and operators were sentenced to a total of 60 months of probation, required to abide by a compliance program plan, and ordered to pay a \$1 million fine and a \$400 special assessment fee for illegally processing meat and poultry products.

Future Work

ODS will be leading a cross-unit OIG team to respond to a Congressional request regarding how to measure FS' progress to address workplace concerns regarding sexual harassment and sexual misconduct. We are assessing the state of oversight work and plan to review related findings and recommendations to help identify standards, guidance, or best practices that agencies can use to measure progress in this area.

We are also conducting a review to determine if USDA has adequate controls in place to protect IT resources, such as Government-issued computers, mobile devices, and the USDA network, from inappropriate use.

Goal 2—Integrity of Benefits

Our second strategic goal is to help reduce USDA program vulnerabilities and strengthen program integrity in the delivery of USDA benefits that support nutrition, rural development, and agricultural production.

Before I discuss our most recent audit and investigative results under this strategic goal, I would like to thank this Subcommittee for the funding provided to OIG as part of the Disaster Supplemental Bill.³ This funding has helped us plan and initiate oversight activities related to USDA disaster relief efforts. In FY 2018, OIG initiated a review of the Food and Nutrition Service's (FNS) disaster relief efforts to provide nutrition assistance to Puerto Rico and address conditions arising from Hurricanes Irma and Maria. We are also currently evaluating controls over two disaster relief programs at the Farm Service Agency (FSA): the 2017 Wildfires and Hurricanes Indemnity Program and the Emergency Assistance for Livestock, Honey Bees, and Farm-Raised Fish Program. ODS is actively involved in these reviews through the development of interactive disaster fund distribution maps using geographic information system technology.

Food and Nutrition Assistance Programs

As an example of our recent work to promote the integrity of nutrition benefits, OIG performed multiple reviews of FNS' controls over its Summer Food Service Program (SFSP) that have, to date, resulted in four interim reports and three final reports. Due to the scope of this project, we approached this work in multiple phases, beginning with a nationwide review, followed by four State-based reviews, and then a consolidation of the States' findings. Phase 1 of our review focused on management improvement, whereas Phase 2 focused on the integrity of benefits in four States—California, Florida, New York, and Texas. As a result of our work in Phase 1, we generally found that FNS' monitoring and oversight procedures do not sufficiently substantiate that States are properly administering SFSP and complying with program requirements. Specifically, management evaluation reviews—FNS' primary tool for ensuring SFSP integrity—lacked the necessary documentation to confirm whether these reviews were completed correctly and contained valid conclusions. Secondly, we found that FNS had not adequately assessed SFSP's risk for improper payments because it based the program's risk assessments on information that was "readily available" versus what would have come from a comprehensive program review. Thirdly, we found that FNS waived SFSP regulatory requirements on a nationwide basis through policy memoranda without following documentation requirements set by law. As an example of our work in Phase 2, we found that a State agency did not adequately assess sponsor eligibility nor monitor sponsor compliance with program requirements. Also, we found that sponsors generally did not

³ Further Additional Supplemental Appropriations for Disaster Relief Requirements Act, 2018, Pub. L. No. 115-123, div. B, subdiv. 1, tit. I.

ensure their sites complied with regulatory requirements and that sites across California and New York improperly counted a total of 166 meals for reimbursement on the day of our site visits. FNS generally concurred with our recommendations from these separate audits. However, our work continues—OIG is completing the last of the State-based reports as well as our “final phase” report, which consolidates our State findings.

OIG devotes a considerable amount of investigative resources to identifying and prosecuting fraud in nutrition assistance programs. For example, OIG recently partnered with the Federal Bureau of Investigation (FBI) to investigate a Detroit store owner with a previous conviction for food stamp trafficking in Florida. Throughout the investigation, the individual purchased Supplemental Nutrition Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) benefits in exchange for cash, cigarettes, and other ineligible items, ultimately committing \$2 million in WIC fraud alone. The retailer was sentenced to 41 months in prison, followed by 36 months of supervised release, and ordered to pay a \$100 fine and approximately \$2.3 million in restitution.

ODS actively supports investigations of retailers who allegedly traffic SNAP benefits. Future work includes the development of predictive risk model prototypes for these types of cases.

Farm and Loan Programs

As part of our effort to ensure the integrity of USDA’s farm programs, we reviewed the National Resources Conservation Service’s (NRCS) controls over its Conservation Innovation Grants Program. NRCS administers this program by awarding grants to State and local governments or nongovernmental organizations, American Indian tribes, and individuals to improve the use of fertilizer, water, and on-farm energy. These grants help improve water quality and make agriculture more resilient to weather extremes. In our review, we found that NRCS needed to strengthen its program monitoring policies and procedures. We also determined that NRCS reimbursed nearly \$4.4 million to grantees who did not adhere to grant agreement terms—for example, by not submitting their quarterly financial reports. By addressing these issues, NRCS should make progress toward achieving grant projects’ objectives, maintaining sufficient records for matching funds, and including program data in its reports to Congress. NRCS generally agreed with our recommendations.

Another example of our work in this area is our recent audit of FSA's Agriculture Risk Coverage and Price Loss Coverage Program (ARC/PLC). This program protects producers against revenue shortfalls and price declines. In our review, we found that FSA did not properly coordinate with appropriate groups when implementing ARC/PLC, causing the public to potentially misunderstand the goal of the program. We also found that the Agency made certain payments based on each farm's administrative county instead of the county where the farm was physically located. Lastly, based on our review of production records and historical FSA records, we found that FSA, for 10 of the 30 PLC yields we reviewed, made \$109,580 in improper payments for crop years 2014 and 2015. FSA agreed with our findings and recommendations.

OIG devotes its investigative resources toward ensuring the integrity of USDA farm programs by identifying and prosecuting fraud. This past year, OIG worked with the FBI to uncover an elaborate scheme in which forged Rural Business-Cooperative Service (RBS) Business and Industry (B&I) Guaranteed Loan Program (GLP) documents—purporting to reflect legitimate borrowers—were offered for sale to an investment firm on the financial secondary market. While out on bond awaiting sentencing for the initial fraud, the leader of the conspiracy devised another scheme to defraud RBS and was caught attempting to flee the country. Ultimately, the leader of the conspiracy was sentenced to 300 months in prison and 36 months of supervised release and ordered to pay \$174.7 million in restitution and forfeiture. His co-conspirator in the initial fraud scheme was sentenced to 120 months in prison and 24 months of supervised release, and ordered to pay \$27.6 million in restitution—jointly and severally with the leader of the conspiracy. Lastly, the third co-conspirator was sentenced to 24 months in prison and 24 months of supervised release and ordered to pay \$7 million in restitution. The court also ordered the forfeiture of \$6.4 million in monetary assets seized from a financial account connected to the conspiracy. Additional action is still pending for the leader of the conspiracy for his role in the second fraud scheme.

Federal Contracts

OIG also identifies and prosecutes contract fraud. OIG recently completed an investigation of a father and son in California who submitted falsified company financial information to the Agricultural Marketing Service (AMS). This information overstated the company's ability to perform duties in order to be placed on the approved vendor list. As a result of the fraud, the father and son were awarded five

USDA food supply contracts totaling more than \$4 million. Ultimately, four of the five contracts were terminated for contractor default after the contractors failed to deliver more than 100,000 cases of fruit juice and raisins to community food banks and lunch programs. The father was sentenced to 57 months in prison and 36 months of supervised release and ordered to pay \$1.7 million in restitution. His son was sentenced to 12 months in prison and 36 months of supervised release and ordered to pay \$1.5 million in restitution.

Future Work

OIG is performing a review to determine whether the National Institute of Food and Agriculture (NIFA) has adequate internal controls over grant fund allocations to States for its capacity grant programs based on statutory formulas. Another example of our upcoming work includes our current review of FNS' Food Distribution Program on Indian Reservations (FDPIR), where we are evaluating FNS controls over household eligibility, administrative costs, and damaged, spoiled, or lost food. Lastly, ODS plans to develop a prototype business intelligence tool focused on financial assistance programs.

Goal 3—Management Improvement Initiatives

Our third strategic goal is to support management improvement initiatives. By conducting audits and investigations that focus on areas such as improved financial management and employee accountability, OIG helps USDA better manage its assets.

Financial Management

As mandated by Congress, OIG completed its review of the financial statements for FY 2018 for USDA and component agencies to express opinions about the fair presentation of those statements, identify deficiencies or material weaknesses, and report on the Department's compliance with the Federal Financial Management Improvement Act. This past year, the Commodity Credit Corporation (CCC) devoted significant attention to financial management responsibilities and ultimately obtained an unmodified opinion on its FY 2018 financial statements. Based on our audit of the consolidated financial statements for USDA, we are pleased to note that USDA continues to make progress by addressing significant challenges to ensure accurate presentations of its financial statements. Overall, USDA's FY 2018 financial statements received an unmodified opinion.

Improper Payments

OIG also performs statutorily-required work intended to ensure that USDA is reducing its improper payments. In our recent review, we found that USDA did not comply with improper payment requirements as set forth by the Improper Payments Information Act of 2002 (IPIA), as amended,⁴ for a seventh consecutive year. Specifically, we found that 6 of the 10 high-risk programs did not comply with one or more requirements, such as publishing an improper payment estimate and meeting annual reduction targets. While we observed no overall decline in the accuracy, completeness, and timeliness of USDA's reporting, we identified one instance of incomplete reporting within USDA's published quarterly high-dollar overpayments reports. We also identified instances of inaccurate reporting regarding the Risk Management Agency (RMA), where it miscalculated its reported amounts for six of the nine crop insurance overpayments reviewed. Although USDA maintained its overall reporting quality of high-dollar overpayments, we stressed continued vigilance to prevent and eliminate improper payment errors. The Department generally agreed with our findings and recommendations.

Progress in Grain Inspections

We completed a recent audit to examine the AMS Federal Grain Inspection Service's (FGIS) controls over its inspection of exported grain. We determined that while FGIS has adequate controls over export grain inspection and weighing, FGIS could still improve its information technology. Specifically, we found that although FGIS developed an online system to improve its grain inspection program's efficiency and effectiveness, its applications continued to rely on manual processes to extract, compute, input, and share data. The reliance on manual processes resulted in program inefficiencies, reduced assurance of data accuracy and reliability, and reduced traceability of inspection results throughout the inspection cycle. When this information is not accurate and reliable, Congress, USDA, and interested stakeholders cannot assess the progress and effectiveness of FGIS' inspection and weighing activities. AMS officials concurred with our findings and recommendations.

⁴ Pub. L. 107-300, 116 Stat. 2350, as amended by the Improper Payments Elimination and Recovery Act of 2010 (Pub. L. No. 111-204, 124 Stat. 2224) and by the Improper Payments Elimination and Recovery Improvement Act of 2012 (Pub. L. No. 112-248, 126 Stat. 2390).

Future Work

OIG is performing an inspection to determine USDA's legal and budgetary authority to execute: (1) the realignment of the Economic Research Service (ERS) under the Office of the Chief Economist, and (2) the relocation of ERS and NIFA offices. As part of this review, we will also determine USDA's adherence to any established procedures relating to agency realignment and relocation and procedures associated with cost-benefit analyses. And, as always, we will continue to provide financial statement audits of programs and work with USDA and its agencies to improve their controls over financial reporting.

Conclusion

In closing, we would like to thank the Subcommittee for your continuing interest in our work. Your support has enabled us to carry out our mission of strengthening USDA's programs and operations in support of the American public.

OIG's appropriations for FYs 2014–2018 totaled approximately \$477 million. During this period, the potential dollar impact of OIG's audits and investigations was \$3 billion, resulting in cost savings and recoveries of more than \$6.20 for every dollar invested. During this same period, OIG made 1,187 audit recommendations to improve USDA programs. Furthermore, OIG investigations resulted in 3,106 successful convictions in that same 5-year period.

We appreciate your support in continuing to provide the funding necessary to perform effective oversight and present beneficial recommendations to Congress and USDA decision-makers.

This concludes my testimony. I would be pleased to answer any questions you may have.

Mr. BISHOP. Thank you very much, Ms. Fong. As I mentioned in my opening statement, I am grateful for all the work that your office does, so I don't want any of it to go to waste. Looking at your last semiannual report, as of September 30th, 2018, there were 359 audit recommendations awaiting final action by USDA agencies. Two-thirds of these pending items were for 2017 and prior years, with the oldest from 2005.

Why do so many take years to be implemented, what are your plans to call attention to those issues, how can you help the agencies or maybe shame them into action, and what do you need from us to help close these recommendations?

Ms. FONG. OK. Let me make a few comments, and then Gil may have some comments as well.

We make a priority to follow up with the Department on our recommendations. This is a joint responsibility between the Office of the Chief Financial Officer and the program agencies and then our office as well. And we have over the years tried to think of initiatives to assist the Department in this area. A year or two ago we issued a report taking a look at the CFO's office and how it was managing that whole system of closing out final audit recommendations. We made a number of recommendations to that office, which I think they agreed with and are in the process of implementing.

In addition, we asked the question, what can we ourselves do to shine more light on this? And so we have started a new line of products, which we call final agency verification reports, where we pick several audits from the past each year and we go in and we take a look at the agency actions to see if the agencies really accomplished what they said they were going to do or whether there is still work to be done. I think the first two that we issued looked good. The agencies were doing a good job. Obviously, there is still more progress that can be made.

Mr. HARDEN. And I would add there is a significant number of outstanding recommendations without final action. That is a discussion we have had with the Department for the last several years to bring focus to that part of the process. We have a continuing dialogue with them to see how that is progressing, but we are also using these final action verification reviews as ways to do an additional check to see that they implemented what they agreed to implement.

We also, for significant audits, we do followup audits. We go in and see how effectively they implemented the recommendations. We have several in that line over the last couple years related to food safety. We have upcoming work related to animal care, where we will look at how they addressed prior recommendations as well.

INFORMATION TECHNOLOGY SECURITY

Mr. BISHOP. OK. In April of 2018, the Council of the Inspectors General on Integrity and Efficiency issued its first-ever report on top management and performance challenges. At the top of the list was information technology security and management.

I am glad to see that you will devote some of your 2019 resources to that issue. Last fall, your office issued an audit of USDA's efforts to improve security of its information technology systems and, in short, you gave USDA an overall score of, quote, "ineffective," end

quote, for IT Security Program. There was also another audit where you found USDA did not fully implement federally mandated security requirements.

What is the primary cause of USDA's ineffective security posture? Is it complacency, lack of management priority, lack of resources, or is it just an impossible problem to fix?

Our subcommittee invests hundreds of millions of dollars a year on IT for USDA agencies to deliver their programs. And based on your audits, would you put money into systems that have ineffective security protection?

Ms. FONG. I think IT systems are a fact of life for managing and delivering complex programs, and our job here is to make sure that those systems are as good as they can be and they meet all standards. We do look at these systems every year, as you mentioned, and USDA is making what I would characterize as slow progress forward.

There is a commitment to attacking these issues at the Department level. The challenge that we have seen over the last 5 to 10 years is that there is a commitment on the part of the CIO's office, but then it needs to trickle down to all the agencies, all the program managers, and that is a difficult thing in a complex, large organization.

Mr. HARDEN. I would add that they have made changes recently to centralize at the agency level, at the mission area level CIO activity, so there is more of a connection between the Departmental CIO and agency CIOs to try and bring that together. This would be the first year that that has been in effect.

And so as we go through doing FISMA, the IT security review that we do every year, as well as other IT reviews that we do, that is a question that we are asking to see how well that is helping them do that.

Mr. BISHOP. Ms. Coffey, anything to add?

Ms. COFFEY. I am going to say that the IT expertise lies with my colleague as opposed to the investigation side of the house. I mean, periodically we do see some issues that arise with IT, but not from really the security perspective from investigations.

Mr. BISHOP. Thank you very much. I think my time has expired.

Mr. Fortenberry.

FOOD SAFETY

Mr. FORTENBERRY. Let's return to the case that I brought up earlier, where you had a massive recall of meat and poultry that was on the market for a number of years. So what broke here? What was not enforced? Why was it not enforced? Why did it take you a long time to catch it?

Ms. FONG. Well, let me offer a couple of—

Mr. FORTENBERRY. And let me step back further and I will ask you one more question: Is our food safe? Now, in all fairness, I asked Dr. Gottlieb last week at the Food and Drug Administration the same thing. There are overlapping responsibilities here. But it ultimately is that question.

Ms. FONG. Our mission in OIG is to deal with the problem situations. I would hesitate to say that the problems are pervasive, but

when they occur they do occur and they have a significant impact. Millions of pounds of recalls, as you mentioned.

Mr. FORTENBERRY. Do you think this is—I would assume this is an isolated incident, but to the degree that we do not want this isolated incident generalizable to a trend or principle, I think you need to speak to how isolated is it.

Ms. FONG. And I think that is a very good point. The questions that we always like to ask are, was this a systemic issue, was there a breakdown in controls, or was it just a real bad actor who got very creative?

This particular fact situation I think was perhaps a little unusual, and Ann can comment. My understanding of it is we had a processor in California who had a grant of inspection for a facility and had a second facility and was processing meat at both of those facilities, did not have a grant of inspection at the second one and was labeling the products from the second facility as coming out of the first. And so on its face—

Mr. FORTENBERRY. He shouldn't do that.

Ms. FONG. No, he shouldn't do that, and I am sure FSIS is not happy.

Mr. FORTENBERRY. So walk through the mechanism by which this was caught, and then why did it take several years?

Ms. COFFEY. So, in terms of how we get the information, normally we have to obtain individuals who step forward. Obviously, FSIS was not aware that there was a second facility that was operating illegally until it obtained information. And I can't really get into the specifics in a public setting as to how we came across that information.

But we identified the fact that there was a second facility that was alleged to be producing this—misbranding the meat that had not gone through Federal inspection.

Mr. FORTENBERRY. I think the question though is, again, did we have enough internal robust controls to find this out or did—look, I understand it happens a lot of times in law enforcement. There is a tip or you stumble upon something inadvertently. I get that.

But, again, I think the heart of the question is, are the controls, the system robust enough to have caught something like this so that we know that it is not systemic, or is this such a peculiar, isolated case that everything that we have in place still wouldn't have caught it?

Ms. COFFEY. I would say that in this particular instance, it is falling under the realm of more peculiar instance where you don't normally—when we have had recalls that you may have seen that have been public previously, they are usually because there has been some sort of outbreak or illness that has come about and it is not necessarily due to a fraud that has occurred. There may be some internal controls within a particular plant that may have broken down that led to that.

In this case, FSIS, if they are not aware that there was a second facility that was operating—

Mr. FORTENBERRY. It just seems the level of volume is high enough to have drawn suspicion, or it is just peculiar that no one would have known that there is some second facility, given the volume here.

Ms. COFFEY. Yes. I mean, it depends—that would be really something that FSIS, in terms of investigations, we look at sort of how the fraud was perpetrated and then proving that it actually occurred and then pursuing prosecution of those individuals.

Mr. FORTENBERRY. So this came to you from external sources?

Ms. COFFEY. That is correct.

Ms. FONG. But you do raise a good point. We will go back and look at our investigative file and see if there is any indication there that a control may have been bypassed that we can pass on to FSIS, in terms of addressing the issue for the future. We will take a look at that specifically.

Mr. FORTENBERRY. Yes. I am just trying to imagine what a second meat processing/packing facility looked like that escaped anybody's notice. It just is, again, a peculiar kind of thing. And it begs the question is the system that we have in place adequate to catch this, or do we defer to that very random peculiar incident that this one fell through the cracks.

Ms. FONG. We will take a look at that and see if there is anything there that we can offer to FSIS in terms of analyzing trend data, perhaps, that might be useful.

Mr. FORTENBERRY. Thank you.

Mr. BISHOP. Ms. Pingree.

ERS AND NIFA RELOCATION

Ms. PINGREE. Thank you very much, Mr. Chair.

Thank you so much for the work that you do and for being here with our committee today.

I have a lot of concerns about the proposed relocation and reorganization of NIFA and ERS, and I think every Democrat on this subcommittee and I have expressed our opposition to the plan. And we have heard from farmers, university, former leaders of these research agencies who are also opposed.

I guess everybody kind of wants to know why this proposal seemed to come out of nowhere, and it just seems like the agency is still pulling things out of thin air to justify it. Stakeholders have suggested to me that the ERS reorganization was proposed because research coming out of the agency didn't align with the administration's views on topics such as SNAP or climate change. That would be of great concern to me, and I think we should take those allegations seriously.

So I am wondering if the OIG's report on the reorganization and relocation of USDA research agencies will look into these allegations.

Ms. FONG. As you mentioned, we have an ongoing review of the relocation/reorganization, and we had set out our scope and objectives very succinctly at the beginning of our review. Until very recently, we had not heard any information that there may be a concern about research not aligning with the administration's views. That is a very new piece of information that we have just heard. It is not part of our audit scope, because it is new.

If there are allegations that are of concern on that matter, we would be very interested in discussing that with anybody who has any information on that. In the meantime, our audit inspection is

going forward, and I think our fieldwork is just about done on that. Gil?

Mr. HARDEN. Yes. We are closing in on the end of fieldwork for that and we will start discussing what issues we have and whether we have recommendations to make with the Department in the very near future and proceed after that reporting.

DIETARY GUIDELINES

Ms. PINGREE. OK. Well, we will follow up with you on that so that, you know, any allegations that are being raised will be clear to you and you can proceed.

So another question: Last month, my colleague Congresswoman DeLauro, who is not here with us right now, and I sent a letter to the Office of Inspector General for the Department of Health and Human Services. And there, we were requesting an investigation into reports that the food and beverage industry had inappropriately influenced public health policy through relationships with high-level CDC officials. There were specific concerns about agencies setting priorities based on industry-funded research.

As I know you know, DHHS and USDA work together to jointly publish the dietary guidelines for Americans every 5 years. The Ninth Edition of Dietary Guidelines will be published in 2020, and the first meeting of the Advisory Committee was just announced yesterday. The Dietary Guidelines have important implications for Federal nutrition programs and inform other health and food policies.

So has your office previously looked into whether and how the food and beverage industry has influenced the Dietary Guidelines, given that there were just reports of potential inappropriate influence at DHHS? How do we make sure that the Dietary Guidelines are based on objective, scientific information and not industry-funded research?

Ms. FONG. To answer your first question, we have not done work on Dietary Guidelines in the past. Gil is confirming that.

In terms of moving forward, we would have to give that some thought as to how we could design work to evaluate that. We would welcome a chance to dialogue on that issue. Since it is a new issue for us, we have not spent time thinking about that.

Ms. PINGREE. Great. Well, I am very happy to raise two new issues for you.

Ms. FONG. Thank you.

Ms. PINGREE. And I will follow up on both so that we can pursue the conversation a little more than just today. But thank you again for your work.

And I will yield back. Thank you, Mr. Chair.

Mr. BISHOP. Mr. Moolenaar.

OPEN AUDIT RECOMMENDATIONS

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And thank you for being here and for the work you are doing to ensure that the USDA is open and transparent and producing recommendations to eliminate and limit fraud within the agency.

I wanted to ask about—according to your written testimony, the OIG in 2018 issued 42 final audit reports and made 203 rec-

ommendations to strengthen and improve USDA programs and operations. And you highlighted certain cases where agencies generally agreed with your findings or recommendations.

It is hard to imagine agencies wouldn't follow up with your recommendations aimed at improving their operations or programs, but are there certain agencies or programs that you find are on your radar screen that don't seem to follow up with your recommendations?

Mr. HARDEN. I guess the way I would start that is that we do have a very good I think professional relationship with all the agencies in the Department, in terms of us bringing the concerns that we have through the audits that we do. We have good healthy dialogue and debate as we are coming to what caused the problems and what would be the appropriate recommendations.

Where, you know, we have seen breakdowns in the past is that the agencies agreed with what we were wanting to do, they went about implementing that, and when we went back in sometimes it wasn't as effective as they wanted it to be and so we may have had some additional work.

But even though there are a large number of recommendations that they are working on, it is not a relationship where there is constant, you know, pushback on what should be implemented at the root of the problem.

Ms. FONG. I would offer that when we have very productive dialogue and there may not be agreement on a recommendation, it is not confined to a particular agency or group of agencies. It would be very topic-specific or recommendation-specific, in the sense that it may be a particular policy that that agency feels strongly about.

Mr. MOOLENAAR. OK. And does OIG have internal enforcement mechanisms to ensure compliance, or it is all based on recommendations and then, as you mentioned, you have the final agency verification reports that kind of report as to whether it is being followed up on?

Ms. FONG. Yes, that is exactly right. We have the power of persuasion.

Mr. MOOLENAAR. OK.

Ms. FONG. And that is it.

FOOD AND NUTRITION SERVICE

Mr. MOOLENAAR. OK. In the audit of the Food and Nutrition Service's financial statements for fiscal year 2017 and 2018, the finding states that the FNS high-risk programs were not compliant with the requirements of the Improper Payments Information Act.

Were there recommendations that you had, or what was it that they weren't in compliance with?

Mr. HARDEN. Yes. Annually we do work on the compliance with improper payment reporting, and that focuses on the ten departmental programs that are high-risk programs. Five of those programs are FNS Nutrition Programs. It is SNAP, school lunch, school breakfast, WIC and CACFP. And they have not met one or more of the requirements over the seven years that we have reported on that compliance.

And so we had a series of recommendations over the years and made recommendations this year. Although we have seen progress

at the Department level in terms of reporting it, it is just a matter of for some of the FNS programs that they get some of their data up to date so that they have ways of producing the estimates of what the improper payments should be and reaching their targets.

Mr. MOOLENAAR. And in your written testimony, you mentioned that OIG makes recommendations to improve how programs operate. During fiscal year 2018, your audit and investigative work resulted in potential monetary results totaling more than \$368 million. That is significant. If there had been—if the recommendation had been made for the audit of FNS' financial statements, how would that dollar amount be affected?

Mr. HARDEN. The information coming behind that does not result in what we would have as a questioned cost, or funds to be put to better use. That is driven by what the agency is doing to comply with those reporting requirements.

We have done work in the past to look at the quality of those improper payment estimates and have found weaknesses, particularly with the SNAP program. We issued a report in 2015 where FNS agreed to kind of retool the whole way that it did the error rate for that program.

Also, we have done work in school lunch and school breakfast, which has very high error rates, so that they can go in trying to look at how they come up with that number and if there are ways that we can offer a better way to get at that number. And they were receptive to recommendations on both of those fronts.

Mr. MOOLENAAR. OK. Thank you.

And thank you, Mr. Chairman.

Mr. BISHOP. Ms. McCollum.

FOREST SERVICE MINERAL WITHDRAWALS

Ms. MCCOLLUM. Thank you, Mr. Chair.

In 2018, the Forest Service was doing an environmental review on proposed mineral withdrawals of the National Forest System lands. Methow Headwaters in Washington State, an area in the heart of the North Cascades and important for water quality, wildlife protection, recreation and salmon recovery and restoration; the Emigrant Crevice in Montana in former Secretary Zinke's backyard; 30,000 acres of public land just north of Yellowstone National Park, where mining could damage the environment and hurt the area's tourism-based economy; and the Rainy River Watershed in Minnesota just outside the Boundary Waters Canoe Wilderness Area, the most visited wilderness area in the country.

Sulfate or mining pollution could cause irreparable harm to these pristine waters, and you don't have to take my word for it. In a letter that I have, former Forest Service Chief Thomas L. Tidwell issued a denial of consent to renew two leases in the withdrawal area. In December 2016, he concluded, and I quote: "The inherent potential risk of mining near the BWCI," I quote again, "might cause serious and irreplaceable harm to this unique, iconic, and irreplaceable wilderness area."

I point this out because the Forest Service completed the studies in Washington and in Montana, but on September 6, 2018, Secretary Perdue issued a one-page press release stating that USDA was canceling the proposed mineral withdrawal study impacting

the Boundary Waters 20 months into a 24-month study. I am concerned that a different standard was neither fair nor consistent as it applied to the Boundary Waters as compared to the other two mineral withdrawals.

USDA and the Department of the Interior followed the established process when assessing the other two applications for mineral withdrawals. The Forest Service completed and released a full environmental assessment, and the assessments were submitted to the Bureau of Land Management as part of a complete withdrawal package. It is unclear why the Forest Service deviated from the established process for the study impacting the Boundary Waters. And a one-page press release from the Secretary is not adequate substitute for a full environmental assessment and submission of a complete withdrawal application to the BLM.

I would ask you, do you agree that canceling the study with just 4 months left seems like an efficient use of time, energy, and taxpayers' dollars? And are you aware of the Forest Service ever canceling a mineral withdrawal in this manner before? If not, can you report back to us who ultimately made this decision to cancel the Forest Service study and how a decision like this was made, based on the other two studies going forward in the good faith in which the BWCA and Rainy River Watershed should have been given the same due consideration.

Ms. FONG. Thank you for raising that. We have not done any work in that area so we are not familiar with the study. It is a very interesting set of circumstances. We would be happy to talk with you and your staff to get more information and figure out what assistance we can provide.

FOREST SERVICE WORKPLACE MISCONDUCT

Ms. MCCOLLUM. That would be helpful. It was very much in the press.

Mr. Chair, I know my time is limited, but I would like to ask any comments you would like to make on what the Forest Service has been doing in its initiatives to address workplace misconduct. I also am the chair of the Interior Committee where there is overlapping jurisdiction. I am very concerned about what is going on and if you think that there is any work that we should be following up on.

Mr. HARDEN. As you know, we just recently issued our report on sexual harassment and misconduct for Region 5. It was designed around the agreement that Forest Service had with the Department at the Assistant Secretary for Civil Rights level and OGC, in terms of a plan for making the workplace better in Region 5.

We found that they had been implementing what they had agreed to in the plan, but there were some other areas where we saw improvements to the workplace that they could make. One of them, notably, was doing better background checks or reference checks on people that are being hired. They weren't asking direct enough questions to know that people had, you know, sexual misconduct/harassment issues in their past, and then they were promoted into other supervisory positions.

In response to questions that we got in a hearing related to that subject last November, one of the things that we are currently doing is that we have asked—I have polled my counterparts in the

oversight community to draw out reports that everybody in the community has done related to this issue so that we can possibly talk to Forest Service about best practices or other standards that others have applied that they may need to consider.

I know that we will be in continuing discussion with Forest Service as well as members and their staffs, because of the interest in this area and in additional work that may be considered.

Ms. MCCOLLUM. Thank you.

Thank you, Mr. Chair. It looks like we have some work to do together.

ERS AND NIFA RELOCATION

Mr. BISHOP. Thank you, Ms. McCollum.

Last September, Majority Leader Hoyer and Congresswoman Norton asked your office to look at USDA's proposal to relocate the Economic Research Service and the National Institute of Food and Agriculture, and to reorganize ERS under the Office of the Chief Economist. Your written testimony indicated your office will be performing this review.

Can you briefly tell us about the scope of the project and what the status is, when do you expect to issue your results, and can you give us a preview of what you found so far?

Ms. FONG. I will be happy to comment on that. We have started work on that in response to the request. The scope of the work is to look at the Department's legal authorities to do a reorganization and a reprogram of those funds, and a relocation; to look at the Department's budget authority to do those actions; and third, to determine if the Department followed any procedures that it has governing relocations and reorganizations. So we are looking at those three issues in particular response to the request.

We have just about finished our fieldwork. We have been working very diligently to obtain all the information that we need. We have been talking to and interviewing witnesses. I think we are almost at the stage where we are going to start drafting a report. And at that point, we will be talking with all of the stakeholders about what we are seeing. We are also very aware of this committee's interest in those issues.

ANIMAL WELFARE INSPECTIONS

Mr. BISHOP. Thank you. I am happy to see that your 2019 audit plan includes a review of animal care programs overseen by the Animal and Plant Health Inspection Services, specifically on animal breeders and exhibitors. Our news reports indicate that there has been a dramatic drop in APHIS citations in 2018 over previous years. Will you be looking into the reasons for that drop?

Mr. HARDEN. Yes.

Mr. BISHOP. Do you have any indications at this point what some of those reasons might be?

Mr. HARDEN. No, I don't have anything on the reasons, but we are aware of what has been reported in the media. But, you know, this work will follow up on work that we did and recommendations that we made to this program in an earlier audit. And knowing what they are reporting is part and parcel to understanding how

they are running the program for both the breeders as well as the exhibitors.

GOVERNMENT SHUTDOWN

Mr. BISHOP. Thank you. We just had the longest shutdown in history during which food inspectors were working without pay. And USDA issued SNAP benefits for February early, causing most recipients to have a gap of up to 50 days while waiting for the March benefits to be issued. This resulted in increased demand for food at food pantries and other assistance outlets. Some FSA employees were called back to work.

Do you have any plans to review any agency operations during the shutdown?

Ms. FONG. That is not in our current work plan. As you mentioned, we published our fiscal year 2019 work plan, and we published that before the shutdown. I think as we go through our work, as it touches those agencies and those programs, if an impact from shutdown surfaces we will certainly address that. And if there are other concerns that come forward, we are happy to consider any other concerns.

HOTLINE COMPLAINTS

Mr. BISHOP. According to your last semiannual report, your office received almost 5,000 complaints through the OIG hotline between April and September of 2018. You reviewed 137 of those complaints, under 3 percent of the total. The majority of the complaints, 91 percent, were referred to the USDA agencies for responsive tracking.

Do you have a process to follow up with the referred entities to see if they took appropriate actions, how do you ensure the agencies did their due diligence, and what do you need from us so that legitimate hotline complaints are properly dealt with?

Ms. COFFEY. Sir, the hotline falls under investigations. We do have a process in place. For the entire year of last year, we received over 12,000 complaints that came into the OIG hotline. The majority I would say, probably about 96 percent of those were related to SNAP recipients, individuals who were calling in to report that there is some sort of fraud in either the eligibility status of individuals who are receiving benefits or that they are misusing their benefits.

In those instances, we usually work with FNS to follow up on those. The ones that we do refer to the program agencies other than FNS, we do have a process in place where the agencies are required to respond to our office to provide information, whatever information they have identified based on the complaint when they have looked into the matter, and we are looking at those responses and making a determination whether or not we believe that that has resolved the matter or they have adequately looked at it or if we need to raise it to a higher level within the agency. So we do follow up on those investigations.

Mr. BISHOP. Thank you. My time has expired.

Mr. Fortenberry.

EPHEMERAL GULLY EROSION

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Who is the expert on ephemeral gully erosion?

Mr. HARDEN. I don't know that I would use the word "expert," but yes, there was a report that had those words in it.

Mr. FORTENBERRY. The Natural Resources Conservation Service issued new guidelines. This can happen to farmers inadvertently. There is an issue about tilling, concern expressed by the agency that this would put someone out of compliance. I support the conservation compliance requirements, but I want to make sure that farmers have time to comply with the new requirements and do not get disqualified from Crop Insurance or other farm programs because there may not either have been time for information, training; or secondarily, is there enough flexibility built into the program, given different regional considerations and different weathering conditions in regions, to make it viable for farmers to actually respond appropriately with enough time, with proper agency notification? Can you comment on these matters?

Mr. HARDEN. I will take it from the aspect that yes, we had concerns with that portion of the program and made recommendations to NRCS to make improvements. We relied basically on their management expertise, in terms of what they needed to do to fix it and if they had a timeframe that they wanted to do that in. We didn't on our side have a way of saying, well, it should have been 10 years or 5 years or 3 years. We usually try and work with them and their expertise in knowing that.

Now, if they went about implementing those recommendations or those changes in response to the recommendations and realized, hey, this wasn't going to work as well as it could have been, if it is related to something they agreed to with us, there is a process in place for them to come back to us and say, hey, what we have agreed to really won't work. We need to change what we are doing so that it doesn't impact the farmers that you are talking about.

Mr. FORTENBERRY. So is it fair to say that NRCS should have to go through a notice and comment period before having these conservation compliance changes go through so that, again, farmers aren't inadvertently caught in a system that may result in the loss of farm program eligibility?

Mr. HARDEN. I would have to go back and find out.

Mr. FORTENBERRY. I think it is an important question. It is the heart of the matter.

Mr. HARDEN. OK. I would have to go back and find out why they did or did not go through a notice and comment period.

Mr. FORTENBERRY. OK. Based upon what is in front of me, that is not clear to me either. But let's presume there was not a comment period. I think, again, the issue, given certain complexities of different regions and certain weather patterns, of having proper advance notice before there is an enforcement against a farmer is only fair.

Mr. HARDEN. That makes sense to me, yes.

Mr. FORTENBERRY. OK. Well, I have learned, Mr. Chairman, how to take yes for an answer, so that is all I have. Thank you.

Mr. BISHOP. Ms. McCollum.

CROP INSURANCE FRAUD

Ms. MCCOLLUM. Thank you, Mr. Chair.

There has been a lot of political angst and discussion over fraud and abuse in the SNAP program, but the fraud and abuse, if there is to be found much in the SNAP program, would pale in comparison to the amount of money that appears to be involved in the Crop Insurance when fraud is happening.

So last year, your office was involved in a few investigations involving crop insurance fraud. The one case, the party in question was found guilty of defrauding taxpayers out of more than \$5.6 million in false insurance claims, sentenced up to 25 months in prison, is prohibited from participating in Crop Insurance Program for 5 years.

Another, the party was sentenced to 13 months in prison for illegally obtaining crop insurance and claiming crop losses for land he did not farm. He had to pay a half a million dollars in restitution.

Crop Insurance is a vital tool for our farmers in Minnesota and throughout this country, but reports of fraud at this level are very troubling. In the budget that was released yesterday, the administration calls for some Crop Insurance reforms, including new means testing that would limit the program to producers with an adjusted gross income of \$500,000 or less.

Do you think reforms like these, based on the information that you have been learning, the one proposed in the President's budget in particular, would help address some of the fraud that we see in the Crop Insurance Program, or can you talk about any other work your office is doing to address fraud within the Crop Insurance Program or other subsidy programs for the authorizers to deal with and to make sure that the appropriators make sure every penny is spent appropriately?

Ms. COFFEY. I have not had a chance to look at the information that was in the President's budget with respect to the Crop Insurance Program. I will say that in a general comment just in terms of both the food assistance programs as well as the Crop Insurance Programs that we are utilizing data analytics, and that is really helpful. It is a significant help for us to be able to identify the fraud that you see, and obviously there are large dollar amounts.

And what we typically have seen in terms of the Crop Insurance is that there are usually multiple individuals that are associated with or engaged in the fraud schemes. It is usually not just one producer. There is usually an agent, a producer. There is a very extensive network of individuals that are involved in those programs. And obviously, we are working with RMA in trying to identify the fraud. And obviously, we will be looking at the means testing that was put in place to see if that would have an impact with respect to perhaps reducing the fraud.

Mr. HARDEN. And on our side, we do have an audit in process that is looking at adjusted gross income requirements for FSA and NRCS programs. We are in the middle of fieldwork on that right now, but that may shed some light on those types of requirements as well.

Ms. MCCOLLUM. One of the things that I am finding in the other committee that I chair with the EPA, we don't have enough people

doing inspections and enforcement. Did you uncover any concerns about inspection and enforcement and if that needs to be beefed up no matter what the reforms are?

Ms. COFFEY. We have not looked at that. Again, we really come in sort of at the tail end where there has been an identification that something has occurred, and we proceed to investigate to substantiate those allegations. But I will say, obviously, the use of data analytics has helped significantly in helping us in that particular aspect. I am not sure if Gil has looked at that aspect.

Mr. HARDEN. Not that particular aspect, but a running theme through a lot of our work is looking at how the agencies oversee the various programs they have in place. And one of the main management challenges that we have pointed out year after year for the Department is maintaining that accountability and oversight and having the right type of focus not only on program delivery, because that is very much important, but also having somebody there in the oversight role knowing that the money is going where it is intended to go for eligible purposes.

Ms. MCCOLLUM. Thank you.

Mr. Chair, any kind of reform has to have good oversight with it, and what seems to be a pattern that I am starting to notice within this administration is that there are jobs that are posted—there are jobs that could be filled, but they are never posted to be filled, especially in enforcement.

So just having the number there without having actually gone out and even sought out the individuals to fill the post will leave the fraud and abuse no matter what reforms you come up with continue to happen.

Thank you, Mr. Chair.

SMALL AND DISADVANTAGED BUSINESSES

Mr. BISHOP. Mr. Fortenberry.

All right. I have just a couple of questions and we will be ready to, I think, wrap it up.

Ms. Fong, small businesses are the cornerstone of our economy, and Federal support is especially important for small and disadvantaged businesses in rural areas. That is why I was disturbed to read your audit from last October that found that over \$42 million went to small businesses that could not support their claim of being certified as small or disadvantaged businesses. That means over \$42 million could have gone but did not go to businesses that were at least 51 percent owned by a woman, by a veteran, by a minority, by other socially or economically disadvantaged individuals.

The audit included three recommendations for USDA to help them do a better job of getting money to those who are actually eligible. Have you followed up with USDA to see what actions they have taken, and how confident are you that USDA has improved in getting much-needed Federal dollars to the businesses that should be getting this help?

Ms. FONG. Yes, I remember that audit very well. It is a very interesting situation. As businesses want to get into the Federal sector, they work with SBA to get certified as to their status. Then once they are certified, they can participate in USDA and other programs.

And I think one of the findings that we had was that over time businesses who may have been eligible initially may have graduated or lost their eligibility because they grew or something might have changed. And we saw that there would be a need there to partner with SBA to figure out how to get to those situations.

We made some recommendations. It hasn't been 6 months yet. So I think the agency still has a little bit of time to implement, but we will be following up on that.

Mr. HARDEN. But one of the most novel things about that recommendation was to get that dialogue going between USDA, asking the questions of people that are part of the program, and sharing what they will learn with SBA and GSA.

2501 PROGRAM

Mr. BISHOP. Well, it is important that we monitor that closely, because we want to make sure that those dollars go to the small and disadvantaged businesses as they were intended to.

The 2018 omnibus included \$3 million of discretionary funds for the Outreach and Assistance to Socially Disadvantaged and Veteran Farmers and Ranchers Program known as the 2501 Program. These funds were intended to supplement \$10 million of mandatory funding and be used for grants to support minority and veteran farmers and ranchers.

Our understanding is that only a third of the \$3 million went to grants, that USDA used over \$2 million for training and for a website. Your current annual plan listed an audit of the grants awarded with this money.

Can you tell us what the status is of the audit, when the audit will be completed, and what can you share about whether the funds were used properly?

Mr. HARDEN. We can definitely take that information into consideration as we are planning the scope and objectives. The original plan for this audit was to follow up on the 2501 Grant Program, because we had issued two reports in I think 2012 and 2015 where there had been serious concerns with how the program was run. We would want to, of course, take a look at current operations to see if they have strengthened the program. That is slotted to begin I think in the fourth quarter of fiscal year 2019, so it will be kicked off before October.

Ms. FONG. If you or your staff have particular concerns or objectives that you would like us to look at, we would welcome dialogue on that as we design the audit.

CLOSING STATEMENT

Mr. BISHOP. Thank you. Ms. Fong, Mr. Harden, Ms. Coffey, thank you all for being here today. I know that there are a few things on which you are going to get back with us. We will also forward additional questions for the record, and we appreciate your diligence in getting your responses to us in a timely manner. Thank you again for your testimony. We look forward to working with you as we continue the fiscal year 2020 process.

With that, this subcommittee is adjourned.

TUESDAY, MARCH 26, 2019.

MEMBERS' DAY

WITNESSES

**HON. GLENN THOMPSON, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF PENNSYLVANIA**

**HON. JENNIFFER GONZÁLEZ-COLÓN, A DELEGATE IN CONGRESS
FROM THE COMMONWEALTH OF PUERTO RICO**

**HON. NEAL DUNN, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF FLORIDA**

**HON. SHEILA JACKSON LEE, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF TEXAS**

**HON. JAMES P. MCGOVERN, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF MASSACHUSETTS**

OPENING STATEMENT—MR. BISHOP

Mr. BISHOP. The hearing will come to order. Let me welcome everyone and say good afternoon. I am very pleased to have this hearing and allow Members to present testimony on their thoughts and priorities for the fiscal year 2020 Agricultural, Rural Development, Food and Drug Administration, and Related Agencies bill.

As I remind people all the time, the work of this subcommittee is far-reaching and it touches the lives of every citizen and millions abroad throughout our international food delivery programs, everything from research to conservation to food safety to domestic and foreign nutrition to food and drug safety to commodity futures.

So this subcommittee has a lot to consider. We are still at the beginning of the process, but this is an important day as we hear from our colleagues. Testifying today, we have a number of Members from each party that represent different parts of the country. The subcommittee has a reputation for working across the aisle, and I expect that bipartisan spirit to continue this year.

I look forward to hearing from all of you today and working with us as the process moves forward. And at this time I am happy to recognize my colleague Mr. Fortenberry for any opening remarks that he might have.

OPENING STATEMENT—MR. FORTENBERRY

Mr. FORTENBERRY. Well, thank you, Mr. Chairman. I really do appreciate your emphasis on bipartisanship. Agriculture is one of the areas that can, when there is the will, transcend any perceived divides. And that is why I think it is good that the general perception of the public is countered by the way in which this committee operates under your leadership. So thank you very much.

I want to also welcome the Members—Mr. Thompson, you are here first, and others who will join us. Agriculture represents a cross-section of diverse constituencies and regions affecting us all.

The food security space is an absolutely critical part of America's public policy and one that is often overlooked. And yet, as we all saw last year, we came together and passed a bipartisan farm bill, and now we are in the process of implementing that.

But it is great to be here again. I thank you for your emphasis on the bipartisan dynamic of the committee, and look forward to hearing from our Members.

Mr. BISHOP. Thank you, Mr. Fortenberry.

I will now recognize the gentleman from Pennsylvania, Mr. Glenn Thompson, for five minutes.

OPENING STATEMENT—MR. THOMPSON

Mr. THOMPSON. Mr. Chairman, thank you. Chairman Bishop, Ranking Member Fortenberry, members of the subcommittee, thank you for your leadership and your service with the appropriations process. Very much appreciated. And I want to thank you specifically for the opportunity to be here this afternoon to share my priorities for the agriculture appropriations bill for the fiscal year 2020.

The programs under this subcommittee's jurisdiction play an integral role in supporting our farmers, ranchers, and, quite frankly, rural America, while also ensuring that America will always have the world's most abundant, safest, and most affordable food supply.

As a lifelong Pennsylvanian, agriculture has always been a critical segment of the Commonwealth's economy. It remains our No. 1 industry today. However, times have been tough for many farmers in Pennsylvania and many other farmers around the Nation over the last decade.

In fact, average farm income has been cut in half for the past 5 years for a variety of reasons. The dairy industry in particular has been hit hard over the past decade as we lost markets, and milk consumption has decreased over that period. With this in mind, I am pleased that we were able to get the 2018 across the President's desk this past December, and I thank all of you for your support through the process.

FARM BILL

The farm bill provides strong support for our bedrock agriculture conservation programs, and that is where I would like to start. These include the Conservation Stewardship Program, the Environmental Quality Incentive Program, the Agriculture Conservation Easement Program, and the Regional Conservation Partnership Program.

Now, these programs help provide farmers and ranchers the tools to be able to implement best management practices on their operations to improve water quality, soil health, and the environment, along with farm productivity. In short, these programs are good for the environment and the long-term sustainability and fiscal health of our Nation's farms and ranches.

In Pennsylvania we are also continuing our efforts to restore the Chesapeake Bay watershed, which makes these programs all the more important. That said, I request full funding for our agricul-

tural conservation programs and the NRCS in accordance to the 2018 farm bill.

From conservation to crop insurance and energy programs to emergency loans, the Farm Service Agency, FSA, provides the boots on the ground for farmers. Because of this important role in providing local expertise and outreach, I request robust support for FSA.

Similarly, we must continue to fund and support agriculture research and extension activities. Agriculture is science and technology and today, and we need that support at both our land-grant universities but also other higher education institutions.

So much important research is performed at our universities. But without the necessary funding and resources, such work would not get out to actually benefit farmers and ranchers. As such, I strongly support full funding for both the Agriculture Research Service and the National Institute of Food and Agriculture.

In terms of Animal and Plant Health Inspection Services, or APHIS, like all farm areas, Pennsylvania continues to have serious challenges with invasive species. While we have had some success in dealing with these threats over the years, our latest pest wreaking havoc is the spotted lanternfly.

First identified in 2014, this insect has been spreading in Pennsylvania. It attacks a variety of plants and trees, fruit trees, hardwoods, hops. And it is a great treat to farmland. Now, for several years now our State Department of Agriculture has been working hand in hand with USDA, Penn State, and others to contain and eradicate this invasive.

Along with this coordination, USDA and this committee have been supportive with funding. As more work remains, I strongly urge the committee to support the APHIS work on invasives through the plant pest and disease program and request continued resources to deal specifically with the spotted lanternfly.

In addition, as in other States with prominent cervid populations, Pennsylvania continues to search for a cure for Chronic Wasting Disease. For those not familiar with Chronic Wasting Disease or CWD, it is a neurological disorder impacting deer, elk, and moose populations, and as the name suggests, contracting the disease always ends in fatality.

While much research and on-the-ground identification has been happening in Pennsylvania, Wisconsin, and Louisiana, just to name a few States, more funding and research is needed to manage and ultimately cure this disease.

The 2018 farm bill recognizes this issue and actually includes language I proposed providing priority status for Chronic Wasting Disease within APHIS animal health programs. For these reasons I request that the committee provide full funding for animal disease research, particularly Chronic Wasting Disease.

And finally, I would like to register my strong support for the Rural Development and Rural Utility Services programs in general.

Again, I want to thank you for the opportunity to be here today, and I look forward to working with you as the appropriations process for fiscal year 2020 moves forward.

Mr. BISHOP. Thank you very much, Mr. Thompson.

Next we will hear from Mr. Neal Dunn of Florida. I am sorry. Mr. Fortenberry.

Mr. FORTENBERRY. Mr. Thompson, if you could for just a moment, all I wanted to do is just thank you for your long leadership on the Agriculture Committee. You have been a stalwart there. The voices that represent agriculture in the Congress have a long continuity of tradition, and you have carried that tradition very honorably and well. I want to thank you.

Mr. THOMPSON. Well, thank you. As you know, agriculture is—we need a strong farm team.

Mr. FORTENBERRY. Yes.

Mr. THOMPSON. And I think we have it through this appropriations subcommittee and the work of the Agriculture Committee. That partnership of authorization and appropriations has always been strong, and I look forward to continuing that.

[The written statement of Mr. Thompson follows:]

Congressman Glenn 'GT' Thompson
Testimony - House Appropriations Subcommittee on Agriculture
March 26, 2019

Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee:

Thank you for the opportunity to be here this afternoon to share my priorities for the Agriculture Appropriations bill for Fiscal Year 2020. The programs under this subcommittee's jurisdiction play an integral role in supporting our farmers, ranchers and rural America; while also ensuring that America will always have the world's most abundant, safest and most affordable food supply.

As a lifelong Pennsylvanian, agriculture has always been a critical segment of the commonwealth's economy and in fact remains our number one industry today. However, times have been tough for many famers in Pennsylvania and many other commodities around the nation over the last decade. In fact, average farm income has been cut in half over the past five years for a variety of reasons. The dairy industry, in particular, has been hit hard over the past decade as we've lost markets and milk consumption has decreased over that period.

With this in mind, I was pleased that were able to get the 2018 Farm Bill across the president's desk this past December and I thank you all for your support through the process. The Farm Bill provided strong support for our bedrock conservation programs, including the Conservation Stewardship Program, the Environmental Quality Incentive Program, the Agricultural Conservation Easement Program and the Regional Conservation Partnership Program.

These programs help provide famers and ranchers the tools to be able to implement best management practices on their operations to improve water quality, soil health and the environment, along with farm productivity. In short, these programs are good for the environment and the long-term sustainability of our nation's farms and ranches. In Pennsylvania, we are also continuing our efforts to restore the Chesapeake Bay watershed, which makes these programs all the more important. That said, I request full funding for our agricultural conservation programs and the NRCS in accordance to the 2018 Farm Bill.

From conservation to crop insurance, and energy programs to emergency loans, the FSA provides the boots on the ground for farmers. Because of this important role in providing local expertise and outreach, I request continued support for FSA. Similarly, we must continue to fund and support agriculture research and extension activities at our land grants and higher education institutions. So much important research is performed at our universities but without the necessary funding and resources, such work wouldn't get out to actually benefit farmers and ranchers. As such, I strongly support full funding for both the Agriculture Research Service and National Institute of Food and Agriculture.

Like all farm areas, Pennsylvania continues to have serious challenges with invasive species. While we've had some success in dealing with these threats over the years, our latest pest wreaking havoc is the spotted lanternfly. First identified in 2014, this insect has been spreading in Pennsylvania, attacks a variety of plants and trees, and is a great threat to farmlands. For several years now, our state Department of Agriculture has been working hand-in-hand with USDA, Penn State and others to contain and eradicate this invasive. Along with this coordination, USDA and this committee have been supportive with funding. As more work remains, I strongly urge the Committee's support for APHIS's work on invasives through the Plant Pest & Disease Program, and request continued consideration of our efforts to deal with the spotted lanternfly.

In addition, as in other states with prominent cervid populations, Pennsylvania continues to search for a cure for Chronic Wasting Disease. For those not familiar with Chronic Wasting Disease, it is a neurological disorder affecting deer, elk and moose populations; and as the name suggests, contracting the disease always ends in fatality. While much research and on-the-ground identification has been happening in Pennsylvania, Wisconsin and Louisiana – just to name a few states – more funding and research is needed to manage and ultimately cure this disease. The 2018 Farm Bill recognizes this issue and actually includes language I authored which provided priority status for Chronic Wasting Disease within APHIS's animal health program. For these reasons, I request that the Committee provides full funding for animal disease research, particularly chronic wasting disease.

Finally, I'd also like to register my strong support for Rural Development and Rural Utilities Service programs in general. Again, thank you for the opportunity to be here today. I look forward to working with you as the Appropriations process for FY2020 move forward.

Mr. FORTENBERRY. Thank you.
 Mr. BISHOP. Thank you very much.
 Mr. Dunn.

TESTIMONY—MR. DUNN

Mr. DUNN. Thank you very much, Chairman Bishop, Ranking Member Fortenberry. I appreciate the opportunity to testify before you today. I am here to advocate on behalf of our Nation's farmers, ranchers, and foresters, and the programs that ensure the continued prosperity of rural America.

Most importantly, and as Chairman Bishop knows all too well, the Southeastern agricultural economy was absolutely devastated by Hurricane Michael in this last year. Hurricanes cause billions of dollars of damage, including \$1.5 billion in Florida alone.

While I remain hopeful that Congress will pass a supplemental appropriations for fiscal year 2019 as soon as possible, these disasters illustrate the critical importance of the farm safety net. We must ensure adequate funding to allow our producers the certainty that when future disasters occur, the Federal Government has programs in place to keep them going until help arrives.

Unfortunately, due to a longer growing cycle, timber producers many times do not have access to these critical programs as other farmers do. I look forward to working with this committee as well as my colleagues on the House Agriculture Committee to correct this going forward.

I would also like to urge the committee to continue to prioritize important agricultural research programs like the Agriculture and Food Research Initiative, and the land-grant universities' research and extension capacity programs. In addition, the 2018 farm bill established the framework for investment in our Nation's research infrastructure.

I support the administration's request for a new \$50 million competitive grant program for facilities improvement at land-grant universities. Programs like this support the scientific innovation at the institutions like the University of Florida, Florida State University, and FAMU in Tallahassee. And there are other great schools, obviously, all over the country.

Recently, Secretary Perdue announced the first down-select list of communities across the country vying to host the USDA Economic Research Service and National Institute of Food and Agriculture. I strongly support his efforts to ensure that the USDA is the most effective, most efficient, and most customer-focused agency in the Federal Government. This decision to bring important USDA resources closer to many stakeholders and improve the USDA's ability to attract and retain highly qualified staff is another great step forward toward achieving that very goal.

ERS/NIFA RELOCATION

I would also like to commend the Secretary for his commitment to ensure that no ERS or NIFA employee will be involuntarily separated during that transition, and I trust that this committee will provide him with the resources to honor that promise. I request

that the committee support the transition and ensure that the relocation is completed as smoothly and efficiently as possible.

Thank you very much, Mr. Chairman, Mr. Ranking Member, and I yield back.

Mr. BISHOP. Mr. Dunn, are you aware that there is a tremendous amount of opposition to that movement of ERS and NIFA?

Mr. DUNN. I had a chance to discuss it with Secretary Perdue, and he was really enthusiastic about it. And he won me over.

Mr. BISHOP. Actually, the committee is going to be holding a hearing tomorrow on it and we will have, of course, a representative from the Secretary's office as well as other stakeholders who will have a say. We will hear from him tomorrow. So I would like to invite you to come and listen.

Mr. DUNN. I will make every effort to be there, Mr. Chairman.

Mr. BISHOP. Thank you.

Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman. Yes. The Chairman rightly points out that this is not yet a settled issue. It is still under debate. We have been forthright in our exchange, and I have a university system that is vying potentially for the site. So we have some differing perspectives.

But tomorrow there will be a hearing to unpack objectively the pros and cons of this and some other considerations. So if you can make it, I think you might gain helpful insights.

Mr. DUNN. Thank you very much for your concern.

Mr. FORTENBERRY. Yes. And we remain very grieved by what happened to your district, and are continuing to try to think creatively as to the appropriate types of assistance that can be applied.

Mr. DUNN. It cannot come soon enough, Mr. Ranking Member. Thank you.

Mr. BISHOP. Thank you very much, Mr. Dunn. I appreciate your taking the time to come and share your interests with us.

Mr. DUNN. Always an honor to be here, sir. Thank you. I yield back.

[The written statement of Mr. Dunn follows:]

Chairman Bishop and Ranking Member Fortenberry, I appreciate the opportunity to testify before you today. I am here to advocate on behalf of our nation's farmers, ranchers, foresters and the programs that ensure the continued prosperity of rural America.

Most importantly, and as Chairman Bishop knows all too well, the Southeastern agriculture economy was absolutely devastated by natural disasters last year. Hurricanes caused billions of dollars in damage including \$1.5 Billion in Florida alone. While I remain hopeful that Congress will pass a supplemental appropriation for FY19 as soon as this week, these disasters illustrate the critical importance of the farm safety net. We must ensure adequate funding to allow our producers the certainty that when future disasters occur, the federal government has programs in place to keep them going until more help arrives. Unfortunately, due a longer growing cycle, timber producers many times do not have access to these critical programs as other farmers do. I look forward to working with this committee as well as my colleagues on the House Agriculture committee to correct this going forward.

I would also like to urge the committee to continue to prioritize important agricultural research programs like the Agriculture and Food Research Initiative and the land-grant research and extension capacity programs. In addition, the 2018 Farm Bill established the framework for investment in our nation's research infrastructure. I support the administration's request for a new \$50M competitive grant program for facilities improvement at land grant Universities. Programs like this support scientific innovation at institutions like the University of Florida, Florida State University, and Florida Agricultural and Mechanical University (FAMU) and other great schools around the country.

Recently, Secretary Sonny Perdue announced the first down-select list of communities across the country vying to host the USDA Economic Research Service and National Institute of Food and Agriculture. I strongly support his efforts to ensure that USDA is "the most effective, most efficient, and most customer-focused agency in the federal government" and this decision to bring important USDA resources closer to many stakeholders and improve USDA's ability to attract and retain highly qualified staff is another great step toward achieving that goal. I would also like to commend the Secretary for his commitment to ensure that no ERS

or NIFA employee will be involuntarily separated during this transition, and I trust that this committee will provide him with the resources necessary to honor that promise. I request that the committee support the transition and ensure that the relocation is completed as smoothly and efficiently as possible.

Thank you for your time, I yield back.

Mr. BISHOP. OK. At this time we would like to invite Representative Jenniffer González-Colón to the podium—I should say to the table. Thank you very much.

Welcome.

TESTIMONY—MS. GONZÁLEZ-COLÓN

Ms. GONZÁLEZ-COLÓN. I really appreciate to have the time today to express our requests coming from Puerto Rico. I am the sole representative for 3.2 million American citizens on the island. I do represent them in Congress, so I want to thank you, Chairman Bishop and Ranking Member Fortenberry, for actually allowing this to happen.

As you are probably aware, Puerto Rico does not participate in the Supplemental Nutritional Assistance Program, or SNAP, like our counterparts in the 50 States, District of Columbia, U.S. Virgin Islands, and Guam, since 1981. Instead, Puerto Rico has a capped block grant called Nutrition Assistance Program, or NAP, which is typically funded to 1.8 to \$1.9 billion per year.

The hurricanes in 2017 revealed the many challenges tied to NAP, starting with the remarkable difference in the benefits our people receive. To give you just an idea of the program on the island, a household of one in Puerto Rico receives \$112 per month, while a household of one in the continental States and the District of Columbia receives \$194 per month.

The amount of funding tied to NAP has proven to be insufficient, especially in the aftermath of both hurricanes, when people were experiencing extreme financial hardships. Additionally, the \$600 million that we are requesting for NAP this year in additional disaster funds—I have been advocating for that—included both in the House version and in the Senate version of the upcoming disaster bill are not yet available to my constituents. And that is the reason the Government of Puerto Rico is cutting more of those \$112 per month to the beneficiaries so they can receive some kind of assistance.

NUTRITION ASSISTANCE PROGRAM

It becomes clear that we need to improve the Nutrition Assistance Program on the island. And with this in mind, I am requesting your consideration for including report language in the upcoming appropriations bill for the fiscal year 2020 related to the Puerto Rico NAP program.

My first request is tied to the Thrifty Food Plan. The calculation of our block grant is heavily influenced by the Thrifty Food Plan calculation of the contiguous 50 States. It is totally different for Puerto Rico. However, we import more than 80 percent of the food items we are consuming, and this is being factored into the price consumers pay when they are purchasing those items.

The proposed language would require USDA to measure the cost of the Thrifty Food Plan in Puerto Rico and give us a better idea of how this calculation will be better addressed and reflect the reality of purchasing food on the island.

The second request directs the USDA to publish information of the NAP program on their website. One of the reasons why NAP

is a challenging program for many to understand is due to the lack of access to reliable data. Having USDA publish information, including basic program rules, monthly enrollment and disbursement data, and other program information will increase the transparency and will inform us on how we potentially can change the program and improve the program, make informed decisions.

Like right now, I am pushing for a complete transition from NAP to the SNAP program for Puerto Rico to have the same way as the U.S. Virgin Islands, Guam, and DC.

I want to just thank you for the consideration of those requests. We are pushing for the \$600 million for the disaster bill that are included specifically for NAP for a year. And believe me, the people of Puerto Rico are really in need.

Thank you, and I yield back.

Mr. BISHOP. Thank you very much for your testimony. And I want you to know that we are very much aware of the specific needs of Puerto Rico. And I am in agreement with my colleague, our colleague, Jose Serrano, who is a very strong advocate for the territories getting equitable treatment with the States.

DISASTER FUNDING

And I know that I have every intention for every piece of legislation that we offer that offers anything for States that the territories be placed in the same condition and be treated with equal dignity. Hopefully we will be able to implement that policy for the Government because I do understand that it is not an even-handed treatment.

With regard to the disaster and the \$600 million, as you know, we are doing our very best to get that disaster bill passed. It is my understanding that the Senate will take up their disaster bill and will offer that as an amendment to it either tomorrow or, at the latest, Thursday. We are hopeful that that will happen.

Of course, the consequences of—I should say the results of what has happened weather-wise in Nebraska and the Northwest over the last week is going to require some additional amendments and considerations for the losses of the grain and the cattle that occurred there. So that could possibly delay it.

We hope that it will not. But as of now—I think Mr. Fortenberry would agree—we do not know what the full estimate is going to be for Nebraska and for the Midwest. And we expect that there will be some significant additional damages. And we are not really in a position to allocate, I believe, an adequate amount to deal with those disasters.

So I am hoping that we can go ahead and finish the disaster bill that we passed through the House on the 16th of January, get that done, and at the appropriate time be able to do another supplemental to deal with what is inevitable for the Northwest. It is tragic. There has been a lot of loss there.

And we do not yet know what the full losses are going to be because snows have not melted, and the waters have not gone downstream fully, and we are not fully aware of what the impact is going to be. But we want to get started on that. We are mindful of that, and our thoughts and our prayers go out to all of those who

are impacted. And of course, as far as Puerto Rico is concerned, we hope that we can get that taken care of forthwith.

Ms. GONZÁLEZ-COLÓN. Thank you, Mr. Chairman. I want to express the same solidarity with our brothers and sisters from Nebraska. We know how difficult it is. In any way we can help, not just with prayers but with actions, we would be more than glad.

And I want to thank the committee, this committee, for actually approving the first \$600 million. And we have been in conversations with the Senate side, with Senator Perdue and Secretary Scott, to the \$600 million that are included already in the Senate version.

I would love to have the Senate version approved, and then in the conference we can put together whatever is missing, because at this time the bill is at a standstill and the people are not receiving the same benefits, even we receive less than the rest of the people living on the mainland. But thank you for that.

[The written statement of Ms. Jenniffer González-Colón follows:]

**CONGRESSWOMAN JENNIFFER GONZÁLEZ-COLÓN**

PUERTO RICO - AT LARGE

Remarks Delivered on Member Day
Re: FY20 Appropriations Request
Subcommittee on Agriculture, Rural Development, Food and Drug Administration,
and Related Agencies
House Committee on Appropriations
2362-A Rayburn House Office Building, 2:50 pm- 3:00 pm

Thank you, Chairman Bishop and Ranking Member Fortenberry.

As you are probably aware, Puerto Rico does not participate in the Supplemental Nutrition Assistance Program, or SNAP, like our counterparts in the 50 States, DC, USVI and Guam.

Instead, Puerto Rico has a capped block grant called the Nutrition Assistance Program, or NAP, which is typically funded at 1.8 to 1.9 billion every year.

Mr. Chairman, the hurricanes in 2017 revealed the many challenges tied to NAP- starting with a remarkable difference in benefits. To give you an idea, a household of one in Puerto Rico receives 112 dollars,

whereas a household of one in the continental states and DC receives 194 dollars.

The amount of funding tied to PAN has proven to be insufficient—especially in the aftermath of Hurricanes Irma and Maria when people were experiencing extreme financial hardships. To make matters more difficult, the Senate’s consideration of a disaster bill has come to a standstill, limiting the access to 600 million in additional disaster nutrition funds.

Mr. Chairman, it becomes clear that we need to improve nutrition assistance on the island. With this in mind, I am requesting your consideration of for including report language in your upcoming appropriations bill for fiscal year 2020 related to Puerto Rico’s NAP Program.

My first request is tied to the Thrifty Food Plan. The calculation of our block grant is heavily influenced by the Thrifty Food Plan calculation of the 50 contiguous states.

However, Puerto Rico imports close to 80% of the food items it consumes, and this is factored in to the price consumers pay when purchasing these items.

My proposed report language would require USDA to measure the cost of the Thrifty Food Plan in Puerto Rico and give us a better idea of how this calculation could be better addressed and reflect the reality of purchasing food on the island.

My second request directs the USDA to publish information of the NAP Program on their website. One of the reasons why NAP is a challenging program for many to understand is due to lack of access to reliable data.

Having USDA publish information including basic program rules, monthly enrollment and disbursement data, and other program information would increase transparency and would inform us on potential ways to improve the program, make informed decisions and- ultimately- strongly consider a transition to SNAP.

Mr. Chairman, thank you for your consideration to my requests and for the opportunity to testify. I yield back.

Mr. BISHOP. Mr. Fortenberry.

NEBRASKA FLOOD DAMAGE

Mr. FORTENBERRY. Thank you, Mr. Chairman and Ms. González-Colón, about the people I represent and others who are so adversely impacted by this flooding.

I will tell you a quick story. I was in a place called T-Bone Cafe, which is in Columbus, Nebraska. And I saw the “before” pictures before I got there. The wall had a line about 4-foot high where the water and muck came in, and it was just an absolute disaster.

By the time I got there, though, a lot of things had been shoveled out and cleaned up. And they looked at me and said, “This is T-Bone’s. We do not mess around. We are Nebraskans. We get it done.” Right outside of there they have good humor; there is a sign on the fence that said, “Mud wrestling tomorrow.” [Laughter.]

But of course you ride down the road a little bit and there is dead cattle on the side of the road. You are exactly right, Mr. Chairman. The ag losses are going to mount. It is unclear as to what they were, as people just pull themselves together and start cleaning up.

The Air Force base there, which I represent, Offutt Air Force Base, was a third underwater. I am not sure many people realize that here. It did not affect our readiness, as planes were able to be moved. And that facility also houses Strategic Command, which is our nuclear nerve center, which was unaffected, thankfully.

But nonetheless, the damage is very high and real. I think the chairman has it right. There is movement in the Senate to add potentially some new language that will make a conferenceable item with what we did in the House, or the House did last year. And then maybe all of this gets tied up. If there is some good news out of bad, I think additional problems actually perhaps create more momentum to get something done quickly.

In regards to your testimony about report language, what you said seemed to me to be eminently reasonable. So I hope that we can potentially work with you on that, and that may land in the bill. And thank you. I do not think most people—do you mind if I reference you as Jenniffer?

Now, we were talking this morning. Jenniffer represents 3.2 million people. Now, you get to run every 4 years; it is a little bit different. But 3.2—

Ms. GONZÁLEZ-COLÓN. I will change that in a minute if I can vote on the floor. [Laughter.]

I do not mind that.

Mr. FORTENBERRY. Every 4 years. Right? But the enormity of her job, to represent that many constituents, only elevates my respect for her intensity to continue to be engaged here at the table. So thank you very much.

Ms. GONZÁLEZ-COLÓN. Thank you.

Mr. BISHOP. I might point out that one of the problems with the Senate bill that I hope that we can fix in conference or prior to the time they bring it to the floor is that they do not add any additional money for the Nebraska or the 2019 disasters. And that is a problem because we were hardly able to adequately fund relief for the 2018–2017 storms that we need.

And of course, we have got to add some additional resources to make good on our capacity to help the folks in the Midwest and Nebraska as well as the people who are already long-waiting in a critical stage for relief from the hurricane that occurred back in the fall of 2018.

So we have got to do that, and we have got to do it quickly. People in the Southeast are at planting season right now, and if we do not get this bill passed, we are soon going to have a lot of people that will not be able to plant, will not be able to service their operation loans from last year, and will find themselves out of business.

Lenders are very, very concerned because they do not know what to do. They do not know what resources will be available to give to the farmers who will then be able to service that debt. So we have got a real critical situation, and I am hopeful that by the end of this week that we can have it addressed and get something to the President for his signature.

Ms. GONZÁLEZ-COLÓN. I agree with that, Chairman. And I just want to add my being very grateful to you guys and for Congressman Jose Serrano. I know he is not running for reelection after yesterday's announcement in the family, having the Parkinson's disease.

But he has been a great advocate for the people of Puerto Rico for many, many years. And he has always been more than a friend to me, like a mentor. He has been helping us out on equality issues across the island for many, many years. And I know everything that we have managed to include during the last 5, 10 years has been because of his hand in the committee.

So please, I want to thank him, but I want to thank all of you for having Puerto Rico in your hearts.

Mr. BISHOP. Thank you.

The committee will stand in recess.

[Recess.]

Mr. BISHOP. The committee will come to order.

We welcome Mr. McGovern. We know that you have a very busy, busy schedule, and so we appreciate your being able to break away and come and to spend a little time with us.

Mr. MCGOVERN. Thank you.

Mr. BISHOP. And we would be happy to entertain whatever thoughts you may have on our 2020 appropriations bill review process.

TESTIMONY—MR. MCGOVERN

Mr. MCGOVERN. Thank you very much. So, Chairman Bishop and Ranking Member Fortenberry, and my colleague Mr. Pocan, and members of the Agriculture Subcommittee, thanks for allowing me to testify here today. I appreciate it.

As your subcommittee begins drafting the appropriations legislation, I strongly urge you to provide robust funding for programs that work to end hunger across our country. You know, as one of the—we are the richest country in the history of the world, and yet we have close to 40 million Americans who are food insecure, who do not know where their next meal is going to come from.

And I believe that hunger is a political condition. I think we have the power and the resources to end hunger in the United States. What we need is the political will.

A few weeks ago, I testified before the Budget Committee in support of the Supplemental Nutrition Assistance Program, known as SNAP, which is a mandatory program. I urged the committee to protect the structure of SNAP, which is our Nation's first line of defense against hunger, and oppose any efforts to diminish participation of able-bodied adults without dependents.

Today, I urge this committee to provide at least \$3 billion for the SNAP contingency reserve account to ensure that all participants have continued access to benefits, even if the program incurs unanticipated expenses or events.

The Special Supplemental Nutrition Program for Women, Infants & Children, WIC, provides 6.8 million low-income pregnant and parenting women and children access to nutritious food, education, and other services. And I strongly urge the committee to continue to fully fund WIC at \$6.1 billion, including, at minimum, \$67 million for the breastfeeding peer counseling program.

I also want to highlight the work of charitable organizations like our food banks in alleviating hunger across the country. But the truth of the matter is, Mr. Chairman, charities alone cannot solve hunger. It takes a strong federal commitment as well.

The Emergency Food Assistance Program, known as TEFAP, provides highly nutritious food that food banks pair with donated items to craft packages for their clients. Although TEFAP commodities funding is mandatory, TEFAP storage and distribution funds are discretionary, and I urge the committee to continue to provide robust funding for the storage and distribution account.

FUNDING FOR NUTRITION PROGRAMS

I also urge this committee to increase funding for nutrition programs administration. Staff morale at the U.S. Department of Agriculture's Food and Nutrition Service has shown need for improvement in recent years. Staff at FNS are largely focused on SNAP integrity.

But at the same time, other programs, including child nutrition and regional operations, often suffer. I urge this committee to continue to provide robust funding for nutrition programs administration, so that they can expand adequate coverage to all of their programs.

Mr. Chairman, I just would like to next say a few words about our international food aid programs. As you know, I led the effort to create the George McGovern-Robert Dole International Food for Education and Child Nutrition Program. Congress established the program in the 2002 farm bill, and since that time it has provided literally millions of the most vulnerable children in the world with a nutritious meal in a school setting for over a decade.

Each year, USDA receives more proposals than it can fund, highlighting the need to expand the program, rather than reduce or eliminating funding.

I have visited many McGovern-Dole programs in Latin America and Africa, and you may have as well. I can testify that these programs advance the health and productivity of children, they im-

prove their school performance, increase attendance rates, especially among girls, and solidify community support for education, health, and nutrition.

And I am very grateful to this committee for maintaining level funding or providing modest increases each fiscal year, often under very tight budget constraints. For fiscal year 2020, I and many of my colleagues on both sides of the aisle are asking for \$235 million for McGovern-Dole, an increase of \$25 million.

FOOD FOR PEACE

Second, Public Law 480, Title II, Food for Peace, is our most important humanitarian food aid program, as well as supporting projects that address chronic food insecurity. As the world faces its greatest refugee crisis since World War II, and increasing numbers of natural disasters, we cannot cut funding for this program. It is simply unfathomable to think otherwise.

This program supports American farmers, whose commodities literally save tens of millions of lives each year. The program is now even more effective in getting food to those in need rapidly and effectively, combining Meals-Ready-to-Eat, vouchers, cash grants, local purchase, and U.S. commodities.

And for the past couple of years, Food for Peace has received about \$1.7 billion each year. And for fiscal year 2020, it needs to receive at least that level funding, and I would recommend a more substantial increase to \$1.9 billion, given the many existing crises requiring urgent attention and the knowledge that more are surely likely to come in the next 12 months. McGovern-Dole and Food for Peace advance U.S. national interests and reflect the very best of American values. I urge continued, robust funding, and marked increases, if possible, for each.

APHIS FUNDING

And, lastly, Mr. Chairman, I just want to speak briefly about another issue unrelated to food and nutrition. Since 2008, my hometown of Worcester, Massachusetts, has been dealing with the largest Asian Longhorned Beetle infestation in North America. More than 35,000 trees have been cut down, and eradication and replanting efforts continue.

I urge this subcommittee to provide at least \$54 million for tree and wood pests under USDA's Animal and Plant Health Inspection Service, including at least \$42 million for efforts to eradicate the Asian Longhorned Beetle, ALB, with no state or local cost share requirement.

I can just tell you that my neighborhood was literally transformed overnight. When I left for Washington one day, there were trees everywhere. When I came back, it was—I could not see a tree in sight. That is how dangerous these Asian Longhorned Beetles are. And we have made progress, but we need to make sure they do not return.

And I would just say, finally, you know, I think that the best of America is in our—is represented in our food and nutrition programs. And I think without them, you know, we would see hunger around the world increase dramatically, and we would see more in-

stability around the world. So I think these are smart investments, and I thank you for your consideration.

Mr. BISHOP. Thank you, Mr. McGovern. I think over the past several years this subcommittee has been very thoughtful in supporting both of those programs and the SNAP program as well. The nutrition programs are vital. It is a key part of our mission, and I think the committee has been very supportive. And that has been on a bipartisan basis.

I think last year I was the ranking member, Mr. Aderholt was the chair, and we worked very well in trying to assure adequate funding for both programs. And I think we were successful in doing that, and I am hopeful that this year we can continue to support them. They are sound programs. They do a lot for the people that are the recipients, but they also do a lot for us in terms of our foreign policy, so I will be supportive.

Mr. Fortenberry.

Mr. FORTENBERRY. I just want to thank you, Mr. McGovern, for your long-held advocacy in this ever-critical space of food security. And we call it the farm bill, but it really is about food security, risk mitigation, processes, policies for our farmers and ranchers, and for those who are in vulnerable circumstances, access to nutritious, good food.

So I recall fondly the days when we worked together in leadership on the Nutrition Subcommittee on Ag. But, again, appreciate your passion and consciousness around this most critical of American issues. Thank you.

Mr. MCGOVERN. I appreciate that. And I just want to point out, you know, these programs are not extravagant. The average SNAP benefit is about \$1.40 per person per meal, and most SNAP recipients end up going to food banks midway through the month in order to have enough food for their families.

So, you know, these are vital and as I said before, I mean, nobody in this country should ever have to go hungry, and I think this program goes a long way in dealing with that.

Mr. BISHOP. Thank you very much, Mr. McGovern.

Mr. MCGOVERN. Thank you. I appreciate it. Thank you.

[The written statement of Mr. McGovern follows:]

Written Statement of Rep. James P. McGovern (MA-02)
Testimony before the Agriculture Appropriations Subcommittee
March 26, 2019

Chairman Bishop, Ranking Member Fortenberry, and Members of the Agriculture Subcommittee – thank you for allowing me to testify before you today.

As your Subcommittee begins drafting the appropriations legislation, I strongly urge you to provide robust funding for programs that work to end hunger across our country.

As one of the richest countries in the history of the world, I find it unbelievable that 38 million Americans live in food insecure households. We have the power and the resources to end hunger in the United States. What we lack right now is the political will.

A few weeks ago, I testified before the House Budget Committee in support of the Supplemental Nutrition Assistance Program, or SNAP, a mandatory program. I urged the Committee to protect the structure of SNAP, our nation's first line of defense against hunger, and oppose any efforts to diminish participation of able-bodied adults without dependents.

Today, I urge this Committee to provide at least \$3 billion for the **SNAP contingency reserve account** to ensure that all participants have continued access to benefits even if the program incurs unanticipated expenses or events.

The **Special Supplemental Nutrition Program for Women, Infants & Children (WIC)** provides 6.8 million low-income pregnant and parenting women and children access to nutritious food, education, and other services. I strongly urge the Committee to continue to fully fund WIC at \$6.1 billion, including at minimum \$67 million for the breastfeeding peer counseling program.

I also want to highlight the work of charitable organizations, like our food banks, in alleviating hunger across our country. But the truth of the matter is, Mr. Chairman, charities alone cannot solve hunger. It takes a strong federal commitment, as well.

The Emergency Food Assistance Program, known as TEFAP, provides highly nutritious food that food banks pair with donated items to craft packages for their clients. Although TEFAP commodities funding is mandatory, **TEFAP Storage and Distribution Funds** are discretionary. I urge the Committee to continue to provide robust funding for the Storage and Distribution account.

I also urge this Committee to increase funding for **Nutrition Programs Administration**. Staff morale at the U.S. Department of Agriculture's Food and Nutrition Service (USDA FNS) has shown need for improvement in recent years. Staff at FNS are largely focused on SNAP integrity—but at the same time, other programs, including child nutrition and regional operations, often suffer. I urge this Committee to continue to provide robust funding for **Nutrition Programs Administration**, so that they can expand adequate coverage to all of their programs.

Mr. Chairman, next, I would like to say a few words about our international food aid programs.

First, as you know, I led the effort to create the **George McGovern-Robert Dole International Food for Education and Child Nutrition Program**. Congress established the program in the 2002 Farm Bill and since that time it has provided literally millions of the most vulnerable children in the world with a nutritious meal in a school setting for over a decade. Each year, USDA receives more proposals than it can fund, highlighting the need to expand the program, rather than reduce or eliminating funding.

I have visited McGovern-Dole programs in Latin America and Africa, and I can testify that these programs advance the health and productivity of children, improve their school performance, increase attendance rates, especially among girls, and solidify community support for education, health and nutrition.

I am very grateful to this Committee for maintaining level funding or providing modest increases each fiscal year, often under very tight budget constraints. For FY 2020, I and many of our colleagues, on both sides of the aisle, are asking for \$235 million for McGovern-Dole, an increase of \$25 million.

Second, **PL 480 Title II – Food for Peace** – is our most important humanitarian food aid program, as well as supporting projects that address chronic food insecurity. As the world faces its greatest refugee crisis since World War II and increasing numbers of natural disasters, we cannot cut funding for this program. It is simply unfathomable to think otherwise. This program supports American farmers, whose commodities literally save tens of millions of lives each year. The program is now even more effective in getting food to those in need rapidly and effectively, combining Meals-Ready-to-Eat, vouchers, cash grants, local purchase, and U.S. commodities. For the past couple of years, Food for Peace has received about \$1.7 billion each year. For FY

2020, it needs to receive at least that level of funding, and I would recommend a more substantial increase to \$1.9 billion given the many existing crises requiring urgent attention and the knowledge that more are surely to come over the next 12 months.

McGovern-Dole and Food for Peace advance U.S. national interests and reflect the very best of American values. I urge continued, robust funding – and marked increases, if possible – for each.

Lastly, Mr. Chairman, I'd like to speak briefly about an issue unrelated to food and nutrition policy. Since 2008, my hometown of Worcester, Massachusetts has been dealing with the largest Asian Longhorned Beetle infestation in North America. More than 35,000 trees have been cut down and eradication and replanting efforts continue. I urge this Subcommittee to provide at least \$54 million for **Tree and Wood Pests** under **USDA's Animal and Plant Health Inspection Service**, including at least \$42 million for efforts to eradicate the Asian Longhorned Beetle (ALB) with no state or local cost share requirement.

Mr. Chairman, as you craft your FY20 appropriations legislation, I ask that you consider the millions of Americans and people across the world who rely on federal anti-hunger programs to feed their families, and I ask that you provide robust funding for these programs and reject

harmful riders that seek to undermine these programs. At a minimum, I ask that this Committee do nothing to make hunger worse.

Thank you for the opportunity to testify here today.

Background on funding requests:

SNAP reserve account -- \$3 billion

- \$3 billion is the recognized necessary minimum contingency funding.
- The reserve should cover at least one month of funding for all participants.

WIC -- \$6.1 billion; \$67 million for breastfeeding

- We must include enough funding to ensure no eligible applicants are turned away, maintain current and anticipated participation levels, and provide funds for nutrition services to maintain clinic staffing.
 - o Although WIC funding is discretionary, since the late 1990s, we have provided enough funding to serve all eligible participants. We should continue this tradition.

McGovern-Dole -- at least level funding

- McGovern-Dole received about \$210 million in FY19. This year, I am asking for a modest increase of \$25 million, but at a minimum, the existing funding should be maintained in FY20.
- Each year, USDA receives more proposals than it can fund, highlighting the need to expand the program. This Committee should provide an increase in McGovern-Dole funding, if possible.

PL 480 Title II -- Food for Peace

- We can't pretend that these crises are going to disappear. Need across the world is increasing, and we will need to come up with the money somehow. The strongest possible funding level should be included up front, in this bill.

Mr. BISHOP. All right. At this time, I am happy to recognize the gentlelady from Texas, the Honorable Sheila Jackson Lee, one of the most hardworking members of this Congress.

Welcome, Ms. Lee, to our subcommittee, and we would be delighted to hear your thoughts about 2020 appropriations process for agricultural development, Food and Drug Administration, and related agencies.

TESTIMONY—MS. JACKSON LEE

Ms. JACKSON LEE. I thank the chairman for his gracious comments, and to the ranking member. I have had the opportunity to work with both of you, as well as my chair, Mr. Pocan, on the CPC. But let me just say that my view of America is that we are the breadbasket for both our Nation and around the world.

And over the years, I have worked with so many organizations dealing with the issue of hunger. And certainly there—more to that, as I look at your regulation over food and drug, I am reminded of an incident that is occurring with those of us who have been breast cancer survivors in the utilization of a certain implant that has caused great illness or recurrence of breast cancer.

So your appropriations is important on many levels, and I want to thank you for your very important work. I also want to thank you, generally speaking, for your important work for farmers and for the agricultural community. Interestingly enough, my district, as large as it is, has been—have added areas that can be subjected to the rural development funding. And I can assure you that is powerful to small communities.

So let me just quickly say that I am supporting the \$85 billion for Supplemental Nutrition Program. I would always argue for more because SNAP is a cornerstone of the Nation's nutrition assistance. It is a safety net, and it really goes to the question of hunger. Many of you know my predecessor, the Honorable Mickey Leland, who was the founding co-chair with Congressman Emerson, the late Congressman Emerson from the Midwest, to deal with hunger in America. We are still there. We are still there.

FUNDING FOR NUTRITION PROGRAMS

I support \$6.5 billion for Special Supplemental Nutrition Program, the WIC Program, and I think I heard Mr. McGovern say that these are not handout programs. These are programs that give families—in equal stair steps for families who get it just automatically because of their status in life. They provide for their infants, their children. They provide good, clean milk for their infants and toddlers, and we need to do so for our children who are not as economically advantaged.

I support \$329 million for Emergency Food Assistance, and I support \$55 million for USDA Summer Electronic. Let me say to you that during Hurricane Harvey, my community, people were starving. I am being very frank with you. They were not able to access, either because of their resources, the devastation of their home, this catastrophic event.

And thank you to the state, working with the U.S. Department of Agriculture, to be able to give us that emergency disaster food

dollars. And we served, in addition to those who had already gotten it, when we determined that people were still in need around the October timeframe, we were able to provide 30,000 more new people, because of these resources, the ability to access food that took them through the November and December timeframe. This is a lifeline to people, and I attest to its importance.

I support \$35 million for grants under section 105 that deals with—and \$22 million for the Senior Farmers Market Nutrition Program. And this provides low-income seniors with coupons that can be exchanged for eligible food.

I support the \$240 million for the Commodity Supplemental Program used in my district, and I support the \$100 million for the TEFAP storage/distribution, \$36 million for the pollinator, which focuses on research and decline in pollinator populations, and I support that, most notably that of commercial honeybees.

I support the \$62 million for the Evan Allens Program that deals with awards to African Americans in agriculture. We have black farmers in Houston and Texas, and I have worked with them over the years.

I support \$35 million for the Healthy Food Finance Initiative, and then I support all of the programs dealing with animal protection, national veterinary medical at \$6.5 million, \$70.5 million for horse protection, and \$28.7 million for the Animal Welfare Act.

As relates to the rural development, the \$350 million for Commodity Futures trading I support, and I support the \$40 million for the Hispanic-Serving Agricultural Colleges, which we worked together with my colleague who was here previously, we worked on HSIs—will play a critical role, crucial role in addressing this education, enrolling 57 percent of the Hispanic college students.

I support the \$16.9 million for the USDA Circuit Rider Program, and I certainly support the work that the agricultural funding is doing for the HBCUs and working extensively with them, and I know your commitment.

CHILDHOOD HUNGER

Finally, let me say, as I mentioned, I am the successor to the Honorable Mickey Leland, so we have been talking about hunger for a very long time. It is tragic that there are children that go to bed hungry here in the United States, and anything that we can do to provide—I will use the word “small” not because it is small, but because in the measure of the largest of this appropriation, the largest of this budget, and the largest of our economy here in the United States, to stop these children from going to school and going to bed without the right kind of nutrition.

I am an almost predominantly—one of my school districts, Title I school, we have breakfast, lunch, and dinner. It is only through your funding. And in the summertime, we are able to open our parks to feed our children only through this funding.

And I believe that was Mickey’s passion. Of course, he saw hunger around the world, but it was his passion that people not go to bed hungry. As you know, he organized the Mickey Leland Hunger Center. That is still going, training young people how to deal with hunger in terms of going into communities and finding creative ways to not have to have people suffer because of their status, their

economic status, or non-status, and their ability to provide for their family.

And it should be made known that people do not do this purposely. They do not do this purposely. They do this because they are in need.

My final point is I represent something called the Interfaith Ministries. They are the largest Meals on Wheels Program, which is so very important to our seniors. And I have gone out with the meals, knocked on doors, and see what a vital program the Meals on Wheels Program is.

So I want to thank you for your work. I have tried to cover things that are so important to my constituency, but as you support our farming industry, our small farmers, large entities, I think it should be reminded that you are feeding people who otherwise would not eat without the various programs that are under your umbrella and the rural development that helps so many communities like mine get an ambulance and help build a devastated police station after the hurricane. Small towns that benefit from these programs.

Thank you.

Mr. BISHOP. Thank you very much, Ms. Lee. You were very, very thorough. You touched upon all of the programs, and you certainly remind us that we live in a country where we produce the highest quality, the safest, the most abundant, and the most economical food and fiber anywhere in the world. And there is absolutely no reason why we should have food deserts, or why there should be hunger.

And I hope through this committee and the subcommittee that we will do our dead-level best to try to reduce that and eliminate it, is possible, so that we can really have a healthy nation, and that we can have healthy people, and we can help our friends outside of our country to be healthy also.

So thank you very much for your comments, and I yield to Mr. Fortenberry for any comments that he might like to make.

Mr. FORTENBERRY. Well, let me echo what the chairman just said in terms of your breadth of not only understanding but advocacy for a whole range of agricultural policies that are essential to both sides of the agricultural question.

The idea of the support mechanisms that create the conditions by which we have the lowest grocery prices in the world, and yet combining that with the humanitarian impulse that Americans have to help those most in mind, to the idea, you are exactly right, of seeing or hearing about a child going to bed hungry in America is heart wrenching, given our abundance and largesse, and yet, at the same time, we respond because we have the capacity to respond and the humanitarian impulse to do so as well.

So thank you for reminding of that essential public policy that is borne out of conscience.

If I could divert one moment. You talk about your interfaith ministry work, how is Pastor Rudy?

Ms. JACKSON LEE. Doing very well.

Mr. FORTENBERRY. Do you remember when I told you I met him on a plane?

Ms. JACKSON LEE. Yes. Yes. Rudy Rasmus—

Mr. FORTENBERRY. Is his part of this?

Ms. JACKSON LEE [continuing]. St. John's—yes—trying to build more housing for the unhoused, actual homeless people on the streets.

Mr. FORTENBERRY. Would you give him my regards, please?

Ms. JACKSON LEE. I will certainly do so. Still working. Let's put it that way.

Mr. FORTENBERRY. Is he? All right.

Ms. JACKSON LEE. Still working.

Mr. FORTENBERRY. Thank you very much.

Ms. JACKSON LEE. Still working, still feeding, still working.

Mr. BISHOP. Mr. Pocan.

Mr. POCAN. Nothing really to add, other than Ms. Jackson Lee is such a fierce advocate for her values. Thank you, Sheila. I appreciate it.

Ms. JACKSON LEE. Thank you very much. Thank you for the time.

Mr. BISHOP. With that, I think we have——

Ms. JACKSON LEE. Thank you for your patience.

Mr. BISHOP [continuing]. Completed our business, and this committee will stand adjourned.

[The written statements of Ms. Jackson Lee and Mr. Posey follow:]

CONGRESSWOMAN SHEILA JACKSON LEE (TX-18)

**STATEMENT BEFORE THE
COMMITTEE ON APPROPRIATIONS
SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT,
FOOD AND DRUG, AND RELATED AGENCIES**

**MEMBER DAY HEARING ON
AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG, AND
RELATED AGENCIES APPROPRIATIONS ACT FOR FY2020
TUESDAY, MARCH 26, 2019
2362-A RAYBURN
2:30 P.M.**

Chairman Bishop, Ranking Member Fortenberry and distinguished Members of the Subcommittee:

- As a senior member of the Committees on the Judiciary Subcommittee and on Homeland Security, let me offer my appreciation and thanks to Chairman Bishop and Ranking Member Fortenberry for the difficult work and choices that must be made to produce a truly bipartisan Agriculture spending bill, and for their commitment to producing a bill that fairly reflects the interests and priorities of the American people.
- Mr. Chairman, I understand that my entire statement will be made part of the record so I will keep my remarks brief.
- In the few minutes allotted I wish to highlight the food security and rural development programs which warrant the Committee's continuing attention and support.

FOOD SECURITY

I support \$85 billion for Supplemental Nutrition Assistance Program.

I support the Supplemental Nutrition Assistance Program (SNAP) and other programs that reduce hunger and help families meet their needs. SNAP is the cornerstone of the Nation's nutrition assistance safety net, touching the lives of 47

million Americans, the majority of whom are children, the elderly, or people with disabilities.

I support \$6.5 billion for Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)

WIC offers nutrition, education, and referral services to low-income pregnant and postpartum women, their infants, and children up to age 5.

I support \$329 million for Emergency Food Assistance Program

The Emergency Food Assistance Program (TEFAP) provides nutritious, American-grown commodities at no cost to low-income Americans in need of short-term hunger relief through organizations like food banks and pantries.

I Support \$55 million for USDA Summer Electronic Benefits Transfer for Children (SEBTC)

Created in 2011, the SEBTC pilot program provides food assistance to eligible low-income children through an EBT card. The initial success can be seen in Connecticut, Delaware, Michigan, Missouri, Nevada, Oregon, Texas, Washington, Cherokee Nation, and Chickasaw Nation, where SEBTC has successfully improved food security and nutritional access for low-income children.

I Support \$35 million for grants under Section 105 of the Healthy and Hunger Free Kids Act of 2010

This funding will help schools reduce hunger among low-income students and boost education and health outcomes. These funds will enable schools to choose the best options and practices that they believe will work to increase the number of children who start the day with a healthy breakfast.

I support \$22 million for Senior Farmers' Market Nutrition Program.

This program awards grants to states, territories, and federally-recognized Indian tribal governments to provide low-income seniors with coupons that can be exchanged for eligible foods at farmers' markets, roadside stands, and community supported agriculture programs.

I support \$240 million for Commodity Supplemental Food Program

The Commodity Supplemental Food Program provides 619,000 nutritious food packages each month in 47 states, the District of Columbia, and two Indian Tribal Organizations.

I support \$100 million for TEFAP Storage and Distribution

TEFAP Storage and Distribution funding will help food banks and emergency feeding agencies with rising costs of storing, transporting, and distributing foods to needy.

I support \$36 million for Pollinator Focuses Research

The significant decline in pollinator populations, most notably that of commercial honey bees, is a national concern. Pollinators are vital to our nation's economy and ecosystem, contributing nearly \$15 billion to the nation's economy and supporting one out of every three bites of food we eat.

I Support \$62 million for the Evan Allens Program

The Evan-Allen program support the training of both undergraduate and graduate students in the food and agricultural sciences and 51.6% of all degrees awarded to African Americans in agriculture. Research has helped increase the nutritional values of crops, investigated causes of obesity, developed new energy systems, and increased food safety.

I support \$35 million for Healthy Food Financing Initiative (HFFI)

The HFFI is a public-private partnership that combats America's obesity epidemic by providing access to affordable, healthy, fresh food options. It also provides loan and grant financing to attract grocery stores and other fresh food retailers to underserved urban, suburban, and rural areas, and renovate and expand existing stores so they can provide the healthy foods communities want and need.

ANIMAL PROTECTION

I support \$6.5 million for National Veterinary Medical Services Act

I request \$6.5 million to address the critical maldistribution of veterinarians practicing in rural and inner-city areas, as well as in government positions at FSIS

and APHIS, by repaying veterinary student debt for those who choose to practice in these underserved areas, as identified by the Secretary of Agriculture.

I support \$705 million for Horse Protection Act (HPA) Enforcement

This funding will remedy serious shortfalls in Animal Care Division account and enforce existing law to stop soring of show horses by providing for inspectors, training, security (to address threats of violence against inspectors), and advanced detection equipment.

I support \$28.7 million for the Animal Welfare Act Enforcement.

There is an urgent need to adequately fund the Animal Care division to improve its inspections of approximately 10,399 sites, including commercial breeding facilities, laboratories, zoos, circuses, and airlines, to ensure compliance with AWA standards.

RURAL DEVELOPMENT

I support \$350 million for Commodity Futures Trading Commission.

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank) expanded the CFTC's regulatory and oversight authority to cover approximately 90 percent of the U.S. derivatives market, trillions of dollars of trading formerly done in the dark. Fully funding this agency is crucial to ensure that the CFTC can implement Dodd-Frank's derivatives reforms and protect consumers from spikes in commodity prices caused by Wall Street speculators.

I support \$40 million for Hispanic-Serving Agricultural Colleges and Universities (HSACU)

The 2008 Farm Bill included a new federal designation, Hispanic-Serving Agricultural Colleges and Universities (HSACUs), for HSIs offering degree programs in agriculture and related areas. USDA's Title VII – Hispanic-Serving Institutions Grants Program offers HSIs the ability to carry out education, applied research, and related community development programs. HSIs play a crucial role in addressing this

education gap, enrolling 57 percent of Hispanic college students and 18 percent of all students in non-profit postsecondary institutions.

I support \$16.9 million for the USDA Circuit rider program

The USDA circuit rider program provides the primary support for small communities to operate safe and clean drinking water supplies, and helps to ensure compliance with current water regulations. It is one of the most successful private-public partnerships that the USDA operates with appropriated funds to provide much needed technical expertise and training to rural communities.

CONCLUSION

Mr. Chairman, I thank you and the Ranking Member for your leadership and for extending me this opportunity to share my major priorities with the Subcommittee.

Rep. Bill Posey (FL-08)

Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee:

Thank you for the opportunity to discuss with you an issue of significance to Florida, my district, and small businesses across the country: FDA regulations on premium, hand-made cigars. I urge the Subcommittee to include H.R. 1854 in the FY 20 bill. The bill explicitly defines and exempts premium cigars from burdensome regulations, including a limitation on products which contain flavor additives.

When Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), there were two key objectives:

- preventing youth access to tobacco products; and
- preventing the negative health effects of addiction.

Traditional, hand- crafted cigars are not a product used by, accessible to, or marketed to, youth; they are an artisan product, produced by skilled craftsmen, sold by small business tobacconists across the country, and consumed by adults in moderation. These small business retailers take great pride in their record of age-verification which is confirmed by data compiled and published online by the FDA.

Despite receiving significant evidence, including research conducted by FDA, that premium hand-made cigars are not utilized by youth, the Agency has still made no changes to these regulations which continue to impose significant economic damage to mom and pop small

businesses and traditional premium cigar manufacturers.

These one-size- fits -all set of requirements will be impossible for manufacturers of these hand-crafted products to meet. As a result, these regulations have hurt Florida which has the most premium cigar industry jobs of any state. The industry is burdened with costly pre-market applications, user fees, warning label administration, and other destructive measures.

To provide a common-sense solution, Rep. Kathy Castor and I reintroduced H.R. 1854 which would define premium cigars and exempt a narrow artisan category from the burdensome FDA regulations which they cannot meet. On day one, our bill attracted the support of 30 of our colleagues from both parties. Last Congress, our bill earned the support of 149 cosponsors from both sides of the aisle.

Please consider including our language in the FY 20 bill. I recognize and appreciate the strides FDA has made reducing the prevalence of youth consumption of tobacco products. No individual under the legal age should consume any tobacco products, period. FDA faces critical challenges addressing existing and new products which have been found to have appeal to youth, and Congress should support those efforts. However, we should not allow the hand-made, premium cigar industry and its tens of thousands of small business jobs to disappear.

Thank you very much for your consideration of my views, and I look forward to working with the Subcommittee and my colleagues on this important issue.

WEDNESDAY, MARCH 27, 2019.

OVERSIGHT HEARING ON U.S. DEPARTMENT OF AGRICULTURE'S PROPOSED RELOCATION OF THE ECONOMIC RESEARCH SERVICE AND THE NATIONAL INSTITUTE OF FOOD AND AGRICULTURE

WITNESSES

KRISTI J. BOSWELL, SENIOR ADVISOR TO THE SECRETARY OF AGRICULTURE, USDA
GALE A. BUCHANAN, PH.D.
JOHN E. LEE, JR., PH.D.
KATHERINE SMITH EVANS, PH.D.
CATHERINE E. WOTEKI, PH.D.

OPENING STATEMENT BY MR. BISHOP

Mr. BISHOP. Good morning. I would like to welcome everyone to today's hearing. Today we will hear from two panels as we discuss the department's proposal to relocate the Economic Research Service, ERS, and the National Institute of Food and Agriculture.

On our first panel, we will have Ms. Kristi Boswell, senior advisor to Secretary Sonny Perdue. She advises the Secretary on a wide array of issues, including intramural and extramural food and agriculture research, and she interacts with all levels of USDA management and stakeholders in the food and the agriculture community.

Our second panel consists of four senior, former USDA officials. Two are former Under Secretaries for Research, Education, and Economics and two are former Administrators of ERS. Combined, they have 70 years of experience at USDA. They bring unparalleled understanding of the agencies' operations.

All of our witnesses' insights will be valuable to the Subcommittee as we discuss the Department's proposal, and I would like to thank you all for your participation here today.

Last August, with very short notice, employees and stakeholders heard that the department announced a plan to relocate ERS and NIFA outside the National Capital Region. Since that announcement, this committee has heard from many, many stakeholders. But to date there has been little or no debate of the proposal in a public forum.

So despite multiple requests for information, USDA has continued to move full speed ahead. And at the moment, there appear to be far more questions than there are answers. And of course, since the proposal was announced last August, we have sent written communications and held phone calls and meetings with USDA and the Secretary and asked for more information, and we have continued to air our concerns about the lack of justification for the proposal and the lack of a cost-benefit analysis showing that it is

a good move. In fact, I cosponsored a bill to stop the move, and we included report language in the 2019 Omnibus Appropriations Bill—all of that to no avail as USDA continues to move forward.

That is why we are holding this hearing today. And in fact, it would be irresponsible for us not to have a hearing on this proposal because it has far-reaching implications. Today we will drill down deeper and examine USDA's intentions and any analysis that was done by the Department about the consequences associated with relocating NIFA and ERS.

I am concerned that the method for rolling this proposal out, and the lack of clear, transparent communication with ERS and NIFA employees, has already done irreversible damage to the Department's reputation. I am concerned that the cost-benefit analysis and input from stakeholders was not done prior to the decision. There are questions of how the Department will attract and retain highly qualified staff for ERS and NIFA if its current workforce loses trust in its leadership.

One of the justifications the department provided for the proposal is that it will place important USDA resources closer to its stakeholders. However, neither the public nor stakeholders were given the opportunity to weigh in and comment. Further, wherever you relocate those agencies, it would be inconvenient for someone. Stakeholders who have limited resources for travel, such as schools and universities, our land-grant schools, moving the agencies outside of DC would mean additional expenses they would have to incur in order to maintain collaboration.

Now, let me suggest that in deciding where to locate a Federal agency, it should be the purpose and the mission of that agency, and the mission of the agenda can best be accomplished. And we understand that not all Federal entities have to be located in the Nation's capital.

In the case of ERS, there were reasons 50 years ago for some of its staff to be located away from Washington in the department's agriculture, economics, and land-grant universities. And those staff worked mainly on economic adjustments that were faced by small and family farms.

But huge changes have taken place in agriculture, and farms are large and efficient and farmers now get their management and marketing technology information from private and public sources worldwide. What they need most today is the unbiased data and the research that provides the bigger picture, the larger economic context within which business decisions are made.

What are the trends in global markets? What factors will affect those trends? How do policies in other countries affect market opportunities? How do changes in patterns of consumer behavior change market opportunities for producers in various commodities?

The answers to these and hundreds more questions like that need to be known and understood by decision-makers in all parts of the trillion-dollar food industry as they consider their management strategies and long-term investments. And it is equally important that Federal policy-makers know the answers to these same questions as they consider—as we consider—policy effectiveness, changes, and alternatives just to understand what is happening in our food system.

This is what ERS does, and ERS is very heavily linked to other Federal agencies that both supply and use ERS information and research. There are regular staff interactions, sometimes through joint working committees, with examples of the Commerce Department, Defense Department, intelligence agencies, Bureau of Economic Analysis, Energy, Census, and multiple USDA agencies.

Partly through these interactions, ERS remains constantly reminded of the key policy issues and industry concerns, all of which help shape the ERS research priorities. The data and the research produced by ERS inform USDA officials and USDA agencies, Members of Congress, and food and agriculture organizations that are headquartered in Washington. In short, moving ERS out of the Washington area will move it away from its most direct stakeholders and strategic partners.

Let me say that, Ms. Boswell, in your testimony, you acknowledge there were missed opportunities to engage stakeholders. And referring to this as a missed opportunity is, I believe, an understatement.

The biggest unknown of this proposed relocation is what analysis the department has done that shows a benefit to stakeholders, department efficiencies, and any potential savings. Instead of providing hard data, the department asserts that there will be savings, and we are not sure how that is going to be determined. I also find it ironic that a proposal involving research and data-driven agencies that keep our Nation well-informed with objective, well-researched data on agriculture in this country and in the global sphere seems to have no hard data supporting it.

If this move were to happen, there is no question that it will disrupt normal operations at each agency. Our Nation's agriculture industry cannot afford delays to the vital economic data that ERS provides and the technological innovations that researchers and universities develop through NIFA support. We must be really careful not to give our farmers and researchers a raw deal by possibly weakening a well-established infrastructure for research that has kept American agriculture number one in the world.

Finally, the Department has proposed to realign ERS under the Chief Economist. Our focus today, however, is on the proposed relocation because Congress has spoken on that issue in the 2019 omnibus.

I want to make very clear that my strong opposition to the realignment is not conflating realignment with relocation for the purpose of halting progress on relocation. I, along with many others more knowledgeable than I, believe that the relocation of these two agencies is simply a bad idea.

So for today, I would like to welcome a robust discussion on this issue, and I know there will be continued interest as we move forward. I deeply appreciate your interest and your active participation.

With that, I would like to ask our distinguished ranking member, Mr. Fortenberry, if he would like to have an opening remarks. Mr. Fortenberry.

OPENING STATEMENT BY MR. FORTENBERRY

Mr. FORTENBERRY. Yes, Mr. Chairman. Thank you very much for convening this very important discussion and hearing today. Ms. Boswell, welcome. I understand you are from Shickley? Yes. I was hoping that you might be in the 1st Congressional District, we just missed you, but it is the neighborhood. Welcome to the hearing.

When the USDA rolled out this proposal last August, the department, it is my understanding, has generated interest from 136 locations from around the country, and is now down to 68. In response to the proposal, USDA energized a handful of groups, mostly in DC, in opposition.

I believe that the concept Secretary Perdue proposed could produce positive outcomes and results, but you do clearly, as the distinguished chairman said, have some work to do to convincing all members of the merit of the proposal.

I should in full disclosure, state that I have signed a letter, along with the Nebraska delegation, commending the prospects for the proposal and asking that we be given due consideration in Nebraska because Nebraska would be good, we think. But we could perhaps submit that to the record, along with a letter here from I believe it is 35 members—is that correct—35 members on the minority side supporting the proposal who sit on the Agriculture Committee.

While there might be some higher priority matters for the subcommittee to consider, such as international trade or biotech foods or the safety of imported food or medical products, I do agree that it is important for us to have this hearing and review the proposal today. As I mentioned to the chairman yesterday, my goal here is to have a fair and open discussion of the merits of the move.

So I would like to acknowledge some other USDA actions and proposals related to this relocation in order to give a full context. To Secretary Perdue's credit, he has taken a number of actions over the past two years to increase effectiveness at the department and improve the delivery of services to our constituents, from farmers.gov to the merger of the Grain Inspection and Packers and Stockyards Administration, GPSA, into the Agriculture Marketing Service, to the Farm Credit/Farm and Production Service Center consolidation.

It is important to note that the proposed relocation of NIFA was prompted by the agency losing its office space by the newly remodeled harbor on the Potomac River, and new office space at that location would not be economical, and the Economic Research Service in a very costly office space, much higher than other rates in the field.

The idea of moving out of Washington, DC is not a Republican idea. The idea has been floated, past and present, by both parties; in fact, one of the members of our current Appropriations Committee once said, "The technology available to us today allows for seamless communication and collaboration regardless of geographic location, and is already allowing a web of Federal offices and agencies across the U.S., such as the Centers for Disease Control in Atlanta, to perform their work without being inside the DC Beltway."

I believe, again, given the diversity and dispersment of agricultural production around the country, again, it lends itself to the prospect of a dispersment of the USDA as well.

I also want to point out that Congress included report language accompanying the final fiscal year 2019 appropriation law. The language requested further documentation in the fiscal year 2020 budget to justify this move. And to my knowledge, and the chairman and I discussed this yesterday, we are still waiting for some information and expect USDA to promptly deliver supporting documentation when it is available.

It is also important to note that neither the 2019 agricultural appropriation nor the 2018 farm bill forbade the USDA from moving forward with this proposed relocation when Congress had the opportunity to actually prohibit it.

So the department has an opportunity now to convince more Members of Congress that the relocation is the right thing to do, both from an efficiency standpoint and benefit to service delivery. So we look forward to hearing from you today.

I yield back, Mr. Chairman.

Mr. BISHOP. Ms. Boswell, I invite you to give whatever statement you would like on behalf of the proposal representing Secretary Perdue. Thank you very much for your participation, and the floor is yours.

TESTIMONY BY MS. BOSWELL

Ms. BOSWELL. Mr. Chairman, ranking member, and members of the committee, thank you for providing me the opportunity to testify before you today.

USDA is committed to being the most effective and efficient customer service department in the entire Federal Government, and as a result, we have looked critically at the way we do business. As part of that department-wide evaluation, USDA assessed the Economic Research Service and the National Institute of Food and Agriculture's mission functions and operating courses within each agency.

That review led to the 2018 announcement to begin the process of relocating most of ERS and NIFA outside of the National Capital Region. That announcement resulted in 136 expressions of interest from 35 States. USDA has retained Ernst & Young to assist in those relocation efforts.

Briefly, I would like to mention that in August, we also announced the intent to realign ERS from the Research, Education, and Economics Mission Area to the Office of the Chief Economist. While the focus of this hearing today is on the proposal to relocate, we generally believe those opposing realignment appear to be conflating realignment with their opposition to relocation.

USDA is committed to answering any continued questions about the proposal for realignment, but appreciates the committee's recognition that these are two separate issues and bifurcating them today at this hearing.

Improving mission function and limiting impact on our current employees during the transition are top priorities for USDA. The relocation allows ERS and NIFA to be closer to the broad array of customers and stakeholders who live and work outside and DC so

that our team can hear ground-level upcoming issues and developing research needs.

Significant research priorities and issue development occur outside of Washington, DC. USDA could have and should have been more agile in setting priorities to address emerging issues like farmer stress and mental health, organic research and extension development, and rural prosperity and hardship.

We also recognize that both NIFA and ERS have many stakeholders here in DC. To that end, we have identified critical functions that will remain in the DC area to fill these important roles, and we have recently shared that information with employees.

Relocation will also improve our ability to attract and retain highly qualified staff with training and specific interest in agriculture, many of whom come from our land-grant universities. Additionally, much of the recruited talent are new Ph.D. and Masters graduates.

The well-documented and empirically understood high cost of living and long commutes of DC limit the ability for some to take these jobs. In a new location, employees will be able to live closer to their workplace, lower their commute times, and improve their overall quality of life.

Additionally, the decision to relocate will benefit the American taxpayer, ultimately allowing for savings on employment and facility costs, which can be more effectively put straight back into research and programs and allow more employees to be retained in the long run, even in the face of tightening budgets.

The heart of any agency is its people. The talented employees of both ERS and NIFA provide our customers valued service and research every single day. Each of those permanent employees will have the opportunity to relocate and remain in their position at a new location, and we hope that many do.

However, we know that this process is hard, and we know that we are affecting real lives and we are affecting real families. And that is not something that we take lightly. We are engaging our employees throughout every step of this process in the site selection analysis, and is why we have established what many have called an ambitious timeline to limit this limbo period of uncertainty.

Lastly, USDA would like to directly address some misconceptions that you may hear today. First, we are confident that both ERS and NIFA will remain trusted and objective sources of information for the food and ag sectors, and ERS will remain a Federal statistical agency. We only need to look at the Centers for Disease Control and Prevention as a clear example of a leading, respected, objective scientific agency that resides outside of Washington, DC.

Second, this decision was not made rashly. The August announcement was the beginning of a still ongoing process led by an expert team at Ernst & Young to perform the site selection analysis. USDA values stakeholder input in this process immensely, and since the August announcement has consistently met with stakeholders, answered questions, and provided for opportunity for feedback at REE listening sessions to ensure those concerns are reflected in the complete evaluation.

Those efforts have occurred at the Secretary, deputy secretary, mission, mission area, agency leadership, and staff levels. We are confident that the completed analysis will show we can be more efficient with our dollars and be in a community that provides for a high quality of life for our employees.

Third, attrition during this transition period is something that we too are monitoring closely to ensure we are delivering our mission effectively. We cannot reiterate enough how much we value ERS and NIFA employees and the work that they do. We plan for a rolling transition of staff to the new location, and have already begun focused hiring to fill any vacated positions to ensure as little disruption as possible.

In closing, we fully believe that by relocating, we can better carry out our mission, placing more dollars on research than overhead, and providing a better quality of life for our employees. Moving forward, we will continue to implement this process in the most transparent way possible, and will continue to keep Congress apprised every step of the way.

Thank you for the opportunity to present this testimony. We look forward to a continued dialogue and answering the committee's questions.

[The information follows:]

Testimony of
Kristi Boswell
Senior Advisor, U.S. Department of Agriculture
Before the Subcommittee on Agriculture, Rural Development, Food and Drug
Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives
March 27, 2019

Mr. Chairman, Ranking Member, and Members of the Committee. Thank you for providing me the opportunity to testify before you today. Agriculture has always led the way in innovation and research, spurred by our networks of Land Grant Universities and nationwide Extension Services that partner with researchers throughout the Federal Government. The high-quality research and analysis provided by the Economic Research Service (ERS) and funded by the National Institute of Food Agriculture (NIFA) are critical contributors to solid, unbiased agricultural research.

USDA is committed to be the most effective, efficient, and customer-focused department in the entire federal government and as a result we have looked critically at the way we do business, with the goal of ensuring the best service possible for our customers, and for the taxpayers of the United States. In some cases, this has meant realigning some of our offices and functions to provide more streamlined and effective services with efficient use of taxpayers' dollars. As part of that Department wide evaluation, the Secretary assessed the ERS and NIFA mission functions, management operations, and operating costs within each agency. That review led to the August 2018 announcement to begin the process of relocating ERS and NIFA out of Washington, D.C. That announcement resulted in 136 Expressions of Interest (EOIs) from 35 states. USDA has retained Ernst & Young (EY), a leading provider of professional services with a dedicated Construction and Real Estate Advisory Services practice, to assist in the relocation efforts.

In August we also announced the intent to realign of ERS from the Research, Education, and Economics (REE) Mission Area to the Office of the Chief Economist (OCE). While the focus of this hearing today is on the proposal to relocate ERS and NIFA, we generally believe those opposing realignment appear to be conflating realignment with relocation for the purposes of

halting progress on relocation. USDA is committed to answering any continued questions about the proposal for realignment and appreciates the Committees bifurcation of the two issues in this hearing.

Improving mission function and program operations are the top priorities for USDA. We believe that by relocating certain functions outside of Washington, D.C. we will improve mission function in the long run. First, ERS and NIFA will be closer to the broad array of agency stakeholders who live and work outside of Washington D.C. providing additional access to hear and observe ground level issues. These stakeholders are farmers, rural communities, 4-H chapters, nutritionists, land grant and non-land grant universities, Historically Black Colleges and Universities (HBCU), and many others. There is not a one-size-fits-all stakeholder for these agencies or USDA, which is why 90 percent of USDA employees are located outside of the Washington D.C. area. By being closer to rural America, ERS will have a stronger pulse on upcoming policy issues and NIFA can be better adaptive to producer and research partner needs. We recognize that both NIFA and ERS also have many stakeholders in D.C. and are a valued resource across Congress, the Department, and throughout the science community. To that end, we have identified critical functions that will remain in the D.C. area to continue to fulfill these important roles and recently shared that information with employees.

Second, relocation will also improve our ability to attract and retain highly qualified staff with training and specific interests in agriculture, many of whom come from our land-grant universities. In both our economic research and our extramural research, hiring employees with agricultural backgrounds and ties to rural America will only benefit the agricultural and food research that is being conducted. Also, this experience is advantageous as we identify priority research areas that are directly impacting the agriculture and food industry. Furthermore, much of the recruited talent are newly out of Ph.D. and graduate programs and the well documented and empirically understood high cost of living and long commutes associated with Washington D.C. are limiting factors in taking these positions. USDA believes that more affordable housing will allow employees to live closer to their workplace, lower commute times, and improve their quality of life.

Third, the decision to relocate will benefit the American taxpayers, ultimately allowing for savings on employment and facility costs. This savings is not only part of an efficient federal government, it ultimately benefits our agency missions by putting more dollars back in programs and by allowing more employees to be retained in the long run, even in the face of tightening budgets.

Retaining and helping our current employees through this process is another top priority for us. The heart of any agency is its people. The talented employees at both ERS and NIFA provide our customers and stakeholders valued service and research every single day. We are proud of their continued commitment to our customers and programs during this time of uncertainty. Each of these permanent employees will have the opportunity to relocate to the new location and we hope that many do. However, we recognize that this announcement and this transition period is very difficult for them. We have established what some have called an ambitious timeline to limit that time of uncertainty for our employees and their families. We also have taken many steps to engage with our employees. First, USDA senior leadership is consistently engaged with employees at both agencies, including participation in all-employee meetings, answering employee questions in person and through Q&A, dedicating staff to conduct smaller more frequent touchpoints sharing consistent feedback and concerns with the Secretary's office. We also believe that the employees bring great value to the work of EY. Each agency has established employee-level committees that provide input on various factors so that matters important to them are heard and included in the analysis of a site recommendation. Additionally, all agency employees have had the opportunity to interact with the team from EY, directly providing feedback and insight into this process. We also expect that employees will participate in site visits of potential locations. Still, we recognize this process is challenging and personal. There are certainly those who believe we could do more, and we are open to hearing that feedback. Our goal is to provide as much information and engagement as possible and we are moving expeditiously to reach a site selection to end the period of uncertainty.

We would also like to address the many assumptions, misinformation, and general concerns communicated regarding the decision to relocate ERS and NIFA.

First, a key narrative from those with concerns about the proposal is the lack of a cost benefit analysis. USDA conducted preliminary cost-benefit analyses that evaluated facility costs, locality pay impact on employee cost, and estimated costs related to employee options on early retirement or voluntary separation. The agencies' present situation was compared against other similarly situated locations at USDA-owned facilities and review of GSA space that is outside of the Washington D.C. NIFA and ERS are both currently located in leased space in Washington D.C. Moreover, NIFA's lease is expiring and the agency must be relocated. ERS and others at Patriots Plaza have reported consistent issues with their space, including water damage and other facility issues. As a result, it was appropriate to consider facility options for both agencies. Due to the high cost of living in Washington D.C., the locality pay for this region is 28.22 percent above general GS pay tables. A determination was made that a new location with a lower cost of living resulting in a lower locality pay adjustment would provide overall savings. These savings would benefit the overall mission of these agencies by allowing more funds to be used to strategically hire additional employees or funds would be made available to support additional investments in research programs.

While this preliminary cost-benefit analysis informed the decision-making process, USDA recognizes that a complete cost benefit analysis, comparing all tangible and intangible benefits with any risk to the mission and other costs, must be completed based on an actual site recommendation. EY will be conducting this in-depth analysis that will be used when presenting a site recommendation. That is information that will be shared when it is available.

Second, we are aware there is concern that by relocating the agencies they will not remain an objective research source. We are confident that ERS and NIFA will both remain trusted, objective sources of information for the food and agricultural sector and ERS will maintain its status as a federal statistical agency. Our goal is that researchers provide analysis to foster policy development and fund emerging research issues, rather than analyzing current policy proposals or providing delayed response. Our federal researchers need the ability to be agile to address upcoming issues that will rise to the national level. USDA will have the ability to be more agile to respond to issues like farmer stress and mental health, organic research and extension development, and rural prosperity and hardship by relocating. Significant research needs, and

issue development occurs outside of Washington D.C. Moreover, USDA recognizes the value of our partnerships with land-grant and other university research institutions. NIFA will continue to fund leading edge research as USDA's extramural research arm, and we believe will ultimately grow even stronger partnerships with universities and the extension community. Additionally, we look to the Department of Health and Human Services Centers for Disease Control and Prevention as a clear example of a leading, respected, objective research agency that resides outside of Washington D.C.

Third, we are aware that there is concern that USDA did not initially conduct outreach to stakeholders when making this decision. We also recognize that, while operational decisions typically do not involve the same outreach that other policy matters undergo, there were missed opportunities to engage stakeholders during this process. However, we have heard that feedback and following the August announcement have consistently met with stakeholders, answered questions, participated in a stakeholder's webinar - absent an invitation - to proactively address concerns, and provided opportunity for feedback at REE listening sessions. These efforts have occurred at the Secretary, Deputy Secretary, Mission Area, Agency Leadership, and staff levels. USDA welcomes additional feedback and is committed to continued transparency in this process.

Last, we are aware that there is concern regarding attrition of our current employees. We cannot reiterate enough how much we value ERS and NIFA employees and the work that they do. Attrition during this transition period is something that we too are monitoring closely to ensure we are delivering our mission. We are prioritizing staffing to build in redundancy to ensure that critical programs and products continue to be administered without interruption. We plan for a rolling transition of staff to the new location along with focused hiring to fill any vacated essential positions at the new location to ensure as little disruption as possible. Currently, agencies are filling some positions based on their strategic hiring plans. The continued uncertainty is challenging for our employees, which is why the Secretary has urged expediency in the site selection process.

USDA is following a rigorous site selection process, with leadership from USDA, ERS, and NIFA involved. EY provides real estate advice to organizations across industries, including the federal government. After being retained, EY began the critical step of developing criteria to evaluate the

Expressions of Interest. As discussed, agency leadership and employee engagement during this process have been and will continue to be instrumental to ensure mission function will be maximized in a new location and employees and their families would have a strong quality of life. Due to the high volume of EOIs, EY created an initial subset of criteria focused on mission operations that include travel requirements, labor force statistics, and work hours compatible with all USDA office schedules to narrow the list from 136 to 67 EOIs. Then using the high-level criteria posted in the Federal Register (transportation logistics, workforce, community/quality of life, and capital and operating costs), EY is using an agency driven analysis to define the following weighted criteria to further evaluate the EOIs.

- Quality of Life: Subcategory examples include Diversity Index, Residential Housing Costs, Access to Healthcare, and Home and Community Safety Ranking.
- Costs (Capital and Operating): Subcategory examples include Cost of Living Adjustment, Commercial Real Estate Costs, Land Costs, and Wage Growth Rate.
- Workforce: Subcategory examples include Labor Force Growth Rate, Unemployment Rate, and the Labor Force Population.
- Logistics / IT Infrastructure: Subcategory examples include Lodging Availability, Proximity to Stakeholders, and Travel Time to / from DC.

We are expecting EY to deliver a short list based from the 67 EOIs by the end of March and teams led by EY conducting further qualitative analysis, site visits, and further negotiations with submitters through April. USDA hopes to have a final recommendation from EY in early May.

We fully believe that by relocating we can better carry out our mission, placing more dollars on research than overhead, and improving service to our customers. Moving forward we will continue to implement this process in the most transparent way possible and will continue to keep Congress apprised every step of the way. Thank you for the opportunity to present this testimony. We look forward to continued dialogue and answering the Committee's questions.

REALIGNMENT OF THE ERS

Mr. BISHOP. Thank you very much. Let me begin the questioning. I will go to the realignment first. Perhaps we will not dwell on that too long.

ERS, as I understand it, removing it from Research, Education, and Economics and putting it under the Chief Economist would appear to reduce assurances of the scientific integrity and the objectivity of the ERS statistics and research, and perhaps would threaten the accuracy of its statistical products.

It is my understanding that the Code of Federal Regulations says that the Office of the Under Secretary for Research, Education, and Economics and the Chief Scientist is explicitly and exclusively charged with upholding scientific integrity. And a number of actions by various REE undersecretaries have countered attempts to prevent or delay publication of ERS research reports or statistical updates.

By contrast, the delegations of authority to the Chief Economist's Office have no such responsibility for scientific integrity, and in fact, it requires consideration of the USDA secretarial policy positions via the requirement that the Chief Economist's Office "oversee and clear for consistency analyst assumptions and results of all domestic matters applying to man, including such estimates and analyses prepared for public distribution by the Foreign Agriculture Service, the Economic Research Service, and by any other agency of the department."

Those seem to be pretty distinct responsibilities. And I would think that to move the agency under the Chief Economist would make it have less integrity and less independence.

Do you not agree with that?

Ms. BOSWELL. Thank you for the question. First, I would like to address the scientific integrity policy. USDA is a science-based, facts-driven agency. And the Scientific Integrity Officer and the work of that team, and under the office of the Chief Scientist, monitors and ensures that department-wide, we are operating with scientific integrity.

That is not exclusive to the REE mission area. As you can expect, throughout the department in all mission areas, there is scientific research being done, economic analysis being done, and that role not only dictates the work done in REE, but again department-wide. And that will continue to operate department-wide.

Secondly, in regard to the claim and criticism that this realignment would somehow diminish the credibility of this research, we fundamentally disagree with that. In fact, we believe that there is more potential for politicization, if there is potential, remaining under REE.

The reason for that is because the ERS administrator is a career SES employee. The Chief Economist is a career SES employee who reports to the Secretary. Under the current position——

Mr. BISHOP. Excuse me. But do they not have different functions? One has the obligation to maintain the integrity under the CFR or the research, and the other has the obligation to carry out the secretarial policy.

Ms. BOSWELL. That is inaccurate.

Mr. BISHOP. Pardon me?

Ms. BOSWELL. That is inaccurate, with all due respect. Again, the scientific integrity policy applies throughout the department. The Chief Economist currently implements WASDE, which is a statistically regulated report that is done under the purview of the Office of Chief Economist. That has not been called into question, as far as I am aware, of that integrity of that report. Also, the REE undersecretary is a political and also reports to the Secretary.

Again, if there is a view that there could be impropriety, we believe that this actually is sheltering ERS through another layer of a career SES employee.

Mr. BISHOP. Thank you. I will yield at this time to Mr. Fortenberry. My time is about expired. We will have another round.

THE SELECTION PROCESS

Mr. FORTENBERRY. OK. Thank you, Mr. Chairman.

Can you give the timeline of the Ernst & Young process?

Ms. BOSWELL. Thank you for the question. USDA, as a Federal Government Agency, had to undergo a little bit of a unique process rather than how maybe a private company would do that.

When the opportunities that we saw to benefit our mission came forward, we knew that we needed expert help to make sure that this was done objectively and that it was done with the expertise that this type of decision warrants. We also knew that we had to notify Congress. And we also wanted to make sure that we were transparent and engaging with our employees.

So the August decision began that process, the process that is still ongoing today. Ernst & Young was retained and is implementing an agency-driven analysis. Employee committees are reporting to their agency leadership, and then agency leadership is coordinating with mission area leadership all the way through the deputy secretary and Secretary's office. That dialogue is consistently occurring. In fact, we have even designated a specific staff to do touchpoints with our employees to make sure that their feedback is delivered to Ernst & Young in this process.

The timeline, as I have mentioned, has been viewed as ambitious. But the rationale for that is that we know that this period for uncertainty for our employees is only causing more angst and anxiety. We were a little bit delayed with the shutdown, but we expect a—we have just released a middle list, from 136 to 67 expressions of interest.

We will have a shorter list determination presented to USDA in the coming days, actually, and through April Ernst & Young will conduct more discussions with submitters. Employees will be able to attend site visits. And ultimately, with a site recommendation and full cost-benefit analysis that we began before the initial decision to start the process, but always anticipated that, again, that was the beginning of a long process that we are still undergoing. And that analysis will be presented in an ultimate site recommendation.

Mr. FORTENBERRY. So its precise timeline is unclear. I understand you are leaving some purposeful ambiguity here. But six months?

Ms. BOSWELL. We anticipate that we will have a site recommendation to the Secretary in early May.

AGENCY TRANSPARENCY

Mr. FORTENBERRY. Regarding the ongoing process, you mentioned in your testimony that you very much value stakeholder input, and reemphasized that here, particularly within the department. Perhaps you noted, though, the chairman's complaint about the slow walk of information to him. And I would like to hear you address that.

Ms. BOSWELL. The Secretary is transparent in everything he does. It is why we are here today, to make sure that we can have an honest and transparent discussion in front of you and answer your concerns. The Secretary has committed to the chairman personally to answer all questions related specifically to the realignment, and we look forward to receiving that from your staff so we can respond to your constituent and stakeholder concerns.

We have consistently engaged and answered questions as they have come before us. We have also voluntarily participated in stakeholder events, specifically a webinar, where we could answer concerns even though we were not initially invited.

We want to be transparent and we want to be open in this process and hear that feedback. And truthfully, that feedback is going into the Ernst & Young analysis to make sure that we can ultimately fulfill our goal, which is benefitting our mission of providing better and more diverse research.

Mr. FORTENBERRY. You mentioned that there are certain critical functions to remain here. Can you define those?

Ms. BOSWELL. Yes. We have announced this to employees and provided additional information in a briefing to the appropriator committee staff. This was an agency-driven analysis. Both ERS and NIFA conducted this through engagement with their employees, and the administrator of—acting administrator of ERS and director of NIFA evaluated that and presented those options to the Secretary.

Because they are two separate and distinct agencies, they are different approaches. For ERS, there will be approximately 76 critical function—employees holding critical function remaining in the National Capital Region. That is nearly a third of the agency.

NIFA, because again they have different roles and different missions, had a different approach, and they are having approximately 20 critical functions and employees holding those positions, remaining in the National Capital Region.

Again, that analysis is based on—

Mr. FORTENBERRY. Out of a total of?

Ms. BOSWELL. For ERS, 253 would be relocated, and under NIFA, 315. And that is based off of current appropriated staffing levels.

Mr. FORTENBERRY. Thank you very much.

Mr. BISHOP. Ms. Pingree.

Ms. PINGREE. Thank you very much, Mr. Chair, and thank you, Ms. Boswell, for being here with us today and for the work that you do at the USDA.

I have been one of the people who has been very concerned about this move. And just to mention a couple of things, I do not feel like it has been a transparent process. Back in August when we first learned about this, we sent a letter—all the Democrats on the committee sent a letter—to the USDA, and we got a two-page response. So that did not feel thorough to us, as the committee that has oversight on the budget.

We also have not been able to find out how many staff—we do not have much data about it—how many staff have actually left since the proposal was announced. And while I understand there is some argument to be made that if people are going to have to go through this dramatic change, leaving them in limbo for as short a period of time as possible is helpful.

On the other hand, a move this dramatic with this many moving parts and this much money associated with it requires more in-depth thinking, in my opinion. And so we should be much more engaged. And I appreciate the point of the hearing today, but I would say up until this point we have not been able to access a lot of information such as how many people have left.

REASONS TO MOVE

I guess let me just ask you a couple of questions from your perspective. When the Secretary did announce this in August, he identified three reasons for the relocation. But one of them was not advancing agricultural research. And I think we should all be able to agree that advancing agricultural research should be one of our top priorities, particularly when farmers are dealing with so many challenges—strained markets, climate change, just a lot of variables out there and a lot of threats to their livelihood.

So why was improving agricultural research not a consideration in this proposal?

Ms. BOSWELL. Thank you for the question. And first, I do want to apologize if there is a feeling that we have not been transparent. I actually have answers to some of those specific things that you raised, and am happy to provide that, either if our time remains here or following.

Mission function was the key focus, and the Secretary viewed a lot of opportunity when we were reviewing the cost of overhead in these two agencies. And he believes that the mission function will ultimately be enhanced by the three specific access: More access to be in the forefront of emerging issues, and being more agile to set priorities; being able to attract and retain the highly talented individuals with ag backgrounds that are all across the country that, unfortunately, do not want to or cannot afford to live in DC; and third, being more efficient in our spending of our taxpayer dollars to allow more dollars into research and programs, and even retaining more staff in the long run, than on overhead cost.

Ms. PINGREE. So I am not sure I agree with you on everything, but I do appreciate that you have answered your perspective on how that would improve agricultural research. But I am not sure we will attract better staff or any of the other things that you said.

Based on that middle list—and while I am sure—and I know the ranking member has left the room, but I am sure that Nebraska

is a fine place to locate this. And you are from Nebraska, and I fully believe that it would be a wonderful place to be.

INPUT ON RELOCATION

All that said, Nebraska does not get any closer to Maine farmers. To Maine farmers, accessing it in DC is actually more helpful. So if USDA is truly interested in providing stakeholders with the best service, why did Maine farmers not get a chance to have some input in all this, and what is to say that they would rather have to deal with an agency in Nebraska?

Ms. BOSWELL. Thank you. Well, first, the expressions of interest notice that went out in the Federal Register allowed for any interested entity, group, university, or all of the above to submit, express interest. And we received broad response from that, 136 in 35 States, of groups of individuals that believe science can be done objectively outside of DC, and that there is a lot of talent that does not live here.

But we do also recognize again that there are important stakeholders and communities like your constituents that would easier access Washington, DC, and that is why we have—

Ms. PINGREE. Let me ask you one more—thank you for that. And let me ask you one more quick thing before I am out of time.

And Mr. Fortenberry, I do want to say that I did acknowledge that although I am opposed to this, I am sure Nebraska would be one of the ideal States, based on your service and Ms. Boswell as well.

On the same day the Secretary announced the relocation, the ERS administrator was reassigned. This administrator was a long time and highly qualified employee. Why was the ERS administrator reassigned on that same day the proposal was announced? I think we deserve some clear answers from the department on that particular fact.

Ms. BOSWELL. I appreciate that question. However, personnel matters cannot be discussed.

Ms. PINGREE. All right. Well, we will take that up at another time. And I yield back my time. Thank you.

Mr. BISHOP. Dr. Harris.

Dr. HARRIS. Thank you very much, and thank you very much for appearing before the subcommittee.

As you know, I represent a rural area in the Eastern Shore of Maryland, and agriculture is one of our most important products, of course. And I appreciate the Secretary being interested in actually helping those kinds of communities.

RELOCATION FROM A RURAL PERSPECTIVE

And I will tell you, in this day and age I do not understand why either of these agencies cannot relocate. We are not in a day and age where you need to be physically present anywhere for a lot of things. And our rural communities need the—and I think that is an important point that is made, is our rural communities really do need the economic boost from having a government agency, especially one that serves the local community like these two agencies do in our agricultural communities, from being there.

That being said, as you know I have actually had three rural areas in my district that were very interested. I am going to say I am disappointed that the two locations that made the medium list from Maryland are not rural areas. The bottom line is, if one of the objectives is to move out of the Washington, DC area and then to pick Montgomery County and College Park—I know they have representatives, but I have got to tell you, you do not see corn growing in College Park.

But from all those three locations that I recommended, you could look out and see grain fields. And they are ones where the cost of living is lower, and again, the economic boost would have been much appreciated.

So that being said, I know that other agencies have—in the government, I know that CJIS, for instance, the FBI's Criminal Justice Information Service, moved out of Washington to West Virginia last year. Our understanding is that that move actually resulted in a higher retention rate at that facility and they did not have much attrition.

I guess, interrupting the narrative that unless something comes inside the Beltway it is not going to work or it is not going to operate or people are going to flee, which I think is a narrative that, again, I think is rapidly—the falsehood of that narrative becomes very apparent once you get outside the Beltway and actually go into communities where people actually think it is nice to be able to own a home instead of having to rent for your entire life. It is nice to actually be able to walk to things or to have short drives, no traffic, all the things associated with rural communities.

So can you address—are you familiar with the move of the FBI's CJIS to West Virginia? And it seems parallel. The only difference is, actually, there is no nexus of the Department of Justice into West Virginia. But there is certainly a nexus of USDA agencies into a rural area or a more rural area.

Ms. BOSWELL. Thank you for that question. I am not personally as familiar with the intricacies and the background of that particular relocation, but definitely agree that especially considering 90 percent of our employees are currently outside of the National Capital Region, and in fact these two agencies are the only agencies that do not have representation outside of the National Capital Region, there is synergies there.

And we are—we believe that this relocation is going to maximize the opportunities to hear on-the-ground feedback and to be at the forefront of emerging policy issues just as your constituents inform you of emerging policy issues, that we will be able to attract the best and brightest with ag backgrounds that may still want to participate in their family operation, or have some ties to their rural communities.

We also believe that we can be more efficient. The work that these two agencies are doing is exceptional already. But we can be better, and the Secretary expects us to be more efficient and provide better service for our customers, ultimately.

Dr. HARRIS. And again, just to reinforce, again part of my disappointment with looking over the middle list, or I guess you call it the middle list, of relocation sites, again, they are not all rural areas. Again, I am just—and speaking for my State, like I say, you

can drive up through College Park today. It is not rural. There is no nexus with USDA except obviously there is the University of Maryland there.

But I would urge the—I think this is exactly the way the Federal Government ought to go. I think we ought to move the—we ought to take advantage of the internet age and move these agencies out among the people because as you know, if you go outside the Beltway, there is a reason why it is the phrase “outside the Beltway,” because people outside the Beltway look and say, “Look, this is not the real world that goes on. People do not understand what the real concerns are.”

And I think this kind of policy decision by the Secretary is a good policy decision, and I yield back.

Mr. BISHOP. Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And thank you for your testimony today. I appreciate you explaining this process. I have just a few pcs-type questions for you, and it has to do with the criteria.

You have mentioned that you have 67 expressions of interest. Are there certain criteria that are public that you are saying, OK, these are the 10 most important things that we are looking for in a new location?

SITE SELECTION CRITERIA

Ms. BOSWELL. I appreciate the question. We have retained Ernst & Young. A very talented team is working on this for us. No USDA political official has seen the expressions of interest. We turned all of them that we received over to Ernst & Young for their evaluation. And because we are a Federal agency, we did have to do this a little bit differently.

I will tell you Ernst & Young typically would do all of the work that they are doing right now in secret. But because, again, we needed to put out the public notice and get that feedback from all across the country, the criteria that they are using was based on the high-level criteria that was in the Federal Register notice: transportation logistics, workforce, community quality of life, and capital operating costs.

Because the 136 is such a large list, they then took a cut at it with five other criteria that were based specifically on mission operations. And that feedback came directly from the agencies on what were the we have to have/we need to have type of criteria.

And that related to compatibility with business schedules, transportation scheduling, labor force statistics—which is critical not only for our employees but our employees’ spouses—and then filtering within the EOIs within the National Capital Region.

We were inclusive. Again, we sent everything to EOI even though the intention is to relocate outside of the National Capital Region. And they conducted an analysis based on proximity to headquarters and comparing that to the Beltsville location.

But as we go forward, now they can do the deep diving. Now they can really get into the weighted criteria that is from feedback from our employees through their agency leadership to the mission area. We have all sat together and went through what is important.

And the following criteria in the weighted order that they will be evaluating them in their model is: quality of life, including diversity index, residential housing cost, access to healthcare, and home and community safety rankings; cost, include cost of living, commercial real estate costs, land costs; wage rate growth, workforce, labor force growth rate, labor force population; and then logistics and IT infrastructure; lodging availability is especially important for NIFA and our peer review panels; our proximity to stakeholders; and travel time to and logistically from those headquarters.

Also I would note, in ERS, access to a census data center is part of that criteria, and also ensuring the IT infrastructure, as they will remain a Federal statistical agency. That is the nuts and bolts modeling that they are using with their expertise. But there are a lot of qualitative factors that go into this as well. This is not a math equation. And in their benefit analysis, they will perform that as well.

Mr. MOOLENAAR. And that is very helpful, just to hear those weighted factors. I was assuming there were some, but I did not know if that was public information or how widely understood that was. But that is very helpful for people, to know that.

And so for next steps, you mentioned going from 136 down to 67, and you said there will be a shorter list coming up in the coming days. And let's say you have a group of 20, or I do not know what that shorter list looks like. Would that group then be asked to submit a proposal? Or is it simply that that is the group that there will be a site evaluation and go through these criteria? Or what are some of the next steps in the process?

Ms. BOSWELL. As I said, we have not seen—I personally have not seen—the expressions of interest. But from my understanding, they vary greatly. Some expressions of interest have one site; some have 20. Actually, the 136 expressions of interest totaled 308 potential sites.

And so Ernst & Young has had their hands full. But there will absolutely be further discussions, negotiations, site visits, and again, looking at that qualitative analysis. The example that Ernst & Young has used that really resonates with me is, you can find a building anywhere. We need to make sure that the community works for our employees and the mission overall.

And so they are doing that process. Once they get to this shorter list—and again, in the coming days and weeks I will caveat that a little bit—and then doing that qualitative analysis and site visits and negotiations, which inevitably, I think, will require additional information from those who submitted.

Mr. MOOLENAAR. Thank you very much. And thank you, Mr. Chairman. I yield back.

CURRENT USABLE FACILITIES

Mr. BISHOP. Ms. Boswell, let me ask you, you mentioned the need for the move, it was spawned by the expiration of leases. But we have not seen any data to support that need. You cite the recruitment and retention, with attrition, but we do not have any statistics on that.

We do know that there was a hiring freeze recently. We know that you are concerned about the cost of the rental space. But we also have information that the department had planned for the expiration of those leases some time ago, and in fact, that there is a plan at USDA to renovate the South Building and the Carver Center, which are USDA-owned facilities.

Would not those facilities, once renovated, provide sufficient space for all of the ERS and the NIFA employees in the Capital Region at an optimal cost? Since you already own it, you would not have to pay rent.

Ms. BOSWELL. Thank you for the question. I am not—as I was not in the previous administration, I am not sure what other considerations were made at that point. But I can speak to that. Secretary——

Mr. BISHOP. The department does not maintain records from previous administrations?

Ms. BOSWELL. I was not personally involved in——

Mr. BISHOP. I am sorry?

Ms. BOSWELL. I was not personally involved in those discussions or what those proposals were. I can talk to——

Mr. BISHOP. But you have been involved in trying to relocate. Would you not look at previous research that was done and plans that were already developed to accommodate the expiration of the leases, which you give as the basis for the move?

Ms. BOSWELL. Absolutely, Mr. Chairman. And in fact, we did, and there was an analysis done for NIFA because their lease was expired, and looking at the cost associated with relocating in the DC area. And Secretary Perdue and USDA currently are reevaluating our space utilization, and that was independent of the decision to relocate ERS and NIFA.

Mr. BISHOP. Would it not be appropriate to do that in the context of property that you already own, that is USDA-owned, and you would not have to rent other space nor pay the expenses of moving?

Ms. BOSWELL. That certainly is going to be a consideration in the Ernst & Young analysis. However, that was only—the cost was one of the factors that the Secretary put forward as furthering our mission. That does not help our employees in their cost of living or quality of life.

Mr. BISHOP. Let me ask you, that was not what I understood the Ernst & Young mission to be. My understanding was it was to take proposals outside the capital area, and the properties I mentioned are right here almost on Capitol Hill.

Ms. BOSWELL. Well, Mr. Chairman, in any cost-benefit analysis there has to be a baseline. And that baseline is going to look at the status quo and other available opportunities within USDA and present a full, robust analysis for the Secretary to consider.

Mr. BISHOP. It seems like you are sort of turning your head or refusing to look at existing plans that anticipated the expiration of leases that you mentioned.

Let me ask you, in terms of the stakeholders, are not the primary stakeholders for ERS and NIFA really the people who have to do that research, and the direct stakeholders are those of us who have to take the data that is produced to make policy decisions? And are not most of those agencies based right here? And would

not that facilitate collaboration? And is that not consistent with the national science principles for statistical agencies?

Ms. BOSWELL. There is no one-size-fits-all stakeholder for these agencies. We have the customers, the farmers, that are using this data, and the market analysis and the forecasting they are doing to make their business decisions. There are the nutritionists that are using the research in school meal planning and other food safety or food program developments.

There are also, as you mentioned, our academic colleagues that work as partners with us in delivering and investing in research. There are also policy-makers, and we believe that we should be informing policy from ground level rather than only reacting to policy and different legislative proposals that occur here in DC.

And the ultimate stakeholder as well is the American taxpayer. And we need to make sure that we are efficient with our dollars to make sure that we are carrying out our mission the most effectively.

Mr. BISHOP. I could not agree with that more. Thank you.

Mr. Fortenberry.

Mr. FORTENBERRY. Just briefly. One question. Mr. Chairman, thank you.

We have talked about the initial request for consideration or request for interest that generated 136 responses at locations across the country. That is abstract. Can you give a better feel for the intensity of interest around the country by various locations?

GAUGING INTEREST

Ms. BOSWELL. Thank you for the question, Ranking Member. We have received stacks and stacks and stacks of support letters from Senators, Members of Congress, governors, community leaders, business leaders, associations, and local communities that are advocating not only for their particular site but the fact that science can be objective and trusted and done very well outside of the National Capital Region. And there is a lot of talent, untapped talent, that we could reach into that, just again, cannot afford or do not want to live in Washington, DC.

Mr. FORTENBERRY. Thank you. I yield back.

Mr. BISHOP. Ms. Pingree.

Ms. PINGREE. Thank you. And thank you again for your answers to the questions. And I do not disagree with the basic premise that there are great people doing science in other places. We have incredible research universities. We have other institutions and labs around the country. All those things are true. I am from Maine. I think we do incredible work there. I do not think everything has to be in DC, and I do not think most of us are DC-centric.

But the question about all this is the role of Congress in this oversight committee and other oversight committees, in being engaged in this conversation and understanding why these decisions were made. And yes, it is cheaper to live somewhere else. But there are also reasons why it is easier to collaborate and do some work here in DC. So there are pluses and minuses about this.

And so I think our general argument is more about being engaged in the process, being part of the conversation, and so far disagreeing that this is a good move. We have been talking a lot, and

you have mentioned multiple times about Ernst & Young and their role here. But I think we have very little understanding on this committee about the role of Ernst & Young.

When were they first contracted? When was this contract first signed with them? What is in the original contract? What are the scenarios in the cost-benefit analysis that they are or have been conducting? What are we paying them? How much have you already paid? What is the—do you have answers to those questions?

THE ROLE OF ERNST & YOUNG

Ms. BOSWELL. Thank you for the question. And again, I really want to apologize if there is a feeling that we have not been transparent. We are striving to be. We take the report language very seriously. The Secretary and the Deputy have both had personal conversations with members of this committee.

We have engaged with staff consistently, answering their questions, have provided the opportunity to visit with Ernst & Young with your staff, and more opportunities like that are always available. And we are eager to answer any more questions.

Specific to the Ernst & Young contract, we retained Ernst & Young following the solicitation and competitive bidding process. I would have to look at the specific day of when it was signed, but I believe it was around October following the extension of the expression of interest period, which I believe ended October 15th.

We recognize that there is obviously a small cost, a cost in retaining that. But we felt that the objectivity and the expertise that they brought to the table would value and bring value to the process rather than having any appearance of political influence in this or lack of expertise in the area. We knew we needed to bring in that expert help.

The two agencies split the cost of that, and that total cost, I can tell you right now, is approximately \$340,000.

Ms. PINGREE. And what is the scope of the contract?

Ms. BOSWELL. To ensure I stay in my lane, I am happy to provide that information back to you. We have—

Ms. PINGREE. You can give me that in writing.

Ms. BOSWELL. Perfect.

Ms. PINGREE. And I would also be interested to know what are the scenarios in this cost-benefit analysis? If we could see the contract, that would be great. If we could know more of the detail of what they are being asked to do.

Ms. BOSWELL. Absolutely. We can provide that. And also I would like to take this moment to mention that that cost-benefit analysis will be made available to you all when it is complete and conducted with a site recommendation.

Ms. PINGREE. Great. Thank you, Mr. Chairman.

Mr. BISHOP. Dr. Harris.

Dr. HARRIS. Thank you. Just very briefly, my understanding is that there actually—in the last Congress there were a bill or bills that actually would not only—would attempt to block the Secretary's reorganization. I take it this is part of the Secretary's reorganization. But it actually might have the effect of actually requiring some of the agency employees that actually are around the country to actually move back to Washington and things.

So I would take it that the Secretary does not agree with that kind of philosophy, I take it, in terms of the centripetal idea, that everything has to come inside the Beltway in order for it to function well?

Ms. BOSWELL. Thank you for the question. Yes. That proposed legislation, we provide technical assistance on. And it would in fact require thousands of employees to move to Washington, DC, and it would close many ARS labs and NASS regional offices as a result of that legislation. It is definitely over-broad.

If the intent was to—you get to the matter at hand, it would have dramatic impact on our scientific agencies across the country.

Dr. HARRIS. And I take it not only would it have a dramatic impact on them, but I guess it would increase the costs, if you are taking people from around the country and moving them into a high-cost area?

Ms. BOSWELL. I would expect that it would.

SITE PROXIMITY

Dr. HARRIS. Now, when you gave the proposals to Ernst & Young—and because when you were going through some of those criteria, some of those criteria are addressable by advances in technology that are not here yet. So for instance, there are communities where a year ago there was not broadband, there was not any, but there is going to be.

One cannot conceive where, within the four years it would take to move an agency or build a building where it is not going to be there. So was that taken into consideration or was Ernst & Young asked to take that into consideration?

It is not only the present capability, but it is the reasonably projected future capability of an area.

Ms. BOSWELL. Thank you.

That is the perfect example of the qualitative analysis that they are doing. Not everything can be put into a model and modeled out.

As you are aware USDA is taking broad initiatives on broadband and working to expand broadband access throughout the country, and so that infrastructure is absolutely not only for now, but we need to make sure that this is laying the foundation for long-term success to deliver our mission and provide more diverse and more effective research in the long run.

Dr. HARRIS. And which Ernst & Young office is doing this?

Ms. BOSWELL. We actually have a team that is based here in DC and in New York. The analysis part of this is led by their construction team that is in New York that does this for private and public entities and has vast experience.

Dr. HARRIS. And when you say New York, do you mean New York City?

Ms. BOSWELL. It is New York City.

Dr. HARRIS. And just out of curiosity, I mean, you are asking people from Washington and New York to judge the ability to move something to a rural area. Are you really confident that the people on the team actually understand how competent a rural area is to handle this job?

Again, I understand the biases, and they are present, and anybody who pretends they are not present, leave the Beltway for a while.

Are you confident that a team based in New York and Washington is going to make an adequate judgment about the ability to move something to an area that is not New York or Washington, that does not look like New York or Washington? Let me put it that way.

Ms. BOSWELL. My role in this is to be the extension of the Secretary and to make sure that his intent is carried out with the guidance of our agency teams through the, again, employee committee processes to the Administrator and Director of NIFA, Acting Administrator and Director of NIFA, through the mission area and making sure that this is an Ernst & Young analysis.

They are only providing the analysis of the information that we are giving them, and that is agency-driven, mission-focused information.

Dr. HARRIS. OK. Thank you very much.
I yield back.

Mr. BISHOP. Ms. Lee.

Ms. LEE. Thank you very much. Thank you, Mr. Chairman.
Good morning.

ERS/NIFA SENIOR STAFFING

Let me ask you a couple of questions with regard to the Acting ERS Administrator, who I understand is not an economist. You have had an Acting Administrator since August.

And it is my understanding you have had trouble finding a permanent person, and my understanding is that the job position for the ERS Administrator, there is no requirement to submit a description of how the applicant's experience and skills reflect Federal executive leadership qualities.

So this is not part of the application process or a limiting factor for selection in the position, and I want to make sure that is correct. And if so, why did that occur?

Why did you do that actually?

And what does this mean for the type of individuals that you are willing to accept as an ERS Administrator?

And then also, in terms of just the budget request, you would only retain, it is my understanding, 160 professional employees at the agency of about 350 employees that ERS had in September of 2017. This seems to be fairly inconsistent with the messaging that has been provided to the staff, nor to the public, by the Office of Secretary at USDA.

So it seems like this request really does gut ERS, and if it does not, how are you going to handle it?

Ms. BOSWELL. Thank you for the question.

First in regard to the posting for the Administrator position, we cannot discuss specific personnel issues. However, we have posted, as you are aware, through the USA Jobs process. That is an ongoing process to make sure that we get the best individual for the job.

That is being carried out through our Mission Area leadership to conduct that analysis, just as—

Ms. LEE. Yes, but Federal executive leadership requirements or qualities, that is not a personnel issue, is it? That you can talk about just in terms of the criteria.

Ms. BOSWELL. The posting that was, again, gone through or has went through the USA Jobs and is now being reissued, I can share that information with you.

Again, that is being led at our Mission Area level as all hiring decisions of the like would be, but I am happy to get you more information about it.

To your second question, the Secretary will be here to discuss the President's budget in detail in the coming weeks, and so I will kind of yield to specific budgetary questions to him.

But I will say that our intention, and we have stood true to this and plan to going forward, this is not a reduction in force. And, in fact, the Secretary has authorized the hiring of 60 positions at ERS, which is the highest single approved hiring plan since it was centralized in DC.

For NIFA, we have approved 75 positions of hiring. So we are making sure that we are hiring to appropriated levels, and we are being strategic in creating redundancy and filling critical positions to make sure we carry out our mission effectively during this transition period.

Ms. LEE. Well, let me go back to the question I asked about the Federal executive leadership experience. I appreciate your getting us a copy of the job description, but could you just answer whether or not that is listed in the job description?

Because I would think you would know and you could tell us whether that is or is not a qualifying requirement for this position.

Ms. BOSWELL. Thank you.

Again, because, again, this is done and operated at our Mission Area level, that is not something as a senior advisor to the Secretary I am directly involved with, but I am happy to get you more information about that and answer those questions.

Ms. LEE. So you just do not know.

Ms. BOSWELL. Correct, and I do not want to speak inaccurately.

Ms. LEE. OK. Thank you very much.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you.

I notice that the President's proposed budget for ERS would cut total funding from \$86.8 million to \$50.5 million. Fifty, point, five million of that is dedicated to the relocation.

ERS staff-years would be cut from 330 to 160, 76 of which would be located in USD Headquarters.

It seems to me that ERS is not being given the resources or not having the resources requested by the administration to maintain the high quality of research that we have enjoyed in the past with that dramatic cut.

ADDITIONAL REASONS

Now, let me ask you. You point out that many USD agencies are located outside of Washington, DC, and you use that partially as a rationale for relocating ERS and NIFA. And that is true, to a certain extent.

But you take USD agencies like NRCS, Risk Management Agency, and FSA. They actually run programs that assist farmers and ranchers directly, and of course, regulatory agencies like GIPSA and Food Safety Inspection Service need to be able to work in the field, and very large agencies like ARS are able to tailor their programs to distinct regional needs, and they obviously need to be distributed across various regions of the country.

But can you tell me some compelling reason for a national level program for policy evaluation to be located outside of Washington, DC, when the major stakeholders, the vast majority of the beneficiaries of ERS research and statistical collections are the Administrators of the USDA programs, the food and agriculture policy decision makers, the members of Congress, and the other Federal agencies that depend upon the research that is done by ERS and NIFA or that is funded by NIFA in any event?

Can you tell me why there is a compelling reason to move it?

We do not have any data that says that you are losing employees because of the cost of living. You did not supply us with that data, and apparently you had resources that you intend to hire additional employees.

You did not look at the cost of renovating the South and the Carver Buildings, which would obviously not require you to pay rent.

Can you tell me what the compelling reason is to move it?

It seems like where I come from they say, "If it ain't broke, don't fix it."

Ms. BOSWELL. Thank you for the question, Mr. Chairman, and the opportunity to even further explain the Secretary's goals here.

First of all, we can always be better, and we can always be more responsive, and again, the teams at ERS and NIFA do great work. But we believe that we can be better and should be better.

The mission of these agencies is agriculture and food research. The primary customers and really facilitators of this research are the agriculture sector and food sectors. This is farmers; this is rural America. These are food companies. It is food and agriculture production.

And while you are absolutely correct that policy makers at the Federal level and other departments utilizing that research, especially specific to ERS, just as your constituents bring policy matters to you, we believe we can bring ground level policy issues to DC and inform that policy in a proactive way rather than being only reactive.

Mr. BISHOP. We have a worldwide interest here, and our producers in America that export worldwide need to have the information, and it is not just localized in our various communities. We have producers all over the country. We have manufacturers and exporters of food all over the country.

Ms. BOSWELL. You are absolutely right, Mr. Chairman, and frankly, we do not see a compelling argument that that research at a global level cannot be done outside of DC.

Mr. BISHOP. Thank you very much.

Dr. Harris.

Dr. HARRIS. Thank you.

RURAL PROSPERITY

Just very briefly, you know, I am reading the strategic goals of the USDA, and goal number four is a very important goal. It is: facilitate rural prosperity and economic development.

I would hope that that actually, again, in this age of technology where you really can site a lot of things in a lot of places, that that would be of a very high priority as you look to relocate these agencies that are paid for by the U.S. taxpayer, but are really for the farmers and for the rural communities.

That is all I would suggest. It is one of the strategic goals. You probably do not need to look any further.

Thank you, Mr. Chairman.

Ms. BOSWELL. Thank you.

Mr. BISHOP. Well, let me thank you very much, Ms. Boswell, for your engagement and your participation, and we appreciate very much your comments in behalf of the department.

And at this time we will take a brief recess so that we can have our second panel.

Ms. BOSWELL. Thank you for the opportunity.

[Recess.]

Mr. BISHOP. The committee will reconvene.

I now would like to introduce our second panel.

Dr. Buchanan and Dr. Woteki are former Under Secretaries for Research, Education, and Economics, who served under President Bush and President Obama, respectively, for 10 years.

Dr. Lee and Dr. Evans served as Administrators of the Economic Research Service for a total of 60 years under Presidents Reagan, George H.W. Bush, George W. Bush, and Obama.

This is a very impressive group with intimate knowledge of USDA leadership, organization, and management. We welcome your insight, and we are very pleased to have you appear before our committee today.

And let me ask Dr. Harris for Mr. Fortenberry if he has any remarks before hearing from our panel.

Dr. HARRIS. No, I do not, but thank you for asking.

Mr. BISHOP. Well, thank you.

And let me recognize our distinguished guests for brief oral statements, and then we will proceed with questions.

I note that each of your entire written statements will be included in the record.

Dr. Buchanan.

TESTIMONY BY DR. BUCHANAN

Dr. BUCHANAN. Well, thank you, Mr. Chairman and members of the subcommittee for giving us the opportunity to share some of our thoughts on the proposals to relocate NIFA and ERS out of the Nation's capital region and to realign the Office of Economic Research Service.

While this might appear to be a simple administrative change, in my opinion, it is a major fundamental change that will have far-reaching implications for our research programs in the future.

Mr. BISHOP. Would you pull your microphone towards you?

Thank you.

Dr. BUCHANAN. Can you hear me better now, Mr. Chairman?

Thank you.

As soon as I heard this back early last fall, I immediately called some of my former colleagues, administrative heads of agriculture, and told them what it was that I had heard and had they heard it, and I got a unanimous concern from all of the people that I called about it.

And so several of us put together a letter outlining our concern, and I have learned that has now been signed by well over 75 agricultural leaders in the Land Grant Universities and some of the support people.

And as of this date I have not gotten a single and I am not aware of any support coming from any individual for the proposal that is not from a group, institutional organization, that is looking to host NIFA and ERA.

And for the past half century, many agricultural research leaders, such as myself and the folks here at this table, have worked hard to try to more fully integrate agricultural science into the greater scientific community in Washington, and I think we made a lot of progress over the years, but we still have a long way to go.

I think that we have got to build and continue to build and strengthen our relationship with all of the agencies involved in research in Washington, and that includes NIH, NSF, EPA, NIST, NASA, DOE, the various National Academies, and other groups that have an interest in research because we want to be a part of the greater research community.

And agricultural research benefits greatly from funds contributed by other departments and agencies in Washington. Funds for co-funded projects reached almost \$2.5 billion above that provided by NIFA for agricultural research.

Research policy is pretty much made in Washington, and we need to be where the action is, and I think that is important.

We clearly see that both State and Federal sides are true partners in agricultural research and education programs. In fact, during the celebration of the 150-year celebration of the land grant legislation that created our Land Grant Universities, USDA and the Land Grant Universities issued a statement about principles of partnership for the future strength of the system and the true beneficiary of this effort is the American people.

The research component for agriculture was ushered in with the Hatch Act by this body of 1887. The Smith-Lever brought in an extension in 1914, but there has been many, many, many major changes and reorganizations of our system since then, starting with the Adams Act of 1906, the Purnell Act of 1925, the Bankhead-Jones Act of 1935, and several others.

Congress recognized a lot of problems along the way, too. For example, the 1890 legislation provided for a land grant status for African Americans. The 1994 legislation provided for a land grant status for Native Americans, and it was not until the 1977 farm bill that the Congress recognized the need for a mission for the 1890s for research.

So this body has been actively involved in so many changes over the years in our agricultural research and education system.

And finally, the 2008 farm bill had a lot of major changes. I know some of you remember those. I was very much involved in that since I was Under Secretary during that time, but in the 2008 farm bill, the Cooperative States Research, Education and Extension Service was reorganized and renamed. That is when we got the NIFA name in the 2008 farm bill.

AN EMPHASIS ON DUE DILIGENCE

But also the bill provided for a Chief Scientist for USDA, which is something that I think is very appropriate that came out of this body after a lot of deliberations, and I know some of you remember.

We had meetings on top of meetings with everybody, and we had private groups that had interest. We had APLU, and of course, the department had interest. So it was a long process.

I share this background for one particular reason, to illustrate the many changes that have been made in our system over the years. But I want to emphasize something that always these changes were made with a lot of discussion and a lot of debate and a lot of input from just about everybody that wanted to have input, never by spur of the moment, unilateral decisions.

Changes are usually based on two criteria: to fix a problem or to make something better. The department has proposed some items to be fixed, such as the high cost of rent, recruitment and retention of staff, working conditions for personnel, and being closer to farmers.

One could question the validity of each of these problems or so-called problems. For example, the idea of being closer to farmers makes absolutely no sense to me. NIFA's primary clientele are not farmers. NIFA's primary clientele are the scientists, administrators, and national agricultural research, and the greater scientific community. That is their primary clientele. They work primarily with other scientists and with the administrators, not directly with farmers.

The department does not offer any rationale at least so far that I have seen for making our research system better. I suspect this is because I really do not see a way that it is going to make our research system any better by relocating somewhere outside of the Nation's capital region.

In view of this, I cannot see why or any value in expending any research resources for this until such time as Congress receives, reviews, and approves a real honest cost-benefit analysis.

I truly hope the Secretary will reconsider this proposal and keep NIFA and ERS in the area where I think they can do a better job of the things that they are supposed to do. They go back all the way back to the first Office of Experiment Stations in 1889, which was set up to coordinate and to try to bring some type of cohesion to the whole system that is spread all across this great country.

In my opinion, our agricultural research system is far too important to be fundamentally changed without careful study and thoroughly investigating all of the options available. Such changes should clearly fix an identifiable problem or to make our system better.

Thank you very much for your attention.

[The information follows:]

Thank you Mr. Chairman for giving me the opportunity to appear before your committee this morning and to share some of my thoughts on the proposal by the USDA to relocate NIFA and ERS out of the nation's capital region and to realign the reporting line for ERS to the office of the chief economist. While this might appear to be a simple administrative change, it is a major fundamental change that will have far-reaching implications for our agricultural research programs in the future.

Frankly, when I heard about the department's proposal to relocate NIFA and ERS outside of the nation's capital region, I was stunned. I began talking to colleagues. Many, in fact most, felt as I did. We put together a letter outlining our concern. It has now been signed by over 75 agricultural leaders from the agricultural research community. As of this date, I'm not aware of any supporter for the USDA proposal that is not from a group, institution or organization trying to host the agencies.

I would like to share some of my concerns. For the past half-century, many agricultural research leaders have been working to more fully integrate agricultural science into the greater science community. Such integration is key to sustaining the knowledge-based productivity gains we have made. Much progress has been made already, but we still have a long way to go to be considered equal players in the research community in the Washington, DC area. Both as a researcher and especially as an agricultural administrator, I've made many visits with NIFA and ERS in Washington. Usually, my visits were coupled with visits to other agricultural agencies, other federal agencies such as EPA, NIH, NSF, or with the state's congressional delegation.

Agricultural research programs benefit greatly from funds contributed by other departments, agencies, and organizations. Funds for co-funded projects reached almost 2½ billion dollars above that provided by NIFA. Research policy is made in Washington, therefore for maximum effectiveness these agencies should be in close proximity.

Relocating NIFA and ERS outside of the national capital region would be a handicap for agricultural scientists and administrators and a step back for the progress in the integration of agricultural science into the greater science community in Washington. Aligning ERS with other research components of USDA is far more logical than simply making them answer to a staff person in the USDA administration

Many would agree, at least I strongly agree, we have a remarkably successful agricultural support system that includes teaching, research, and extension functions in agriculture. Starting with the passage of the Morrill Act, now known as the Land-grant Act that was signed into law by President Abraham Lincoln in 1862. In my opinion, this is among the greatest piece of legislation ever conceived by men and women. Across the years, the U.S. Congress has made numerous changes – always with much debate and consideration of multiple options and approaches.

Many who have not “grown up” in our “System” don’t realize that our greatest strength is in the unity of our relationships. We clearly see that both state and federal sides are true partners. In fact, during the celebration of the 150th anniversary of the land-grant legislation, USDA and the LGU’s issued a statement about principles of partnership for the future strength of the system. The beneficiary of this relationship is the American people.

The research component was ushered in with the Hatch Act of 1887 and extension with the Smith-Lever Act of 1914. Even after passage of the Hatch Act of 1887, there were numerous changes in research programs brought about by the Adams Act of 1906, the Purnell Act of 1925, the Bankhead Jones Act of 1935, Research and Marketing Act of 1946, and the New Hatch Act of 1955. However, work was not complete on the Morrill Act of 1862. The people recognized that the African-American community was not included in the 1862 legislation. The U.S. Congress recognized and proposed legislation creating the second Morrill Act that we now know as the 1890 legislation. But this did not fix the research component for the 1890 institutions. There was some progress made in the 1960s to provide some support for research by the 1890 institutions; however, it was left to the U.S. Congress led by Sen. Jim Allen of Alabama to formalize a research mission for the 1890 institutions. It is, indeed, fortunate because these institutions today contribute substantially to the agricultural research mission for the country.

The 1994 Department of Agriculture reorganization Act provided for land-grant status for Native American tribally-controlled colleges and universities.

Finally, the 2008 Farm Bill reorganized and changed the name of the Cooperative States Research Education and Extension Service (CSREES) to the National Institute of Food and Agriculture (NIFA). Also, this bill provided for a USDA, Chief Scientist. I would emphasize all

of these changes were made after extensive discussion by Congress with great input by stakeholders.

I share this background information to illustrate how such progress has been made in our agricultural research and education system across the years. Most fundamental changes have always been brought about by the legislative process that provides an opportunity for all sides to share input, thoughts, and ideas. Changes are usually based on two criteria, (1) to fix a problem, or (2) to make the system better. The department has proposed some items to be fixed, (1) the high cost of rent, (2) recruitment of staff, (3) working conditions for personnel and (4) be closer to farmers. Each of these could be addressed more easily than simply by moving and relocating the agencies to someplace outside the national capital region. For example, relocating NIFA and ERS outside of the area to less expensive property would be a possible solution. The idea of being "closer to farmers" makes absolutely no sense. NIFA's primary clientele are the scientists and administrators of the national agricultural research programs. They work primarily with other scientists and administrators, not farmers. Soon after passage of the Hatch Act of 1887, it was realized there needed some means of coordinating the effort of the State Experiment Stations. Hence was born the Office of Experiment Stations. In a sense this was the beginning of NIFA. The need to foster collaboration among the State Experiment Station has not changed.

The department does not offer any rationale for making the research system better. I suspect this is because I do not see how this relocation and realignment will improve our System. In view of this, I cannot see any value in expending any research resources for this until such time as Congress receives, reviews and approves a cost-benefit analysis.

Our agricultural research system is far too important to be fundamentally changed without careful study and thoroughly investigating all options. Such change should clearly fix an identifiable problem or, clearly, make the system better. Thank you.

Mr. BISHOP. Thank you, Dr. Buchanan.
Dr. Woteki.

TESTIMONY BY DR. WOTEKI

Dr. WOTEKI. Good morning, Chairman Bishop, Dr. Harris, Ms. Pingree. Thank you for this opportunity to testify today.

I am opposed to the Secretary's proposal and believe that it will significantly weaken the scientific enterprise that is so critical to Americans' food, economic, and national security.

There are four main reasons that I oppose the proposal, and I explain those reasons in more detail in my written testimony, which I have submitted for the record.

I also believe that the proposal that is the topic of today's hearing should be considered together with the President's budget request for fiscal year 2020, which was recently made public. Taken together, they undermine America's ability to address looming threats to our food security and national well-being.

Briefly, my four reasons for opposing this proposal are:

One, the organizational structure and location of these agencies are not the problem. The major problem facing agricultural research is the disinvestment in public funding that has occurred over the last 30 years and that imperils our future agricultural productivity and poses threats to our economic competitiveness and national security.

Two, throughout this process justification, consultation, and due process have been lacking. The Secretary's plan did not have appropriate review and consultation prior to sending out the request for expressions of interest from States, and the reasons provided for moving the agencies, quite frankly, do not hold water.

Neither NIFA nor ERS experienced any extraordinary issues with recruitment and retention, does not put them closer to stakeholders, and no analysis of costs and benefits has been provided.

Studies by the Office of Personnel Management, the National Academy of Sciences, and the Office of Science and Technology Policy have shown that low pay is the biggest problem for recruitment and retention of scientists and economists. This proposal will actually lower pay and make it more difficult to recruit a talented workforce.

My reason number three is that realigning ERS to report to the Chief Economist is really a fundamental misreading of roles and responsibilities. ERS is a research and statistical agency and appropriately belongs in the research, education, and economics mission area.

Lastly, the functional capacities of ERS and NIFA are being damaged, and since the Secretary's announcement both agencies have lost experienced, well trained staff, and the President's budget, as you pointed out, Mr. Bishop, proposes cutting 170 staff-years from ERS.

In conclusion, I want to thank the members of this committee for holding this oversight hearing and providing the opportunity for me to share my views on what I consider to be a proposal that is ill-considered and terribly damaging to our long-term future.

I urge you to include language in the fiscal year 2020's appropriation spending bill that will provide no funding to relocate ERS

and NIFA outside the National Capital Region, prevents the realignment of ERS or NIFA outside of USDA's research, education, and economics mission area, and that includes a general provision prohibiting any other funds from being used for the realignment or relocation of either ERS or NIFA.

I look forward to your questions.

[The information follows:]

Testimony of Catherine E. Woteki, Ph.D.
 Former Chief Scientist and Under Secretary for Research, Education and Economics
 Before the House Appropriations Agriculture Subcommittee
 March 27, 2019

Chairman Bishop, Ranking Member Fortenberry and members of the Subcommittee, thank you for the opportunity to testify today and share my views on the Secretary of Agriculture's proposed relocation of the Economic Research Service (ERS) and the National Institute of Food and Agriculture (NIFA) and on the realignment of ERS into the Office of the Chief Economist. I am Catherine Woteki and from 2010-2016 I held the position of Chief Scientist and Under Secretary for Research, Education and Economics (REE) at USDA. In that capacity, I had direct oversight responsibility for ERS and NIFA as well as for the Agricultural Research Service (ARS) and the National Agricultural Statistics Service (NASS).

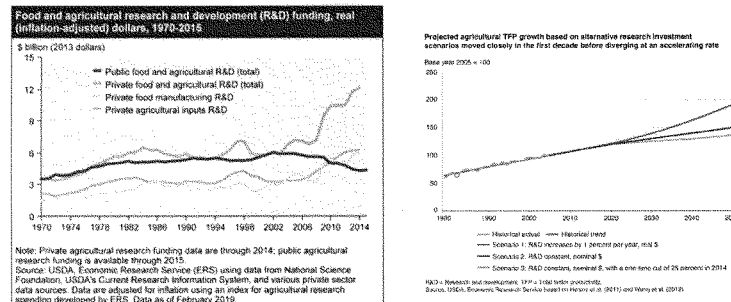
I am opposed to the Secretary's proposal and believe that it will significantly weaken the scientific enterprise that is so critical to America's food and fiber supply, and to economic and national security. There are four main reasons that I oppose the proposal: (1) structure and location are not the problem; (2) lack of justification, consultation and due process; (3) realigning ERS to report to the Chief Economist is a fundamental misreading of roles and responsibilities; and (4) enormous damage is being done to the agencies' functional capacity. I also believe that the proposal that is the topic of today's hearing should be considered together with the President's budget request for FY 2020 which was recently made public. Taken together, they undermine America's ability to address real threats to our food security and economic vitality.

Organizational structure and location are not the problem.

The major reason for my opposition is that the biggest problem facing agricultural research and statistics is not the organizational structure or the location of the agencies, rather it is the historic disinvestment in public funding that has occurred over the last 30 years. As shown in the graph¹ on the left below, the current level of funding for agriculture, food and natural

¹ Agricultural Research Funding in the Public and Private Sectors. <https://www.ers.usda.gov/data-products/agricultural-research-funding-in-the-public-and-private-sectors/>

resources research is less than in the 1980's as measured in inflation-adjusted dollars. Both Federal funding and state funding to support agricultural research have stagnated and the end result is that the US is in danger of losing its leadership role in areas critical to our long-term welfare.



This has implications for farmers and for our national security because since World War II productivity growth in the farm sector has come almost exclusively from science-based innovation or what economists call total factor productivity. Based on ERS research and shown in the graph² on the right above, we can expect little change in US farm sector's total factor productivity over the next few years, but beyond that it is expected to slow and how much our agricultural productivity will be harmed depends on the current and future amount of public investment and its coordination with other federal research agencies' programs.

In the meantime, some of our rivals have made substantial public investments in agricultural research. China's investment now surpasses ours. For the time being, the US is maintaining its scientific preeminence in agricultural fields as measured in publications, citations and patents, but each year we are losing ground to other countries that are providing more public support for agricultural research.

All of this has long-term implications for the national security of the United States. The 2019 Worldwide Threat Assessment of the US Intelligence Community³ identifies the erosion of the US lead in science and technology as one of ten global threats because research produces

² Wang, SL et al. 2015. Agricultural Productivity Growth in the United States, p. 56. https://www.ers.usda.gov/webdocs/publications/45387/53417_err189.pdf?v=0

³ Coats, D.R. Statement for the Record, Worldwide Threat Assessment of the US Intelligence Community, Senate Select Committee on Intelligence, January 29, 2019. <https://www.dni.gov/files/ODNI/documents/2019-ATA-SFR---SSCI.pdf>

disruptive technologies and threats to economic competitiveness. The assessment calls out rapid advances in biotechnology, including gene editing and synthetic biology, as posing new economic, ethical and regulatory challenges. At the same time that these technologies hold great promise for agriculture, they also introduce risks as adversaries may use them to develop biological warfare agents and threaten food security. A second global threat pertinent to agriculture is environmental and ecological degradation that is likely to fuel competition for resources, economic distress, and social discontent now and in the future. Drought, floods, wildfires, and soil degradation are intensifying and threatening food security on both domestic (viz. the recent Midwest flooding) and global scales which in turn can spur social unrest, migration and tension between countries. Agricultural research to develop resilient agricultural systems is key to being able to respond to more unpredictable and extreme weather patterns and provide for long-term food security at home and abroad.

Justification, consultation and due process are lacking.

The Secretary's plan did not have appropriate review and consultation prior to sending out the request for expressions of interest from states, and the reasons provided for moving the agencies don't hold water. As my colleagues have pointed out in their testimony, there was no consultation with the Land Grant Universities – the 150-year partners with USDA for research, education and Cooperative Extension – about the wisdom of relocating the agencies outside of the Washington, DC area. USDA appears to have violated its own requirements as detailed in departmental regulation⁴ requiring that any agency reorganization and/or relocation has to go through a thorough review of the costs and benefits, the potential effects on employees, and the impact on civil rights. None of that appears to have been done last August when the Secretary precipitously solicited proposals from communities to host the 700 staff members employed by ERS and NIFA.

Secretary Perdue offered three reasons why he made the proposals and, based on my six years as Under Secretary and Chief Scientist, none of them make sense. Neither NIFA nor ERS experienced any extraordinary issues with recruitment and retention in those 6 years. They do face one issue that all science agencies face, and that is that government salaries have a hard time competing with academic and private sector jobs. Moving the agencies outside of the DC area

⁴ Departmental Regulation 1010-001. Organization.
<https://www.ocio.usda.gov/sites/default/files/docs/2012/DR1010-001.htm>

won't fix that problem, it will only decrease salaries and lessen the ability of two-career families to find meaningful employment for both partners. The second reason that Secretary Perdue offers is that this will place them closer to their stakeholders but he doesn't define who those stakeholders might be. My experience is that having ERS and NIFA in DC makes it easier for them to consult with their stakeholders, as well as their federal colleagues. Finally, the Secretary says that taxpayers will save on lower costs but, because no analysis is provided, this is an empty statement. During my tenure at USDA, the department began implementing a long-term plan to cut down on rented office space. The plan focuses on renovating the South Building and moving agencies from rented space back in and much thought and consideration had been given to the plan. Using the end of NIFA's rented space in the Waterfront Centre as the impetus to relocating the agency is a red herring. The end of the lease was long-anticipated and planned for.

Moving ERS to OCE is a fundamental misreading of roles and responsibilities.

Moving ERS to report to the Office of the Chief Economist (OCE) is a fundamental misreading of its role in the research and statistical functions of USDA and possibly a violation of the 1994 USDA Reorganization Act. ERS is a research agency and one of the 13 Federal statistical agencies that are covered by OMB directives to safeguard against political interference. Within the REE mission area, ERS functions as an independent agency, and also as a key contributor of social and economic research in the multidisciplinary approach to solving agricultural problems that is described in the REE Road Map for Agriculture Research and Action Plan⁵. Although the REE Under Secretary is a political appointee, his/her role is to set broad priorities for research and to assure the scientific integrity of the work produced by the four agencies. The Chief Economist is a career civil servant, however his role is to support the Secretary's policy initiatives and to act as the Secretary's Sherpa in international matters. I believe that moving ERS to report to the Chief Economist will open the agency to political interference in the scope of research it undertakes as well as in the release of its scientific and statistical products. Compounding this, the President's budget for FY 2020 proposes severe cuts to ERS research in such fields as agricultural markets and trade, farm conservation, food assistance, nutrition and diet quality, the rural economy and food safety. The severity of these cuts raises questions about the future evidence base of economic research that is so consequential for USDA's program decisions and Congress's policy decisions.

⁵ REE Action Plan, <https://www.usda.gov/sites/default/files/documents/usda-ree-science-action-plan.pdf>

In 1994, Congress passed a law reorganizing USDA and establishing the position of Under Secretary for Research, Education and Economics⁶. It instructs the Secretary of Agriculture to delegate to the Under Secretary “those functions and duties under the jurisdiction of the Department that are related to research, education and economics (emphasis added).” And the law also requires that the Secretary obtain public comment on proposed reorganizations when “delegation of major functions ... to any agency or office of the Department” occurs. The Secretary must provide advance notice to the public about a reorganization and opportunity to comment. That was not done prior to the Secretary’s announcement last August.

Maybe some of OCE’s ongoing work that is more statistical in nature, like publication of the WASDE, should be moved to REE where it better aligns with NASS and ERS. Once the door for reorganization is opened, all worthy proposals should be considered and have the opportunity for open discussion and review of the merits.

The functional capacities of ERS and NIFA are being damaged.

Finally, moving ERS and NIFA will cause loss of key staff that will take many years to recruit and train. Since the Secretary’s announcement last August, the agencies report losing 3-5 employees a week. Now that the lists are published of which positions will stay in DC and which will be moved to another location, we can expect more attrition. The President’s 2020 budget calls for more planned attrition in ERS by requesting a reduction of 170 staff years from 330 in 2019 to 160 in 2020. These dramatic staff cut proposals will only hasten departures. The jobs in both ERS and NIFA are highly specialized jobs and require training and experience to perform well. We are losing capacity to perform the agencies’ key functions even before the relocation site is identified with no assurance that capacity can or will be rebuilt.

In conclusion, I would like to note that former Under Secretaries, past NIFA Directors and ERS Administrators and most Administrative Heads of Agriculture at Land Grant Universities oppose the Secretary’s proposal. I want to thank the members of this committee for holding this oversight hearing and providing the opportunity for me to share my views on what I consider to be a proposal that is ill-considered and terribly damaging to our long-term future. I look forward to your questions.

⁶ Department of Agriculture Reorganization Act of 1994. <https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg3178.pdf>

Mr. BISHOP. Thank you very much.
Dr. Lee.

TESTIMONY BY DR. LEE

Dr. LEE. Thank you, Mr. Chairman and committee members.
I appreciate the opportunity to make a statement.

My name is John Lee. I had a 32-year career with USDA's Economic Research Service, the last 12 years as Administrator, and my remarks today are focused on ERS, but I would be happy to speak to the importance of NIFA, which I think is a tremendously important agency.

Now, regarding ERS, I would like to make just three points and the fleshing out of these points is in my submitted testimony.

The work of ERS is very important. Much of what Americans know about U.S. agriculture and the food industry comes from ERS. For decades ERS has monitored changes in the structure and organization of the agriculture and food industry. It has explained the economic and technological forces driving these changes. It has analyzed the consequences and implications of these changes and evaluated the effectiveness of alternative policies in dealing with those changes.

ERS is not a policy organization. It is a non-political research organization whose work is available to all who make decisions about agriculture and food and natural resources in the interest of evidence-based or informed decision making.

And most people do not see ERS on the stuff they pick up and read in the papers or read in farm magazines or read in the commodity magazines, but most of the stuff there has ERS product as a basis for what is in there.

Second, the reasons given by the USDA administration for relocating ERS out of the Washington area and reassigning ERS to the Office of the Secretary, I believe, could easily be challenged, and I do that in my larger testimony.

And, third, I think the very existence of ERS could be under threat. ERS staff continues to do the best they can with the resources they have. They turn out excellent work, but talk of politization of the agency and uncertainty about location weighs heavily on morale.

Top researchers are being hired away, and proposals by the department for further draconian cuts of ERS staff and budget could be the beginning of the agency's demise.

Mr. Chairman, I will be happy to speak further to any of these points and to others. I deeply appreciate your interest and that of the committee members in protecting the access of American agriculture to honest information and analyses.

I urge the Congress to see that ERS stays intact, stays in Washington, and stays non-political and adequately funded.

Thank you, Mr. Chairman and members of the committee.

[The information follows:]

Testimony of John E. Lee, Jr.

March 27, 2019

ERS NIFA Hearing

Thank you, Mr. Chairman, for the opportunity to make a statement at this hearing. I am John Lee, and I have had the privilege of serving American agriculture in two Land Grant Universities and as Administrator of the USDA's Economic Research Service. My remarks today focus mainly on the Economic Research Service, ERS, because I know it best. But, I have great respect for the mission and work of the National Institute for Food and Agriculture, NIFA. As a former Professor and Department Head at Mississippi State University, I can testify to the importance of NIFA to the Land Grant University system. NIFA is the Agency that today is most responsible for maintaining the USDA-Land Grant partnership, established by this legislative body through a series of Acts over the last 150 years. Any actions proposed that might threaten the effectiveness of NIFA should be carefully scrutinized.

So much of what Americans, including farmers and those throughout the food industry, know about the agricultural/food sector of the U.S. economy stems from the work of the Economic Research Service. Over the years, ERS has tracked the changing structure and organization of agriculture, explained the economic and technological forces behind the decline in small farms and the rise of large farms, explained the relationship between agriculture and threats to the natural resource base that sustains it, and has researched the most cost effective options to reduce that threat, provided an understanding of how changes in agriculture have driven changes in the organization of agricultural and food markets, recognized early on how changes in the rest of society have driven changes in consumer behavior and what that means for demand for farm products, explained how American agriculture keeps producing more and more with fewer and safer inputs, making U.S. agriculture one of the most efficient economic sectors of any country in the world, and analyzed the consequences of all these changes on the people who live in rural areas, and the implications for economic development.

On almost any day, somewhere in America, someone picks up a newspaper, or a trade magazine or watches the news on TV, and finds an article or graphic with some need-to-know information

about agriculture or food. If any credit is given, in small print one can read, "Source: Economic Research Service, USDA." Sometimes no credit is given, or a different source is given, which, if traced back far enough, originally came from ERS. There is an army of consultants out there who survive by convincing farmers, cooperatives, and others in agriculture that they have more dependable data, analyses or forecasts than their competitors or even USDA. But, the basic information that underlies what they all do are data and analyses from ERS, the National Agricultural Statistics Service and other USDA agencies. That's all good because all these consultants and advisors serve to extend the work of ERS and USDA to specific users. Again, not to belabor the point, but much of what Americans know or need to know about agriculture and food comes from ERS.

ERS has always been non-political. The focus there is always on honest and competent answers to important economic questions, whether those questions come from the Secretary, the Congress (sometimes through the Congressional Research Service or other routes), or from the researchers themselves who observe important economic trends and anticipate likely future questions. The staff of ERS are widely recognized as being well trained and highly competent. That is why ERS staff are sought after by so many organizations and agencies in Washington.

All this is to say that ERS is very important to USDA's capacity for policy analysis, and even more important to America's agricultural and food industry. The Agency has survived persistent budget and personnel cuts by adopting numerous innovative internal changes and innovative external partnerships with other agencies and organizations, made possible by their close proximity in the Washington area. All the while, ERS has continued to produce report after report of high quality and relevant research.

Last August, USDA Secretary Sonny Perdue announced that the Department would be relocating both the Economic Research Service and the National Institute of Food and Agriculture outside of the Washington, DC area. The rationale provided in the brief press release cited high attrition, the difficulty of hiring agricultural economists into D.C., the desire to lower costs, and the importance of the agencies being closer to their stakeholders. The Secretary also announced plans to re-assign ERS from the Office of the Chief Scientist to the

Office of the Secretary. The Department then asked for bids from states, cities, educational establishments, private entities, and other parties who might be interested in having all or parts of the two agencies located on their sites. Reportedly, 136 bids were received, and that number has been narrowed to 76.

In my view, a primary criterion for locating a Federal agency should be the purpose or mission of that agency and where that mission can be best accomplished. Certainly, not all Federal entities have to be located within the Nation's Capital. In the case of ERS, there were reasons 50 years ago for a small portion of its staff to be located away from Washington, mostly in Departments of Agricultural Economics in Land Grant Universities. Those staff worked mainly on economic adjustments faced by small and family farms.

But, huge changes have taken place in American agriculture: farms are large and efficient, and farmers now get their management, marketing, and technology information from private and public sources worldwide. What they need most today are unbiased data and research that provide the bigger picture, the larger economic context within which business decisions are made. What are the trends in global markets and what factors will affect those trends? How do policies in other countries affect market opportunities? How do changes in patterns of consumer behavior change market opportunities for producers of various commodities? The answers to these and hundreds more questions like them need to be known and understood by decision makers in all parts of our \$1 trillion food industry as they consider their management strategies and long-term investments

It is equally important that Federal policy makers know the answers to these same questions as they consider policy effectiveness, changes, and alternatives, or just need to understand what is happening in the food system. This is what ERS does. ERS is heavily linked to other Federal agencies that both supply and use ERS information and research. There are regular staff interactions, sometimes through joint working committees, with, as examples, Commerce, Defense, Bureau of Economic Analysis, Energy, Census, and multiple USDA agencies. Partly

through all these interactions, ERS remains constantly reminded of key policy issues and industry concerns, all of which help shape ERS research priorities. The data and research produced by ERS inform USDA officials and agencies, Members of Congress, and food and agricultural organizations headquartered in Washington. In short, moving ERS out of the Washington area will move it **away** from its most direct stakeholders and strategic partners..

With regard to recruitment, ERS has generally been effective in hiring experienced and new economists. The new OPM hiring authorities for economists, announced in October, will make it even easier to hire and retain economists in Washington. Other agencies, especially in USDA, have long seen ERS's outstanding staff as potential recruits, resulting in a slightly higher rate of attrition than the overall average for USDA. Rather than a problem, this should be seen as a compliment to the agency's staff and management.

Over the years, ERS has built a reputation for quality and objectivity in its research, statistics, and analysis. I recently learned the Agency is now ranked the #4 agricultural economics research institution in the world. USDA should be very proud of ERS. A major physical move that causes the loss of many experienced staff would cripple the Agency and mean years of rebuilding and training to regain its present eminence. Moreover, reported plans that keep some leadership in Washington and put parts of programs in the field will sever the team spirit and approach to research and reduce the overall effectiveness of ERS.

I fear that the reassignment of ERS to the Office of the Secretary, the dividing of the staff into two or more locations, and the drastic cuts proposed in ERS's already depleted staff and budget, will signal the demise of the Agency. That would be a major loss for agriculture and America.

As Administrator of the Economic Research Service—one of 13 primary Federal statistical agencies—under Presidents Ronald Reagan and George H.W. Bush, I feel that USDA's proposal will be a long term negative for the Department. Mr. Chairman, I deeply appreciate

your interest and that of the Committee members in protecting the information interests of American agriculture. I urge the Congress to see that ERS stays intact, in Washington, non-political, and adequately funded.

Thank you, Mr. Chairman

Mr. BISHOP. Thank you, Dr. Lee.
Dr. Smith Evans.

TESTIMONY BY DR. SMITH EVANS

Dr. SMITH EVANS. Thank you.

I get to do clean-up. So many good points have been made.

Thank you, Chairman and members of the subcommittee, for this opportunity.

John has me beat, but I was with ERS for 29 years, 10 of which was associate or acting or actual Administrator.

ERS has worked since 1961, collecting critical data and doing research that serves the public good, and the agency focuses on national issues, not local; U.S. global food security, which are elements of national security; the efficient and effective design and management of food and agricultural programs; and the collection, compilation, and interpretation of statistics that describe national phenomena.

I want to give a couple highlights from my testimony on realignment and also rebut some of the USDA's rationale for relocation.

So OMB's statistical Directive Number 1, which currently is being codified under the foundations for Evidence-based Policy Making Act, identifies the independence of Federal statistical agencies from political bodies as a necessary principle, going so far as to say that even the perception that its data collection, research, or dissemination of its findings might be manipulated for political or partisan reasons is unacceptable.

The REE Under Secretary's Office is the buffer, has always been the buffer that protects that from happening.

It has been said, you know, the Under Secretary is a political appointee, and the Chief Economist is a civil servant, but that is totally beside the point. As was already pointed out, the Under Secretary in the Code of Federal Regulations is given responsibility for scientific integrity.

And I have seen that responsibility exercised expertly and routinely by these two and other REE Under Secretaries. It is not easy to talk back to the Secretary and say, "That is science. We are not going to delay the publication of that report," and they have done it.

And the Chief Economist has no responsibility for research, much less scientific integrity.

Now, turning to USDA's rationale for relocation, I agree. Somebody else said it does not hold water. It surely does not. While farmers and ranchers are informed by ERS work, they are not direct recipients or users of most ERS products.

ERS is not a regulatory or farm program agency that must work directly with agriculture producers. It is not a large research agency like USDA that has a regional component. So the comparison of ERS with agencies located primarily outside of Washington, DC is meaningless, I think.

Finally, I am not sure that the Secretary's Office has visited a Land Grant College Department of Agricultural Economics lately. I value them. I have many, many colleagues there, but few students anymore are the sons and daughters of farmers and ranch-

ers. They used to be. They are not, and there are not enough of them to populate the Land Grants.

Many are city folk, and according to information from the National Science Foundation, increasing numbers of Ph.D. recipients are not American citizens, which means they cannot be hired by ERS.

So I do not see how the relocation in any way helps use, recruit or retain people by virtue of our proximity to Land Grants.

I look forward to your questions. Thank you very much.

[The information follows:]

Testimony of Katherine S. Evans before the House Agricultural Appropriations Subcommittee
March 27, 2019

Thank you, Chairman Bishop, Ranking Member Fortenberry, and members of the Committee for the opportunity to speak with you about the implications of USDA's plans to realign and relocate the Economic Research Service (ERS) and relocate NIFA.

My name is Katherine (Kitty) Smith Evans. I worked in various capacities at ERS for 29 years, including 10 years as Associate Administrator, Acting Administrator, and Administrator. I subsequently served 5 years as Executive Director of the Council of Professional Associations on Federal Statistics, and am currently with the American Economic Association (AEA), a professional society of over 20,000 economists who rely on the accuracy of federal statistics.

I begin my testimony by describing what I believe will be the consequences of realigning ERS *from* the Research Education and Economics (REE) Mission Area of USDA *to* the Chief Economists' Office and of allocating a diminished total number of ERS positions between Washington, DC and to an as yet determined location outside of the DC Metropolitan Area. Later I turn to debunking several myths that the USDA Secretary's Office has perpetuated in its defense of these moves.

First, removing ERS from REE and putting it under the Chief Economist reduces assurances of the scientific integrity and objectivity of ERS statistics and research, and threatens the accuracy of its critical statistical products.

Under the Code of Federal Regulations, the office of the Under Secretary for REE and the Chief Scientist is explicitly and exclusively charged with upholding scientific integrity (<https://www.govinfo.gov/content/pkg/CFR-2018-title7-vol1/xml/CFR-2018-title7-vol1-part2.xml#seqnum2.21>). And so, they do! A number of actions by different REE Under Secretaries have countered attempts to prevent or delay publication of ERS research reports or statistical updates. By contrast, Delegations of Authority to the Chief Economists' Office include no such responsibility for scientific integrity and, in fact, require consideration of USDA Secretarial policy positions via the requirement that the Chief Economist's Office "Oversee and clear for consistency analytical assumptions and results of all ... domestic commodity supply and demand, including such estimates and analyses prepared for public

distribution by the Foreign Agricultural Service, the Economic Research Service, or by any other agency or office of the Department.” (<https://www.govinfo.gov/content/pkg/CFR-2018-title7-vol1/xml/CFR-2018-title7-vol1-part2.xml#seqnum2.29>) without regard to individual estimates’ scientific merit. There are good reasons to combine qualitative analysis, experience-based beliefs, and political realities along with research findings to inform Departmental projections and proclamations. But at the same time, it is critical that the Under Secretary responsible for research has cleared the technical basis and scientific integrity of the research methods and results used in such amalgamations.

Secondly, ERS is one of 13 agencies designated by OMB as Principal Statistical Agencies of the U.S., and USDA plans for ERS restructuring violate several principles laid out for these unique and valuable agencies. The National Academy of Sciences’ authoritative *Principles and Practices for a Federal Statistical Agency* (<https://www.nap.edu/catalog/24810/principles-and-practices-for-a-federal-statistical-agency-sixth-edition>) states that “to be credible, trustworthy, and unhindered in its mission, a statistical agency must maintain a position of independence from undue external influences...[and] avoid *even the appearance* that its collection, analysis, or dissemination processes might be manipulated for political or partisan purposes...” and that “a Federal statistical agency [must] have the necessary authority to protect independence.” The current separation of ERS from the Secretary’s Office and the protection afforded it by the Office of the REE Under Secretary, are important in assuring the agency’s independence. The proposed realignment would diminish that assurance

Statistical agencies require adequate resources to ensure the quality of statistics; to invest in new ways to measure our changing economy; and to protect the privacy and confidentiality of households and businesses, whose answers to government surveys and provision of administrative information are the basis of economic statistics. Among the critical practices laid out in *Principles and Practices for a Federal Statistical Agency* is “an active research program.” The President’s proposed 2020 budget for ERS would cut total funding for ERS from \$86.8 million to \$60.5 million, less \$15.5 million dedicated to relocation. ERS staff years would be cut from 330 to 160, 76 of which would be located in USDA Headquarters to focus exclusively on “core data analysis related to agricultural production.” Neither the remaining 84 staff years nor the reduced financial resources would be adequate for ERS’ on-going, high-quality economic

research programs in food assistance, food safety, rural economic development, natural resources and in other areas that have provided evidence-based evaluations to inform program and policy decision making.

Principles and Practices for a Federal Statistical Agency additionally asserts that “coordination and collaboration with other statistical agencies [is] critical for the effective, principled operation of a statistical agency.” Such coordination and collaboration require a lot of face-to-face contact and hands-on teamwork -- interactions that would be difficult and expensive to accomplish if the bulk of ERS is located outside of the DC area where the other 12 Principal Statistical Agencies are located.

What’s at stake?

Agencies of the USDA and the Congress would have decidedly less access to informed, objective, research-based information to consider in making program and policy decisions.

The Economic Research Service’s intramural research program has been guided by the needs of public-sector food, agricultural, natural resource and rural community decision-makers. It provides objective, policy-relevant research to advance our understanding of complex relationships that inform thinking about and taking action on everything from farm finance to food waste, from research and productivity to rural health care, from soil conservation to commodity markets, and more. While economic researchers outside of ERS also have addressed these topics, they lack the mandate to work with and on the issues of USDA program agencies, as well as ready access to some program data and the general trust of those agencies.

The public sector can likely kiss goodbye such things as:

- ERS’ formidable and impactful intramural and extramural research programs on economic and behavioral factors affecting the success of USDA food and nutrition programs, including: Supplemental Nutrition Assistance Program (SNAP); Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); National School Lunch Program; School Breakfast Program; Child and Adult Care Food Program; Summer Food Service Program; and After-School Snacks and Suppers
- The kind of ERS natural resource program evaluation that demonstrated the extent to which conservation incentive programs could be enhanced by tying receipt of commodity and price

support payments to participation in NRCS soil and water conservation programs (a linkage referred to as conservation compliance) -- research that led to conservation compliance becoming law.

- ERS' work to measure domestic support policies that helped lay the foundation for the Uruguay Round Agreement on Agriculture. ERS research on the multiple factors affecting trade and their complex interactions with one another have been critical to the agency's continuing and resource-intensive development and updating of economic models that can be used for just-in-time analysis informing trade policy and negotiations.
- ERS research on rural America that addresses the economic, social, spatial, demographic, farm and nonfarm factors that affect the income and poverty status of rural residents, and derives implications for rural economic development programs.

Expected drastic reductions in staff levels and financial resources would also likely lead to the elimination or reduced frequency of statistical measures, including those describing household food purchases and acquisitions, commodity market dynamics, farm and farm household income, agricultural productivity, agricultural trade multipliers, food waste, and food security. Under the conditions created by the intentions of the Secretary's Office, it simply will not be possible to retain all current statistical series and maintain their accuracy. Legions of statistics-dependent individuals and groups, including academic researchers, students, agribusinesses, trade associations and public interest organizations, would be affected.

Some quick myth-busting:

- The USDA Secretary's Office insists that ERS has historically (prior to 1994) been under the Chief Economist. This is absolutely false. From its establishment in 1961 through 1994, ERS reported to an Assistant Secretary for Economics who was explicitly given responsibility for the quality and integrity of ERS and NASS (then the Statistical Research Service) research and statistics. A separate responsibility was for producing inter-agency projections of commodity markets. An ancillary group under the Assistant Secretary for Economics was a small Policy Advisory group -- a staff function that is not unlike what the Chief Economist's staff does now. Before 1961, there was no ERS. From 1961-1994, there was no Chief Economist. After 1994, ERS reports to the Under Secretary for REE.

- The Secretary's Office seems to think that the statistical and research products of ERS are developed principally for farmers and ranchers. While farmers and ranchers are among many who benefit from knowledge about markets and farm and farm household income, the vast majority of beneficiaries of ERS research and statistical collections are the administrators of USDA programs evaluated by ERS, and food and agricultural policy decision makers, including those in Congress. The portfolio of evidence-based research findings and statistics from ERS inform policy and program decisions across numerous dimensions, including food assistance programs, rural development efforts, natural resource and conservation programs, food safety, international trade negotiations, and food policy.
- The Secretary's Office points to the fact that many USDA agencies are located outside of Washington, DC as a rationale for relocating ERS. That is true, but agencies like NRCS, RMA, and FSA are running programs that do assist farmers and ranchers directly, regulatory agencies like GIPSA and FSIS need to be able to work in the field, and very large agencies like ARS are able to tailor their national program to distinct and different regional needs and are distributed across America. There is no compelling reason for national-level program and policy evaluation to be located outside of Washington, DC.

Mr. BISHOP. Thank you very much, Dr. Evans.

On the issue of realignment in your testimony you mention the scientific integrity as set forth in the Code of Federal Regulations, and you also mention the National Academy of Sciences' authoritative principles and practices of a Federal statistical agency.

EXPLAINING THE MOVE FURTHER

Would you, and each of you if you care to, comment on how this move would violate those principles and violate that responsibility, as well as, again, elucidate or elaborate on the Chief Economist as opposed to the scientists, the researchers, and the roles within the department with regard to the Secretary and policy versus data and research?

Dr. SMITH EVANS. The Chief Economist has responsibilities for coordinating across many agencies in the department, the production of situation and outlook, commodity situation and outlook and trade statistics.

It is an amalgamation of information that is qualitative and quantitative; that is opinion based; and some of the agencies sometimes do insert some political opinion—opinion; let's just say "opinion"—and it is the Chief Economist's responsibility to take all of that and come out with a projection or a baseline that is used as a baseline for evaluating USDA policies.

But it is not research. You are not testing any hypotheses.

Mr. BISHOP. On the other hand, the—

Dr. SMITH EVANS. And the Under Secretary does have. I said and elaborated in my testimony that that function is for research and science. Yes, responsible for scientific integrity across the department, but focusing on the science agencies.

Mr. BISHOP. Anyone else?

Dr. WOTEKI. Well, I might further expand on that since that scientific integrity policy was developed during my watch to actually respond to what had been abuses of science during the previous administration or I should say perceived abuses.

The scientific integrity policy, as Dr. Smith Evans said, resides for its overall enforcement with the Chief Scientist, who is also the Under Secretary for REE, and it is a department-wide purview.

The other key role of the Under Secretary for REE is setting the broad priorities for the research programs under the purview of the REE mission area, and those were laid out in the road map for science that was required in the 2008 farm bill and subsequently elaborated further in the Agricultural Research and Action Plan.

The work that the Economic Research Service does is integral towards achieving those research objectives, and ERS research, along with its role as a statistical agency, I believe are more secure, will be better protected if the agency remains within the REE mission area.

Mr. BISHOP. Thank you.

What are the reasons that as a national function ERS and NIFA should be in the capital area as opposed to in a regional location? And my time is almost up.

Dr. SMITH EVANS. Very quickly, we worked—"we," I still say "we." I have been done for 8 years.

ERS works closely with other people in different statistical agencies. It meets monthly with all of the statistical agency heads. I do not think you can do that by Skype.

A lot of it is informal. You are talking on the side, and you know, as proceedings are going along, and we would miss out on that.

Dr. BUCHANAN. I would like to comment.

I think the single most important thing is the opportunity to visit with all of these other agencies. We have so many collaborative relationships. A lot of you do not realize.

EPA, for example, we have many, many cooperative relationships between NIFA and EPA, the educational component, but all kinds of activities. And it is not done just at the leader level. It is done at the worker bee level.

So if you move, if you divide your troops, it leaves so many people here, NPLs, for example. Certainly they will be one way to coordinate, but that is not where all of the coordination is done. The coordination is done very often at the lower level of echelon of personnel, at the scientist level.

REASONS TO HALT THE MOVE

Mr. BISHOP. My time is up, but, Dr. Woteki, you wanted to respond to that?

Dr. WOTEKI. Yes, just one further brief point. These are national programs, as Dr. Smith Evans pointed out. In the 90 percent figure that Ms. Boswell provided of USDA personnel being located around the country, those are service delivery functions, the inspectors for the Food Safety and Inspection Service, the people who are working in the national forests, the people who are working in the county offices for NRCS and the Farm Services Agencies.

So they are quite distinct and different roles.

Mr. BISHOP. Thank you.

Dr. Harris.

Dr. HARRIS. Thank you very much.

And thank you all for your service to the agriculture community.

Now, I assume all of you are aware that the USDA has stated that a core group of staff will remain in DC from these agencies. So they are not moving everything out of DC.

So, Colonel Buchanan, because I like that title best for you, I was a commander in the Navy. I like the Colonel title.

In your testimony you say the idea of being closer to farmers makes absolutely no sense, but I am going to ask you, and I do not know if you were in the room when I asked the last panelist. You know, I brought up the strategic goal of the Department of Agriculture. One of them is to facilitate rural prosperity and economic development.

Now, I assume all four of you are going to agree that is a reasonable goal, and I assume all four of you understand how farming communities work. They work in a cycle. You get a bunch of bad weather. You are in a bad cycle.

One thing that can save that community is having something in their economy that actually has no cyclicity, and ladies and gentlemen, the Federal Government has no cyclicity. OK? I know we have shutdown, but everybody gets paid. Those paychecks come in. There is no cyclicity.

And representing the rural community is of critical importance, that we have economic development in those communities of something that offsets the cycles of agriculture.

So, Colonel Buchanan, would you not say that if you could put this agency one hour and 15 minutes away where you open the windows and you see corn fields all around you, but you could drive into Washington for that monthly meeting maybe or you are close to the capital area, that might fulfill the requirement?

Dr. BUCHANAN. Being located in the National Capital Region—

THE VIRTUES OF PROXIMITY

Dr. HARRIS. OK. Let me back up just a little bit. National Capital Region is an artificial designation. If you look at the map, it includes the entire Loudoun County, but it only includes half of Anne Arundel County in Maryland. It includes none of my district right across the Bay Bridge, which is within one hour and 15 minutes' drive to NIH, to the USDA headquarters.

So when you say you cannot move it outside the capital, do you really mean that or do you really mean you should be within reasonable driving distance for an occasional meeting that has to take place downtown, but where the cost of living is one-half of what it is in Washington, where bringing those Federal dollars could be very important?

Would you agree with me that that might be reasonable?

Dr. BUCHANAN. Of course, and this is where a real honest to goodness debate would have been helpful.

Dr. HARRIS. I could not agree with you more. Let me keep on going because we have got votes in a few minutes.

Dr. WOTEKI, you say this has to be taken in context with the President's budget request, but you have been around Washington long enough to know that the President's budget is dead on arrival in Congress, and that the President's budget had to be low because Congress has not set new budget caps that are above even the budget cap deals from 2 years ago, right?

So the President merely followed the statute. I mean, did you want him to create a budget that did not follow statute?

I mean just basically because two of you brought up the issue of the President's budget and ERS decrease in funding positions that we know are never going to occur. Is that not a straw man?

Dr. WOTEKI. No.

Dr. HARRIS. Well, I am going to disagree with you on that.

Dr. WOTEKI. No, sir.

Dr. HARRIS. I think it is a tremendous straw man, and my prediction, Doctor, is that next year we will have the same number or more of ERS positions, and our agriculture funding will be level.

So I think it is a straw man, and I will be proven out.

Dr. Lee.

Dr. WOTEKI. The President's budget is an expression of policy.

Dr. HARRIS. Ma'am, ma'am, it is not. It is expression of the failure of Congress, and that is a shame because you could have made the argument, and I respect you making the other arguments you made, but as soon as you brought up the President's budget in the context of the failure of Congress to pass budget caps, it became a partisan argument.

Agriculture should never be partisan. It should be about a very important economy in our country to that.

And I will tell you again, and, Dr. Lee, I was just going to say, again, you know, putting it within reach of a reasonable drive of Washington seems like that is kind of win-win.

Because agriculture communities, and I just want to reinforce this, and I think everybody up here kind of represents agricultural communities in their districts. They need that constancy of some of the economics. So whenever we can, we should think of creative ways to move these, move some of the economic development that a Federal agency can bring to a region to one of those regions.

And I would urge that we think outside the box on this, and if we need to move it outside what is technically the National Capital Region but into an area that does have the economic swings of an agriculture community, we ought to do it.

And with that, I yield back, Mr. Chairman.

Mr. BISHOP. Ms. Woteki, I think Dr. Harris cut you off. You were trying to elaborate on the relevance of the budget to the scientific research.

SCIENCE AND THE PRESIDENT'S BUDGET

Is there some relationship between the standards set by the principles that you referred to in your testimony?

Dr. WOTEKI. Well, sir, in my response, what I was trying to say was at least during my tenure, 6 years that I was Under Secretary and Chief Scientist at USDA, we did our best to put together a budget that reflected what our priorities and principles were for research.

And so my dismay at seeing the President's budget and the implications for the Economic Research Service, the budget is at direct odds with the stated testimony of Ms. Boswell, who just preceded us, of the intent to invest in these agencies and particularly ERS.

Mr. BISHOP. Just before I yield to Ms. Pingree, the principles and practices for Federal statistical agency, which OMB has designated ERS as one, include an active research program, which means that it has to be adequately funded; is that not correct?

Dr. WOTEKI. This is correct, sir.

Mr. BISHOP. So this would not be consistent with the National Academy of Sciences' standards.

Dr. WOTEKI. Correct, sir.

Mr. BISHOP. Thank you.

Ms. Pingree.

Ms. PINGREE. Thank you, Mr. Chair.

And I would just say that, Dr. Harris, that Mr. Fortenberry should have never left the room because he had the chance to make the case for Nebraska, and you have been making the case for Maryland. [Laughter.]

He is kind of losing out with your argument there.

But that said, I still oppose the move out of Washington, no matter what, even if it is nearby. I do not think that works.

But first, I want to thank you all for your service, for the hard work that you have done over the years for the USDA and for the American people and for keeping scientific integrity in this agency,

which is critically important, and you have all made really wonderful cases for why this move should not happen.

And I appreciate your taking the time today to come and do that, and come back to help us better understand why that is challenging.

And in many ways, I do not have any other questions for you. I think you have done such a good job articulating it. I could ask you some more questions to restate what you have already said, but I am not sure I need to.

One thing that did occur to me in listening to you talk, you brought up some other interesting information that I would just like to hear a little bit more.

PUTTING AN EMPHASIS ON RESEARCH

At different points in your testimony, and anyone can feel free to elaborate on this, you mentioned that one of the real problems is just our overall disinvestment in public research, which I think is true in many ways, and that is also reflected here.

And one of the reasons that it may be difficult at times to find the people to do the jobs is low pay, not that we need to move them to some other part of the country to find a pool of people to do those jobs, especially when you are talking about people with the skills and experience we are looking for.

And then just any underlying concerns that you have that this move is related to a general undermining of scientific integrity or just valuing science. It may not be just to skew the science, but are we increasingly putting less and less value on investing our Federal dollars in science to have the information that people need, especially as decisions get more difficult going into the future?

So I am sorry. That was a long explanation, but you have all said a little bit about this, and anyone who wants to elaborate on any of those things, I would just like to learn more.

Dr. BUCHANAN. Well, I would like to say that I think the perception that I have is there is a failure to really understand the real role of NIFA in our system, and that causes decisions to be made that I think are counterproductive.

I go back to what I mentioned earlier about the Office of Experimentation. You know, with the passage of the Hatch Act in 1887 by William Henry Hatch, he was chair of the Agriculture Committee at that time, and he is the one that took the lead after the guy from Iowa and the guy from Illinois lost the election.

So he picked up the mantle and drafted the legislation that created the Hatch Act, but there had already been about 14 States that had started some type of experiment station, mostly on a shoestring, but that was the impetus to get it started.

But it only took a year before they realized that they had created this system of State experiment stations that were quite independent. The way the experiment station was structured was very, very unique, and the money was allocated to the State, and then the State determined what research would be done.

But they needed some way of coordinating the effort of all of these independent State experiment stations, and that is when the Office of Experiment Stations was created, and in one sense that is, I guess, the forerunner.

Going back to then, there have been Lord knows how many changes over the years to get to NIFA. Of course, I lived through CSRS, and then CSRES, and now NIFA, and what comes next I do not know, but there has been many, many changes, but always looking to how we could make the system work better.

And so I guess that would be my response to your question.

Ms. PINGREE. Thank you. That is very helpful. Thank you.

Dr. WOTEKI. I have included a couple of graphs with my testimony.

Ms. PINGREE. Oh, great.

Dr. WOTEKI. They are actually based on ERS research and make some of these points that you just asked some questions about.

And I know that the Appropriations Committees have had a tough time over the last several decades in finding funds to continue the public investment in agricultural research, but the situation we are in now is that the current level of public investment in agricultural science in constant dollars is less than what it was in the 1980s, and that at least for the short term, it does not look like we will be seeing that changed or any decline in agricultural productivity.

But the future trends in agricultural productivity because that is so tightly tied to the public investment in agricultural research are at risk. And this is based on research that ERS has done, the kind of research that I think is in danger with the budget proposal and with this relocation and realignment proposal that is on the table.

So there is more in the written testimony if you would like to take a look at that.

Ms. PINGREE. I will go through that. Thank you.

Dr. SMITH EVANS. Thank you.

I would like to point out something we have not talked about, and that is that the research and the commodity outlook and projections were highly complementary, highly complementary of each other; that the outlook projections benefit from the research that is done on basic principles of commodity markets and so forth, and the research benefits from the deep knowledge of commodities by the commodity analysts.

To separate them reduces the effectiveness of both, and according to the stay list that the USDA released, it is the IT people and the commodity experts that would stay in DC, and everybody else, which I guess is the research staff of 84, would be outside there.

And I think that the coordination and collaboration between the two would be damaged.

Ms. PINGREE. Thank you. That is helpful.

Dr. LEE. Monday night I had a call out of the blue from the president of the University of Nevada at Reno. I was surprised to get the call. I met this man years ago, but he had seen I was coming here.

And he said, "I just want to impress upon you the critical importance of keeping ERS in Washington and keeping it objective, keeping it in a situation that it provides sort of the intellectual center, if you will, of what we are doing out in the States and the universities. It is so important to us, and we could not function if there were any perception of loss of integrity or objectivity."

And the same Monday afternoon, I got an email from a department head in a southern State who said, "I just want to let you know that it does not have to be any loss of integrity if there is just the perception of loss of integrity, we will not be doing business with you because we cannot afford to be affiliated with an agency now that has a loss of integrity."

I think those two points are very important.

Ms. PINGREE. Yes. No, that speaks to a lot.

And I thank the chair for indulging me on the extra time, and I thank you all for your answers.

I just will add one quick thing. While I completely understand why every State that has capacity would want this to move to their State and it would be a benefit for a rural area, I was at UC, Davis a couple of months ago for a conference related to food waste, but I was talking to a lot of the people in the department and I was struck by the fact that they said across the board to me, "Even though we would really like this to move here, of course, we think this is a very bad idea and it should not move."

So I think there is something to be said for exactly what you said.

So, again, thank you for all of your time and your testimony today.

Mr. BISHOP. Mr. Fortenberry.

ONE LAST EFFORT

Mr. FORTENBERRY. Yes, just briefly for everyone on the panel, and I am sorry if the question sounds redundant, but if you could in one sentence, and we will just go through everyone, tell me why this will not work.

Dr. LEE. Anything can be made to work, but what is missing, I think, is overwhelming evidence that it would work better than it works now, and I think that is where I stand on it.

Mr. FORTENBERRY. Thank you.

Dr. SMITH EVANS. It will not work because you will not be able to recruit the best and the brightest, even in the nicest rural area that you can find. Many ERS staff come from economics departments. They are married to people who have jobs here or want to have jobs here.

This is where the market is for economic analysts, and it will not work if you are located elsewhere.

Mr. FORTENBERRY. Thank you.

Dr. WOTEKI. I cannot improve on Kitty's statement. I agree completely.

Mr. FORTENBERRY. OK.

Dr. BUCHANAN. Well, I agree with what Kitty said, but I think the biggest problem is the question that it would work better in other ways. It certainly will not be as effective as having the opportunity to have our research agency located with other research agencies.

If you move all of the others, if you move NSF and NIH and all the other research agencies out to where we are going to move it to, then maybe it might work, but that is not possible.

So it just is a matter of degree of working. We have to make it work if it is done. We have no choice but to make it work, but it just will not work as well.

Mr. FORTENBERRY. Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Thank you very much, Mr. Fortenberry.

And let me thank all of the witnesses for your willingness to engage and to give us advice and counsel on this very, very monumental change.

Dr. Buchanan, Dr. Woteki, Dr. Lee, Dr. Evans, thank you all for being here today, and we very much appreciate your taking your time out to share with us your knowledge and your wisdom.

I hope the irony of making decisions about data-driven agencies without data is not lost on anyone, but again, thank you all for your testimony.

And with that, this hearing is adjourned.

[The testimony of Sonny Ramaswamy follows:]

Testimony of Sonny Ramaswamy

Chairman Sanford Bishop, Jr., Ranking Member Jeff Fortenberry, and members of the committee. I thank you for giving me the opportunity to submit this written testimony on the proposal to relocate the National Institute of Food and Agriculture (NIFA) and the Economic Research Service outside the National Capital Region (NCR).

My name is Sonny Ramaswamy. I currently serve as the president of the Northwest Commission on Colleges and Universities. From May 6, 2012 to May 5, 2018 I served as director of NIFA in the Obama and Trump administrations.

The United States Department of Agriculture (USDA) shocked the scientific, academic, and farm communities with the announcement on August 8, 2018 (<https://www.usda.gov/media/press-releases/2018/08/09/usda-realign-ers-chief-economist-relocate-ers-nifa-outside-dc>) to relocate NIFA and ERS out of the NCR. As a scientist and former director of NIFA, I will speak to the potential impacts of the proposed relocation of NIFA. I can state unequivocally the rationale for the proposed relocation—attracting and retaining highly qualified staff, placing the agency closer to stakeholders, and cost-savings—does not stand to reason and evidence.

NIFA was established by the United States Congress in the 2008 Farm Bill, as the federal food and agricultural science counterpart to the National Science Foundation (NSF) and the National Institutes of Health (NIH). By investing in science and solving critical issues—such as farm productivity and profitability, nutrition, obesity, climate change, renewable energy, and positive youth and workforce development—NIFA's work is integral to the health and security of all Americans.

NIFA's track record of attracting and retaining staff has been outstanding. Just between 2016 and 2017, NIFA hired staff from Colorado State University, University of Florida, Monsanto, NIH, Office of Management and Budget, and Environmental Protection Agency (EPA). Indeed, position announcements received tens to hundreds (and in some cases thousands) of applications from across America. In early 2018, despite multiple requests, over 60 vacancies at NIFA were not approved by USDA; I have learned this continues. If the proposed relocation does occur, nearly every individual in the NCR would likely quit for family reasons. Since the announcement of the proposed relocation, NIFA has been hemorrhaging: three to five staff members are leaving each week.

The proposed relocation would deal a devastating loss in brainpower and institutional knowledge of managing and deploying NIFA's \$1.6 billion budget that, along with an additional over \$2 billion leveraged from other agencies and organizations, is critical to address societal challenges.

NIFA's myriad stakeholders—farmers, students, professors, scientists, extension professionals, entrepreneurs, 4-H members, and laypeople—are in every state and island territory; thus, collocation of NIFA on a single land-grant university campus will create significant conflict of interest. Potentially, this one university could have undue influence on the administration and management of funding for research, extension, and education.

NIFA is part of the U.S. government's science agenda, created by the Office of Science and Technology Policy, which brings together NSF, NIH, EPA, Food and Drug Administration, Department of Energy, Department of Defense, and others to address compelling societal challenges, including agricultural. Relocating NIFA from the NCR would not only take the agency out of the critically needed national conversations and partnerships, which NIFA often convenes, but also would have significant negative impact on our nation's ability to solve societal problems and ensure its global competitiveness, a vision articulated by President Donald Trump.

Finally, the proposed relocation would entail significant costs to the American taxpayer for shutting down operations in the NCR, including buyouts for early retirements, startup costs in a remote location, recruitment of personnel and relocation costs, and costs for the creation and deployment of information technology and grants, financial management, and policy infrastructure. Recreating NIFA in the new location would likely take two to five years, and in the meantime, its ability to convene the best knowledge and ideas and deployment of funding to solve problems of farm productivity and profitability, nutrition and obesity, mitigation of the impacts of droughts, extreme weather events, and environmental and other societal challenges will come to a halt, potentially resulting in decades-long negative impacts on farmers and consumers and our nation's international trade.

Foundational changes in organizations, including relocation, must result in improved efficiency, effectiveness, transparency, and accountability. Indeed, President Donald Trump's 2018 Management Agenda (<https://www.whitehouse.gov/wp-content/uploads/2018/03/Presidents-Management-Agenda.pdf>) focuses on mission, service, stewardship, efficiency, and effectiveness. The proposed relocation of NIFA is not supported by any of these criteria.

During the last few years, NIFA has used evidence-based, six-sigma continuous process improvements in the operations to reduce its footprint, streamline processes, develop and deploy paperless transactions, enhance transparency and accountability, and create dashboards to track changes. These continuous process improvements have already contributed to reduced costs and savings of millions of dollars each year—NIFA has the data.

NIFA's legacy dates back to 1862 when President Abraham Lincoln signed the Morrill Act into law. During the last century and half, the partnership between the federal government through NIFA and its predecessor agencies, state and county governments, and the 1862, 1890, and 1994 Land-Grant Universities resulted in the most effective system of agricultural science and education: there is no other such system in the world! The outcomes of the oversight and convenings provided by NIFA for our nation's research, education, and extension enterprise have created the most productive agricultural production system in the world, allowing America to become the wealthiest and most powerful nation.

By relocating NIFA, which could potentially lead to the loss of its global influence, I am perplexed at how USDA believes America can solve the continuing societal and agricultural challenges, while remaining the global leader in the food and agricultural enterprise.

I call on Congress to proscribe USDA from moving forward with its proposal to relocate NIFA and ERS before undertaking a transparent, evidence-based, and unbiased review and analysis of costs and benefits, lest they destroy the finest research enterprise the world has ever known. I thank you for this opportunity to submit this testimony.

TUESDAY, APRIL 2, 2019.

OVERSIGHT HEARING ON THE RURAL ECONOMY

WITNESSES

DALLAS P. TONSAGER, BOARD CHAIRMAN AND CEO, FARM CREDIT
ADMINISTRATION

JEFFERY S. HALL, BOARD CHAIRMAN, FARM CREDIT SYSTEM INSUR-
ANCE CORPORATION

PAXTON POINTEVINT, PRESIDENT AND CEO, SOUTHWEST GEORGIA
FARM CREDIT, BAINBRIDGE, GA

MARK JENSEN, PRESIDENT AND CEO, FCS OF AMERICA/FONTIER
FARM CREDIT, OMAHA, NE

ROD HEBRINK, PRESIDENT AND CEO, COMPEER FARM CREDIT, SUN
PRAIRIE, WI

OPENING STATEMENT BY MR. BISHOP

Mr. BISHOP. The subcommittee will come to order. Before we begin, I want to raise a small piece of old business.

During the Members Day hearing last week, we committed to include Representative Posey's testimony in the record because he was unable to attend. Because of the press of time and votes, we did not ask unanimous consent to do that during the hearing.

Similarly, it had been our intention to ask unanimous consent to include the written testimony of former NIFA administrator Dr. Sonny Ramaswamy in the hearing last week on relocation. We also failed to do that.

I would like to accommodate both of these with a unanimous consent request. This has been cleared with the minority staff. And I ask unanimous consent to include both traumas in their respective hearing transcripts.

Without objection, so ordered.

Good morning, and let me welcome all of you to today's hearing. This morning we are examining the state of the rural and farm economies through the lens of farm credit. We have two panels to help us understand the challenges and opportunities our farmers, ranchers, producers and rural communities are facing.

The first panel consists of two members of the Farm Credit Administration board, Dallas Tonsager, who is the chairman and CEO of the Farm Credit Administration, and Jeffery Hall, who is an board member and chairman of the Farm Credit System Insurance Corporation.

While few people outside of the agriculture world may know about this small, independent agency that is tucked inside the executive branch, it has an important regulatory role in overseeing the banks and associations within the Farm Credit System.

The second panel consists of three CEOs of regional Agricultural Credit Associations within the Farm Credit System. Created by

Congress more than 100 years ago, the Farm Credit System, which is the largest agricultural lender, provides safe, sound, and reliable source of credit and related services to farmers and rural communities.

The members on this panel represent large portions of the country, from the Southeast to the Midwest, and will give us a sense of what is happening on the ground and lend a voice to our farmers. I thank everyone for being here today, especially those who had to travel a great distance to get here.

This discussion comes at a critical time for our farmers, our ranchers, our producers, and for our rural communities. Recent natural disasters across the country—including hurricanes and tornados in my home State of Georgia and unprecedented flooding in Nebraska, the home State of our distinguished Ranking Member Mr. Fortenberry, and other disasters across the country and in the territories—have created stress and uncertainty, on top of the impacts from the ongoing tariff situation.

And that is not to mention the fact that farmers have faced years of declining commodity prices. I have heard from my constituents, as I am sure my colleagues have, too, and there is a lot of anxiety. Farmers and ranchers are resilient by nature, but for many the future holds a lot of unknowns.

To be honest, I did not think we would still be sitting here in April without a disaster aid package that had been signed into law. I am hopeful it will happen soon, but I am extremely frustrated and am eager to hear from our witnesses on the second panel who are having to deal with the aftermath of disasters firsthand.

Even with all that uncertainty, there are reasons to be optimistic. As if 2017, the Farm Credit System made more than \$9 million in outstanding loans for young farmers and more than \$12 million in beginning farmers investing in the future of agriculture, whether it be research of people. It is a priority of this committee, and I am looking forward to hearing more about Farm Credit Administrations and the Farm Credit System's outreach to these farmers.

In addition to making loans, farm credit banks and associations serve as a trusted resource of information for people in agriculture in rural America. They build relationships, offer trainings, support trade associations, and donate time and resources after natural disasters have occurred.

Finally, as the chairman of this subcommittee and as a member from a rural district in southwest Georgia, rural development is one of my top priorities. I have a real passion for trying to utilize this opportunity to see that rural America is able to prosper. It should not matter what zip code a youngster is born into or in which his or her family lives. That should have no impact on their capacity or their ability to realize their full potential. I was glad to see all our witnesses took time to address the issues of rural America in your written testimony, and we will explore this topic further.

I want to thank all of our witnesses for being with us today, and I look forward to today's discussion.

I would like to ask my distinguished ranking member and my friend, Mr. Fortenberry, if he would like to have some opening remarks.

OPENING STATEMENT BY MR. FORTENBERRY

Mr. FORTENBERRY. Yes, I would. Thank you, Mr. Chairman, and thank you for convening this important hearing. Good morning, gentlemen, and welcome to the subcommittee. We look forward to your testimony.

I am eager to get an update on the Farm Credit System and how it continues to play a critical role in providing stable and dependable sources of financial credit for, as the chairman mentioned, the hard-working men and women of rural America.

I am pleased to see that our chairman, Chairman Bishop, has called the Farm Credit back to testify here. Only the second time, as I understand it, before the subcommittee in the last 21 years. So welcome home, and again, thank you, Mr. Chairman, for your initiative.

Your appearance before us is timely, as our farmers, ranchers, and producers face a number of threats to their livelihoods, from low commodity prices and tight margins to the externalities born of hard but necessary trade negotiations as well as the problem of natural disasters, and something very often overlooked that is that is really impacting rural America, the high cost of healthcare.

Most prominent in my mind is the historic levels of damage caused by the Platte and Elkhorn and Missouri Rivers to farming and rural communities in my district, as well as certain urban communities, but also, the many neighboring districts in the Midwest. And thank you, Mr. Chairman, for recognizing that in your opening statement.

To see the power and devastation of this once-in-every-500-year series of events bomb cyclone, as it has been called, it leaves an indelible mark on you, especially when there is uncertainty about what both private and public resources will be available to support these communities as they recover. So on a related note, I do want to thank the Farm Credit Administration for the public statement that you offered, encouraging credit institutions to use flexibility following the disasters so it can help borrowers get back on their feet.

Chairman Bishop, as he mentioned, has also seen this type of disaster in Georgia after the hurricane last fall and hurricanes from previous years. So we are hopeful that Congress can move quickly to pass a disaster supplemental for all of the 2018 and 2019 disasters in order to reassure lenders that the Federal Government is there to lend a helping hand.

Today we will discuss the function of the Farm Credit Administration within the context of the Farm Credit System. And you all will touch upon the operations of the budget of the administration, its policies and regulation, and something that I think we need to spend a little time on, the worsening financial situation in today's farm economy.

Many outside the agricultural community have little familiarity with what you all do and how it plays a critical role in ensuring that America has among the lowest per capita grocery prices in the

world. We overlook this. We are among the lowest in terms of food cost in the world. But this also depends upon certain preconditions. Without farmers' and ranchers' access to affordable credit, the less access we potentially have to abundant and good-quality, affordable food.

So as your testimony points out, the Farm Credit System remains healthy despite some challenges, including a decrease in net farm income, and uncertainty of revenues tied to exports, and the impact of these natural disasters. You also point out that the system is well-capitalized and the portfolio credit risk remains manageable. I think this is the key component of this hearing that we need to unpack.

Agricultural financing is a unique and challenging sector of our economy, with certain unpredictable swings in commodity prices as well as land values. So if risk to the system continues to rise, the Federal Government and the Farm Credit System must be ready to respond.

So Chairman Tonsager, thank you very much, Chairman Hall, for appearing before us today, and we look forward to your testimony. I yield back, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Fortenberry.

Mr. Tonsager, without objection, your entire written testimony will be included in the record. And I would like to recognize you now for a brief opening statement, and then we will proceed with questions.

OPENING STATEMENT BY MR. TONSAGER

Mr. TONSAGER. Thank you, Chairman Bishop. Thank you, Ranking Member Fortenberry. My name is Dallas Tonsager, board chairman and CEO of the Farm Credit Administration. On behalf of my colleagues on the board, Jeffery Hall of Kentucky, and Glenn Smith of Iowa, and all the dedicated men and women of the agency, I am pleased to provide this testimony.

I would like to thank the subcommittee members and their staffs for their assistance during the most recent budget process. The resources provided will be critical for recruiting and training highly qualified staff to maintain the safety and soundness of the Farm Credit System (System or FCS) and the Federal Agricultural Mortgage Corporation (Farmer Mac).

FCA is an independent Federal agency that regulates and examines the banks, associations, and related entities of the FCS and Farmer Mac. Our responsibility is to ensure that the System and Farmer Mac meet their congressional missions—for the System to provide a dependable source of competitive credit for agriculture and rural America, and for Farmer Mac to provide a secondary market for agricultural real estate loans, rural housing loans, and rural cooperative credit.

For more than 100 years, the System has helped our Nation's agricultural producers provide the most abundant, affordable, and safest food supply in the world. The System includes four banks and 69 associations. The banks provide loan funds to the associations, which in turn lend to farmers and ranchers, farm-related businesses, and other eligible borrowers.

Of the four banks, only CoBank has retail lending authority with express authority to lend to agricultural cooperatives and to support rural infrastructure like water, power, and communications. The System obtains loan funds by selling securities on the national and international money markets. These securities are not guaranteed by the Federal Government. Investor demand for all System debt remains positive, allowing the System to continue to issue debt on a wide maturity spectrum at competitive rates.

U.S. farmers are facing challenging economic conditions. After several years of robust times, many farmers and ranchers are facing declining financial conditions amid large commodity supplies and weak prices for crops and livestock products. Higher operating costs for labor, farm inputs, and other expenses are putting stress on farm cash flows and liquidity levels.

At current price levels, many farmers will be under financial stress in 2019 despite the USDA's projected increase in U.S. net farm income. For example, profitability of corn and soybean enterprises remains well below levels reported earlier in the decade.

Adjusting production costs to meet expected commodity prices will challenge many producers. Despite these headwinds in the overall farm economy, I am pleased to report that the System's banks and associations, as well as Farmer Mac, are fundamentally safe and sound, and they maintain a strong position to carry out their mission.

While overall portfolio credit quality has declined compared to a year ago, credit quality in the System's loan portfolio remains strong. Non-performing assets totaled \$2.3 billion at the end of 2018. While elevated from \$2 billion at the end of 2017, the System's loan portfolio continues to perform well.

Other factors supporting the overall strength of the System are stable earnings, a strong capital base, and reliable access to debt markets. For calendar year 2018, the system reported \$5.3 billion in combined net income, and the System's total capital equaled \$58.4 billion, up from \$55.4 billion a year ago.

Finally, the System's loan portfolio continued to grow in 2018. The System currently supplies around 41 percent of our Nation's farm credit. At year-end 2018, gross loans totaled \$271.9 billion, up 5.1 percent from 2017. I would also note that Farmer Mac's business volume grew by \$717 million to \$19.7 billion during 2018, and overall credit quality remained stable, with substandard assets and 90-day delinquencies remaining well below historic averages.

I appreciate that you have included my written statement for the Record. Thank you, sir.

[The information follows:]

**Testimony of the Honorable Dallas P. Tonsager
Chairman and Chief Executive Officer
Farm Credit Administration
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
U.S. House of Representatives Committee on Appropriations
April 2, 2019**

Mr. Chairman and Members of the Subcommittee, I am Dallas P. Tonsager, board chairman and CEO of the Farm Credit Administration (FCA or agency). On behalf of my colleagues on the FCA board, Jeffery S. Hall of Kentucky and Glen R. Smith of Iowa, and all the dedicated men and women of the agency, I am pleased to provide this testimony. Mr. Hall also serves as chairman of the board of directors of the Farm Credit System Insurance Corporation (FCSIC).

In my testimony today, I will discuss the agency's responsibilities, the current state of the farm economy, and the conditions of the Farm Credit System (FCS or System). I would also like to take a moment to thank the subcommittee members and staff for their assistance during the most recent budget process. The resources included in the FY 2019 budget will be critical for recruiting and training highly qualified staff to maintain the safety and soundness of the System.

FCA's responsibilities

FCA is an independent agency responsible for examining and regulating the banks, associations, and the related entities of the System. The FCS is a government-sponsored enterprise (GSE) created by Congress in 1916 to provide American agriculture with a dependable source of credit. The System's banks and associations form a nationwide network of cooperatively organized lending institutions that are owned and controlled by their borrowers, serving all 50 states and Puerto Rico. The System is currently made up of 4 banks, 69 associations, 5 service corporations, the Federal Farm Credit Banks Funding Corporation, and the Federal Agricultural Mortgage Corporation (Farmer Mac).

As directed by Congress, FCA's mission is to ensure that System institutions and Farmer Mac are safe, sound, and dependable sources of credit and related services for all creditworthy and eligible persons in agriculture and rural America. We accomplish this mission in two important ways.

First, we protect the safety and soundness of the FCS by examining and supervising all FCS institutions, including Farmer Mac, and we ensure that they comply with applicable laws and regulations. Our examinations and oversight strategies focus on an institution's financial condition and

any material existing or potential risk, as well as on the ability of its board and management to direct its operations. We also evaluate each institution's compliance with laws and regulations to ensure that it serves all eligible borrowers. If a System institution violates a law or regulation or operates in an unsafe or unsound manner, we use our supervisory and enforcement authorities to take appropriate corrective action.

Second, we develop policies and regulations that govern how System institutions conduct their business and interact with customers. Our policies and regulations protect System safety and soundness; implement the Farm Credit Act; provide minimum requirements for lending, related services, investments, capital, and mission; and ensure adequate financial disclosure and governance. We approve the corporate charter changes of System institutions, System debt issuance, and other financial and operational matters.

Current state of the farm economy

U.S. farmers and ranchers are facing challenging economic conditions. After several years of robust times, many farmers and ranchers have encountered declining financial conditions amid large commodity supplies and weak prices for crops and livestock products. Higher operating costs for labor, farm inputs, and other expenses are putting stress on farm cash flows and liquidity levels. Abundant commodity supplies, resulting in part from favorable weather and continued gains in agricultural productivity, have collided head-on with changes in trade policy.

For decades, lower tariffs and improved access to foreign markets have benefited U.S. agriculture. The sector is now in the crosshairs of retaliatory tariffs as the administration pursues larger policy objectives. As a result, price risk has increased for agriculture and affected key commodities, including soybeans, pork, dairy, almonds, and citrus. During the last quarter of 2018, U.S. agricultural exports declined 9 percent from the same period in 2017.

We await a speedy resolution to the United States–Mexico–Canada Agreement and trade issues with China and other countries so that longer-term damage to U.S. agricultural export demand can be avoided. Farmers want to fully share our nation's abundance with the rest of the world, and exports are at the core of a healthy farm sector. This statement is as true today as it was in 1976 when I started my career as a dairy farmer.

U.S. farm income stabilizes

As spring planting gets underway, generally favorable conditions continue for both the U.S. and global economies, underpinning domestic and foreign demand for agricultural products. Global gross domestic product on a per capita basis is expected to continue near 2 percent in 2019 for the third consecutive year. U.S. unemployment is low, and consumer wages and income are growing. This supports consumer spending, which powers the economy. Off-farm income is a significant source of loan repayment, and many farmers are relying on it more than ever.

Several concerns are apparent, though. Labor availability and costs are straining some sectors, including farm commodity sectors, such as specialty crops and dairy, that use significant amounts of labor. The U.S. Department of Agriculture is forecasting a somewhat better net cash farm income situation for 2019 (\$95.7 billion), but this is still well below the level achieved five years ago.

In the past year, a lot of attention has been focused on farm price pressures, but cash receipts were mostly steady to higher in 2018 because the higher quantities sold boosted farm revenue. Instead, the main driver of lower income last year was higher production expenses. The income drop-off in 2018 was moderated by USDA trade-related payments to farmers, most of which went to soybean producers.

At current price levels, many farmers will remain under financial pressure in 2019 despite the projected increase in farm income. For example, profitability for corn and soybean enterprises remains well below levels reported earlier in the decade. Adjusting production costs to meet expected commodity prices will challenge many producers.

Outlook for agricultural commodities

Corn and soybean producers represent the largest group of crop producers financed by System institutions, particularly those serving the Midwest. The soybean market weakened considerably last summer, a result of a record U.S. crop and implementation of China's 25 percent tariff. U.S. exports to other countries have increased, but not enough to prevent a significant stock pileup of soybeans. For the current marketing year ending this August, stocks relative to use are forecast to be the highest in more than three decades. Some producers in regions with a very weak basis and/or poor yields are facing negative returns. However, farmers with good yields likely turned a profit because they received a payment of \$1.65 per bushel under the Market Facilitation Program. For the 2019 crop, profit margins are expected to turn negative due to weak pricing and higher costs.

The corn market has not broken out of its four-year sideways price trend because there are plenty of stocks globally, no serious threats to production, and no big run-up in demand. Still, both domestic and export demand is helping to cut burdensome supplies. Given a sharp drop in prices for the 2013 through 2016 crop years, the profitability picture for corn producers was negative during those four years. For 2017 and 2018, though, profitability improved to near or slightly above breakeven levels for producers with good yields. But those with lower yields and/or a higher cost structure are feeling significant financial pain. No improvements are expected for the crop harvested this fall if trend yields and current price levels remain the same.

Dairy producers are also experiencing stress. Milk prices in 2018 were 8 percent below the previous year due to increases in milk productivity, excess supplies, and weakening cheese export demand from additional tariffs by Mexico and China. Higher feed costs squeezed dairy returns even further. A long period of poor margins is driving some small dairy producers into liquidation. While these supply adjustments are starting to lift milk prices slightly and improve returns marginally in 2019, dairy profits will likely remain under pressure. As authorized in the 2018 Farm Bill, the Dairy Margin Coverage program will provide improved and more affordable protection against low margins, especially for dairy farmers with small herds. Program payments could help slow the exit of dairy operations.

Another significant commodity financed by System institutions is cattle. Cow/calf producers have seen moderate profits in the past two years, and the same is expected for 2019. Fortunately, beef supplies appear to be well balanced with demand. Even with large U.S. beef and other meat supplies, the relatively strong domestic and export demand for beef is supporting prices. From a lender's standpoint, in the grain-producing areas, producers with both cattle and grain are doing much better than those with grain alone.

Tree nut production has been expanding in recent years, with California almonds leading the expansion after heavy acreage investment. The industry has done well to develop both domestic and export demand, yet farm prices have been near \$2.50 per pound in recent years, down from a record \$4 in 2014. As with other agricultural commodities, the question is whether demand can keep up with future supplies. The increased tariffs by China affect between 10 and 15 percent of the California crop, so restoring the previous trade situation is also critical for these producers.

Weather is, of course, an ever-present risk for farmers and ranchers. Last year, Hurricanes Florence and Michael severely damaged poultry, cotton, and other farms in parts of the Southeast. In the West, wildfires damaged California vineyards and wineries, as well as rangeland and some cropland. Most recently, the mid-March “bomb cyclone” dropped heavy rain and triggered massive snowmelt, which led to widespread flooding in the Midwest, particularly in Nebraska and Iowa. Damages include loss of livestock, production facilities, and grain in storage. Also, saturated soil is adversely affecting preparations for spring planting. Federal agricultural disaster and crop insurance programs are expected to cover some of the losses.

FCA has provided policy guidance to System institutions to address actions they should consider in the face of natural and man-made disasters. My fellow board members and I continue to support this policy and encourage System institutions to continue to work with their borrowers when these disasters strike by extending the terms of loan repayments, restructuring borrowers’ debt obligations, and easing some loan documentation or credit-extension terms for new loans to certain borrowers. In addition, we inform System institutions that if disasters impair their ability to comply in a timely way with regulatory reporting and publishing requirements, the institution should contact FCA if relief from specific regulatory or reporting requirements is needed.

Land value stability

About 46 percent of the System’s loan volume at the end of 2018 was for real estate mortgages. The System is the largest source of credit for farm- and ranchland. Farmland value trends across major production regions were mixed in 2018 and early 2019. Some local markets and land types continued to be strong while others experienced modest price declines on waning demand. The volume of land for sale continues to be relatively modest and balanced with demand in many land markets. In general, farmer and investor demand for high-quality land is stronger than for lower-quality land.

Surveys of lenders and real estate professionals indicate these experts foresee stable to somewhat lower cropland prices for the balance of 2019. Higher interest rates and lower commodity prices have been negatively impacting farmland valuations over the past few years. Further rate increases in 2019, coupled with even a modest decline in major commodity prices, could lead to much sharper declines in valuations going forward. For 2019, it is unclear how small changes in volume might affect pricing and whether demand for good-quality land remains intact.

Farm liquidity and farm-level adjustments

As has been the case for the past several years, farm liquidity has been declining as low or negative returns deplete producers' financial reserves (their working capital). An individual farm's liquidity level depends in part on its level of debt.

The University of Illinois published 2017 data that point to the serious challenge facing some Illinois grain producers. Farms with high and very high debt have current ratios at or below 1.0 — meaning their current assets are equal to or less than their current liabilities. These farms, which are either in or approaching the danger zone, account for about 12 percent of total grain farms. For the remaining 88 percent, the current ratio is considerably better, and some producers may have improved their financial position in 2018 because of high yields, pre-harvest hedging, and receipt of trade-related USDA payments. The concern is that, if returns again drop below the breakeven point in 2019, there will be further deterioration.

As of early March, USDA forecasts call for farm equity in 2019 to rise slightly because of a small rise in farm real estate values. However, when adjusted for inflation, farm assets and equity would decline slightly. Total farm debt is forecast to rise 4 percent because of a rise in farm real estate debt, in part from increased debt restructuring by farmers. Farm sector solvency ratios will be weaker in 2019, with the debt-to-asset ratio rising to 13.9 percent from 13.5 percent in 2018. Working capital is forecast to decline almost 25 percent from 2018, while the current ratio for the farm sector is forecast to decline from 1.43 in 2018 to 1.31 in 2019.

Many farmers are working through this difficult period by finding ways to reduce costs, improve their marketing strategies, take advantage of risk management programs, reduce living expenses, and work with their lenders. Farmers who own their land have options for dealing with cash flow problems by restructuring debt, while those with a significant portion of rented land have fewer options and are more vulnerable during periods of weak or negative returns.

Farm programs offer support, but the support levels are generally not enough to help operations with higher total costs. As previously mentioned, the Market Facilitation Program payments issued in 2018 and 2019, particularly for soybean producers, likely helped extend the viability of some operations into 2019.

Some farmers are deciding to voluntarily exit the business while they still have equity in their operations. Farm bankruptcy rates, while rising somewhat, remain low, but this could change, depending on how crop and livestock markets develop this summer and fall.

Condition of the FCS

The System is in a strong position to carry out its mission and to support its membership, which extends directly to farm families, farm businesses, and rural communities that depend on agricultural credit. Overall, the System is safe and financially sound. For calendar year 2018, the System reported strong earnings that continued to support capital growth. While overall portfolio credit quality has declined from last year, System institutions have strong risk-bearing ability and are well-positioned for the challenges facing agriculture.

The System also continues to benefit from a strong capital base, which enhances its risk-bearing capacity at a time when System borrowers in certain agricultural sectors face significant financial stress. As of December 31, 2018, total System capital equaled \$58.4 billion, up from \$55.4 billion a year before. The System's total capital-to-assets ratio at year-end 2018 was 16.7 percent as compared with 16.8 percent for 2017. Overall, almost 80 percent of total capital is in the form of retained earnings. The increase in total capital is due in large part to the System's strong earnings performance. For 2018, the System reported net income of \$5.3 billion, up from \$5.2 billion in 2017. Net interest margin was 2.46 percent compared with 2.48 percent for 2017.

The System continued to grow in 2018. Gross loans totaled \$271.9 billion at year-end, up \$13.2 billion or 5.0 percent from 2017. Real estate mortgage lending was up \$5.4 billion or 4.5 percent because of continued demand for cropland from new and existing customers. Overall, real estate mortgage loans represent almost 46 percent of the System's loan portfolio. Production and intermediate-term lending increased by \$1.7 billion or 3.3 percent from the year before, and agribusiness lending for processing and marketing increased by \$3.3 billion or 15.1 percent.

Credit quality in the System's loan portfolio continues to be good. Nonperforming assets totaled \$2.3 billion, or just 0.84 percent of loans and other property owned at the end of 2018. While nonperforming assets were up from \$2 billion at the end of 2017, or 0.78 percent, the System's loan portfolio continues to perform well. Comparatively, the System's allowance for loan losses was equal to 75 percent of the System's nonperforming assets.

The System continues to have reliable access to the debt capital markets. Investor demand for all System debt products remains positive, allowing the System to continue to issue debt on a wide maturity spectrum at competitive rates. Risk spreads and pricing on System debt securities remain favorable relative to corresponding U.S. Treasuries.

With a balance of \$5 billion at year-end 2018, the Farm Credit Insurance Fund further enhances the financial integrity of the System. Administered by the FCSIC, this fund protects investors in Systemwide consolidated debt obligations. System banks also maintain liquidity reserves to ensure they can withstand market disruptions. As of December 31, 2018, the System's liquidity position equaled 182 days, significantly above the 90-day regulatory minimum required for each FCS bank.

Young, beginning, and small farmers and ranchers

Consistent with the mission of the FCS to provide sound, adequate, and constructive credit for all farmers and ranchers, Congress requires each association to have a program to provide credit and related services to young, beginning, and small (YBS) farmers and ranchers. In the late 1990s, FCA established a system to monitor the associations' YBS programs and activities and to receive reports regarding the associations' YBS lending. We compile data from these reports into our annual reports to Congress.

Using some of the increased resources recently approved by Congress, we have examined the System's data on YBS farmers and ranchers in a more sophisticated manner and have found potential areas for improvement in data collection, quality, and granularity. The current approach for reporting allows a farmer's or rancher's loan to be reported in each of the categories for which it qualifies — young, beginning, or small. In addition, more than one institution may be participating in the financing of an individual YBS farmer; since each participation interest is counted, further duplication occurs when the institutions' numbers are consolidated. As a result, for certain purposes, reconciling and analyzing the data can be difficult. Separately, the definitions of who is a YBS farmer or rancher have not been updated since the 1990s and may be out of date.

With the goal of improving the quality and usefulness of the System's YBS data by taking advantage of new tools and resources as well as 20 years of experience, we decided to begin a transparent process of reevaluating the YBS data collection process and definitions. On February 21, 2019, we published an advance notice of proposed rulemaking to seek public comment on ways to improve the YBS data collection process and definitions. We believe that with better data we can improve service to YBS

farmers and ranchers. We are looking forward to reviewing the comments that we receive from the advance notice.

Condition of Farmer Mac

Congress established Farmer Mac in 1988 to create a secondary market for agricultural real estate and rural housing mortgage loans. Farmer Mac has authority to create and guarantee securities and other secondary market products that are backed by agricultural real estate mortgages and rural home loans, USDA-guaranteed farm and rural development loans, and rural utility cooperative loans. As mandated by statute, we have a separate office — the Office of Secondary Market Oversight — through which we regulate, examine, and supervise Farmer Mac's operations.

Farmer Mac is committed to enhancing the availability of reasonably priced credit to agriculture and rural America through its secondary market activities. Under specific circumstances defined by statute, Farmer Mac may issue obligations to the U.S. Treasury Department, not to exceed \$1.5 billion, to fulfill the guarantee obligations on Farmer Mac guaranteed securities. Farmer Mac is not subject to any intra-System agreements and, unlike System banks, is not jointly and severally liable for Systemwide debt obligations. Moreover, the Farm Credit Insurance Fund does not back Farmer Mac's securities.

As measured using generally accepted accounting principles (GAAP), net income available to common stockholders in FY 2018 (ended September 30) was up 15.0 percent from FY 2017 to \$92.0 million.¹ The increase was due to an increase of \$3 million in after-tax net interest income; a \$5 million gain in fair values of financial derivatives; and the lower federal corporate income tax rate, which resulted in a \$4.5 million decrease in income tax. The increases were partially offset by deferred tax asset remeasurements and adjustments to the allowance for losses.

Core earnings, a non-GAAP measure based more on cash flow, were up by 30.3 percent over FY 2017 to \$81.5 million. Core earnings differ from net income by excluding infrequent or unusual transactions that are not indicative of future operating results, leading to a clearer depiction of the financial performance of Farmer Mac. The increase was primarily driven by the decrease in income tax expense

¹ All references to time periods and fiscal years refer to the federal government's fiscal year, not Farmer Mac's fiscal year, which corresponds to the calendar year.

relating to the lower federal corporate income tax rate, in addition to a \$6.7 million increase in net effective spread. The increase was partially offset by increases in operating expenses related to technology and business infrastructure investments, increased staffing, and new leases on office space. Net effective spread in FY 2018 increased to 93 basis points, up from 92 basis points 12 months earlier. Earnings were also up due to growth in program volume, as well as continued improvements in LIBOR-based short-term funding costs for floating-rate assets indexed to LIBOR.

Farmer Mac's healthy earnings led to an increase in its core capital through retained earnings. As of September 30, 2018, Farmer Mac's core capital totaled \$713.6 million, which exceeded its statutory requirement of \$539.8 million. This compares to \$653.4 million in core capital as of September 30, 2017. The increase in core capital helped support business volume growth. The total portfolio of loans, guarantees, and commitments grew 4.8 percent to \$19.5 billion.

Credit quality trends remained favorable, and credit quality in all program business lines remained satisfactory. Credit risk was manageable, and adversely classified volume remained stable. As of September 30, 2018, substandard loans were 3.1 percent of total direct credit exposure, down 0.2 percent from a year earlier. Loans more than 90 days delinquent decreased to 0.53 percent compared with 1.01 percent in the prior year.

Conclusion

We at FCA remain vigilant in our efforts to ensure that the Farm Credit System, including Farmer Mac, remains financially sound and focused on serving agriculture and rural America. We will continue our commitment to excellence, effectiveness, and cost efficiency and will remain focused on our mission of ensuring that System institutions and Farmer Mac are safe, sound, and dependable sources of credit for agriculture and rural America.

Mr. BISHOP. Thank you, Mr. Tonsager. Your excellent and frank testimony seems to raise at least a flashing yellow light with respect to our rural economy, which is the subject of our hearing today.

FARM BANKRUPTCY

You cite a 9 percent decline in U.S. agriculture exports in the fourth quarter of 2018, labor availability concerns, net cash farm income that is well below the level achieved 5 years ago, somewhat lower cropland prices for the rest of 2019, a 4 percent increase in total farm debt, and a rise in farm bankruptcy rates. And I thank you for noting the serious impact that extreme weather events have had on farmers in many parts of the country. Taken together, all of this is very, very concerning.

Would you say that we are at a tipping point in 2019? And what would you say are the major warnings signs that we should be paying attention to as we go forward, preparing for 2020?

Mr. TONSAGER. Yes. I think there is great concern, especially related to net farm cash income. That number alone should cause all of us engaged in helping agriculture concern. I do believe that the Farm Credit System is in the strongest possible position in my memory to help deal with the challenges associated with that.

That all being said, there is nothing more difficult than being someone in bankruptcy and having to deal with the issues associated with that. I think that farmers grew a general strong balance sheet some 5 years ago or so when things were quite good. But there is an erosion of that that is occurring.

And I think that the early participation of Farm Credit System loan personnel with producers to help them deal with—whether it be the difficulties of the farm economy, the physical difficulties of the storms that we have had—I think is absolutely crucial. And I think that the System is prepared to engage with producers that way, and is engaging with them.

Mr. BISHOP. You mentioned USDA's projection of net cash farm income in your testimony. For my colleagues, I want to point out that it is the Economic Research Service that does this estimate. My staff checked the Farm Credit Administration website and found that there are many, many citations to ERS studies in your reports and publications.

Does the Farm Credit Administration value the independence and the work of the Economic Research Service?

Mr. TONSAGER. Yes, we do. We have a small economic staff but a very good one, five, six people that are directly engaged in the economic issues. They rely heavily on the ERS's work as a check on our own work, as well as an early warning system, if you will, that points to trends that may be occurring. So yes, we rely on them significantly.

Mr. BISHOP. I understand that the Farm Credit Act and the Farm Credit Administration regulations require credit programs and annual reporting on young, beginning, and small farmers. Can you discuss these credit programs?

And in today's market, with the challenges that you have discussed, are young people deciding not to go into farming and to

pursue something else, given the tremendous challenges that we are now facing?

NEW FARMER PROGRAMS

Mr. TONSAGER. I think that the Farm Credit System program for young, beginning, and small farmers is probably the best in the country. It was initiated on a rulemaking in 2000, so it is about 19 years since that rulemaking occurred. The rule requires that each institution of the Farm Credit System establish a program to work with their producers, so it is identified to their particular regional needs.

And so it might be reduction in interest costs. It might be reduced collateral requirements. But each of them enthusiastically embraced this effort to make sure it works. So they report to us. We examine them to make sure that they are following the program they have established.

But you may be aware that we have recently put out an advance notice of proposed rulemaking on the 2000 provisions because we think after 19 years, it makes sense to reexamine what the System is doing in that area, especially the reporting information that we get, and hope to improve it.

Mr. BISHOP. Thank you, Mr. Tonsager. My time has expired, and I would like to yield to Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Mr. Tonsager, I have your name written out phonetically in my opening notes, but we are going to get to the bottom of this once and for all. [Laughter.]

Did I say it wrong the first time and right the second time?

Mr. TONSAGER. Well, yes, you just did now. Thank you very much. I have encountered that issue a number of times over the years. [Laughter.]

Mr. FORTENBERRY. OK. Thank you. But you will answer to either in case I do that again?

Mr. TONSAGER. Most people just go with Dallas.

Mr. FORTENBERRY. Mr. Chairman, would that be all right? [Laughter.]

Let's try to reconcile a few things here that are being talked about. And frankly, I think I heard the answer embedded in your testimony.

Investor demand for your securities are positive?

Mr. TONSAGER. Yes.

Mr. FORTENBERRY. Cash flow, farm cash income, is down?

Mr. TONSAGER. Yes.

Mr. FORTENBERRY. USDA predicts a little rosier scenario. Do you or not? That is one question. So I think the question becomes, farmer debt levels, have they significantly decreased? You referenced strong balance sheets having been built 5 years ago.

So are we living now off the seed corn, if you will, of a stronger balance sheet, which gives us a better position to weather the net income loss at this time, which then contributes to, again, investor confidence in your securities. Is this a correct analysis?

Mr. TONSAGER. Yes. I think that we would agree with USDA's analysis of the income. We do not attempt to recalculate that ourselves. We rely on their calculations when we talk about it.

BOND MARKETS

I think that the Farm Credit System has done an excellent job of building confidence in the marketplace in the bonds issued. So for generations, there has been very little disruption on the part of the System relative to the bond markets.

The bonds have always been paid, and the bond markets give them one of the highest ratings in the world for the quality of the bond issuances that the System does, which is an enormous benefit to all of the 500,000 stockholders that are participants in that. So it is a huge advantage.

And the very strong capital position helps the System, I think, address some of the issues that are involved with credit and to be able to be assured the System we can continue to pay those bondholders back, or they can pay the bondholders back on those securities.

Mr. FORTENBERRY. Well, there has to be another dynamic here as well, another variable. I would assume that, again, the adjustments of the farm bill, the authorized programs that provide more robust risk mitigation, create the scenario in which, again, with the ups and downs of incomes, it does not as significantly impact credit risk as it used to.

Is that a fair statement?

Mr. TONSAGER. Absolutely. I think the crop insurance program and the other risk mitigating factors you described certainly are key to all lenders—not just the Farm Credit System, but others. Without that basis, we would be much farther behind in our ability to help producers get credit.

FARM CREDIT DISASTER RESPONSE

Mr. FORTENBERRY. I may bring this up with the next panel, but you are intimately familiar with what has happened to us back home in the Midwest. So how is the Farm Credit System responding?

Mr. TONSAGER. Well, I think the strategy that the Farm Credit System pursues, and we press them, is to seek the best possible outcome for all producers. I think, in looking at a disaster situation or the general erosion of farm income and assets, asset preservation needs to be part of that dialogue with producers.

In the 1980s, and I was a dairy farmer in the 1980s in South Dakota, people went a long ways in borrowing money. So they wanted to stay on the farm. It was absolutely critical to them. We ended up with a real crisis that resulted in a tremendous amount of bankruptcies and other factors.

So the term that we have pressed the System with and they talk about themselves is trying to seek the best possible outcome for every producer.

Mr. FORTENBERRY. Let me go back to an earlier question before my time expires, regarding debt levels that farmers are carrying, because I do not think I got an answer from you in that regard.

Mr. TONSAGER. There has been an increase in debt level. Generally it is a restructuring process, where longer-term debt is taken out and replaced with shorter-term debt. And so while the farmers'

position still looks good, they have lost some ground in their available short-term—

Mr. FORTENBERRY. Maybe, as you proceed in your testimony, you can unpack as compared to when. I would like to know the historical comparison. I am out of time, but maybe we can come back to that.

Mr. TONSAGER. Sure.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Mr. BISHOP. Mr. Cuellar.

Mr. CUELLAR. Mr. Chairman, thank you, And to the ranking member also.

TARIFF MITIGATION

Mr. Tonsager, let me ask you, in your written testimony you mentioned the tariffs that the administration has imposed on China and other countries. And as you know, they have resulted in retaliatory tariffs on many of the American agricultural products. In fact, I was just communicating with some of them right now.

Mr. TONSAGER. Sure.

Mr. CUELLAR. This has increased price risk for our agriculture and key commodities that many farmers grow in my district and across the Nation. Can you talk a little bit more about what the Farm Credit Administration has done to marketing the negative effects that these tariffs have had on farmers.

And my personal opinion on this—I do not want to see subsidies or bailouts for farmers. We went through that in 2009, and some of those folks that were complaining are now getting what they complained about some years ago. So I do not want to see bailouts for them.

I think the most important thing is to get markets because you understand the way this works—if they lose a contract to somebody else, they just cannot turn on that contract right away. I mean, once they lose that, it might be gone for a while. So I would rather give them markets instead of subsidies or bailouts.

Tell me what you all are doing on that aspect.

Mr. TONSAGER. Well, I think we are being very much aware, and we are anxious to—we are anxious to be prepared for the issues associated with that. The Farm Credit System is a credit provider. And the need for producers is if there are short-term issues, and hopefully prices are short-term issues, that the System is in a position to help producers get through that difficult time.

So we are following it closely. The System is following it closely. We are trying to help, or the System is attempting to help, producers get through that difficult period while paying attention to their situation over time. So we know that there are issues that hopefully will be resolved regarding trade, and that will help producers move forward.

Mr. CUELLAR. We have even talked about the President trying to shut down the border. I mean, if you want to talk about economic impact to our agriculture folks, that would have an extremely negative impact. Every day there is more than 1.6-, \$1.7 billion of trade between the U.S. and Mexico. That is over a million dollars a

minute on it. So that is another issue because Mexico is a huge partner to the agriculture industry.

Let me ask you about 2017. Hurricane Harvey, as you know, hit Southern Texas. And you know the numbers, and the agricultural losses topped more than \$200 million. I really appreciate the good work that you all have done to support recovery efforts. And if you can just tell me, update me on your efforts. And I have heard a lot of good, thanks to what you all are doing. But if you can just tell us where we are right now.

Mr. TONSAGER. Well, I think we examined it and discussed this yesterday. The Farm Credit System, I think, when you look at the disaster, of course, you get into all the issues associated with what disaster assistance there was, and crop insurance, and regular insurance.

But it appears that that whole region that was subject to that has been recovering nicely, that the credit issues have not been extreme. They have not put the association in any kind of jeopardy in that area. And so of course there are risks. I am sure there were cases where producers lost their farms or otherwise.

But by and large, it has recovered nicely. Delinquency rates have not gone up dramatically. So people have done their jobs and done their work, and I think it has been very beneficial.

Mr. CUELLAR. Thank you. I appreciate the good work you have done on that. I have a defense appropriations; as you know, they are all at the same time. So again, with your respect, I will be stepping out.

Thank you, Mr. Chairman and Ranking Member.

Mr. BISHOP. Thank you, Mr. Cuellar.

Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Mr. Chairman, and thank you for being here today.

HEMP GROWER FINANCING

One of the areas in the farm bill of 2018 classified hemp as a commodity, and in turn, it makes it eligible for crop insurance. And some farmers in my district have expressed an interest in growing it as part of their rotation.

Could you explain what the next steps would be for farmers that are interested in growing hemp in terms of financing?

Mr. TONSAGER. I would like to offer some thoughts. In addition, we are prepared to provide some guidance to the Farm Credit System on exactly that subject. And so it is clear that the hemp that is low-THC levels, under 3/10ths percent, is now legal to be produced. The 2018 farm bill also established a program to be operated by the Secretary and the States to help the growth of the hemp program. But they do not believe that it is going to be available until 2020, is my understanding.

The Secretary has recommended that people operate under the authority of the 2014 farm bill that is granted and been out there and available to people to use on a pilot basis. We have identified a list of criteria that we are going to be giving to the Farm Credit System, under which they could potentially finance it.

I would like to offer to my colleague here; I know he has great interest in the hemp issue as well.

Mr. HALL. While there is a lot of clarity, there is a lot of uncertainty, too. It is not USDA but the Food and Drug Administration who is going to have to make some decisions on hemp products.

We really see there are three different categories we find States in right now. Some States do not even have State authority to produce hemp, sell hemp, market hemp. States like Kentucky and several others—I think maybe 20, 25 others—have a pilot project that has been in operation since 2014 once it was a pilot project in that farm bill. Those States are moving forward.

And then there is a middle ground, where States do not have a pilot project. They are working to try to develop one. And so we are trying to put out guidance to address all three of those situations. But it is clear, as the chairman stated. It is legal now, and we are trying to make sure that we get the proper guidance out to System institutions so they can provide credit to borrowers.

Mr. MOOLENAAR. And you said to rely on—it will not be available until 2010?

Go ahead.

Mr. HALL. I think that 2020 is when we anticipate USDA putting out their regulations. I know they are in the process; in fact, I am attending a field hearing next week with AMS to get some more information on that. But just given the growing season, something is going to have to come up pretty soon, and I just do not see anything, probably, this growing season. It is going to be those States that have some pilot project already in place who will be able to produce.

Mr. TONSAGER. But I am saying that we are ready to provide guidance now to the Farm Credit System regarding financing.

TRADE ISSUES

Mr. MOOLENAAR. OK. Thank you. Also, to follow up on the discussion on some of the trade issues, you mentioned in your projections corn and soybeans. You felt that that was going to be down right now.

How do you account for things? I know China has said they will take more of our soybeans. I do not know where that stands today. But how do you factor in those kinds of considerations, and are you doing that?

Mr. TONSAGER. Well, we rely generally on ERS's projections for those. We study closely. We talk to the System institutions. They have policy established for financing. And so each institution would establish what they think the right number is for the value of the crop in their region in calculations of how they would support producers, along with, of course, as we talked about earlier, crop insurance and the other risk mitigating tools that are available.

Mr. MOOLENAAR. And then when it comes to the USMCA, my understanding is that will help open some dairy markets in Canada. Overall, does that affect any of your projections? And are you urging passage of that? Would that be a benefit for the farm economy?

Mr. TONSAGER. We have provided guidance to the Farm Credit System regarding what was in the farm bill approach for improvement, and asked them to look at that closely. I am not as familiar with the USMCA.

Mr. MOOLENAAR. Is that something that you would typically weigh in on? Is that something that—

Mr. TONSAGER. Yes. Well, we certainly—it has been pointed out to us by several parties that there is help coming for dairy producers, and that the System should allow for that help to be made available, and that they should account for that in their lending practices.

Mr. MOOLENAAR. OK. Thank you. Thank you, Mr. Chairman.

Mr. BISHOP. Mr. Aderholt.

RURAL DEVELOPMENT

Mr. ADERHOLT. Thank you, Mr. Chairman. Thanks. Good to be here today. Sorry I am a little late; we have had a full morning. But I think most everybody that is on this committee, whether you experience it firsthand or whether you just know about it from your colleagues, know that rural America is different from urban America. And it is no surprise that rural lending needs, particularly to farmers and ranchers, are also unique.

I am comforted knowing that there are entities like Farm Credit who understand the needs of rural America. And I appreciate all the work you do for producers and for the districts like that I am proud to represent in North Alabama.

Financing needs of farmers in rural communities are more than any one type of lender can handle alone, in my opinion. Could you talk about your instrument, how it works cooperatively with community banks and others in the area to meet the needs of the overall communities and agriculture?

Mr. TONSAGER. Yes. There, I think, one of the unknown things is there are thousands of transactions occurring all the time between the Farm Credit System and community banks in serving agricultural producers. Sometimes there are arguments over the institutions.

But they, in the field, do a significant amount of risk-sharing on farmer projects particularly, but also on rural projects. There are quite often community facility kinds of loans made where the System attempts to be helpful for a community facility and bank. We require that they seek the participation of the bankers with them in developing these kinds of projects.

And of course the System engages in water or sewer system, broadband communications, and it tries to participate broadly with other lenders in those areas. So I think in general, there are good working relationships that occur between community banks and the Farm Credit System.

Mr. ADERHOLT. Are there ways to encourage more cooperation that would help meet rural financing needs that you could think of?

Mr. TONSAGER. Yes, I believe so. I think we currently provide individual—the board approves individual projects under the Farm Credit Act in community facilities in rural America. And I think more of that could be done. I think they are treated as third party investments. So if a project is coming to finance in rural America, a package is put together that the Farm Credit System, bankers and others, can participate together in.

And as a former undersecretary of rural development, to be successful, I think, in development in rural America, it is about spreading risk, putting together deals where multiple parties take a piece of the risk. And so it is not too much for any one institution to take.

And I think the more that can be done in creating these kinds of participatory arrangements, the better off rural America is going to be. We need everybody in rural America participating together and sharing risks together to make sure that there is success because nobody can take the whole risk.

USDA is a great example. It participates with its community facility programs with private partnerships and helping put deals together.

LOSS MITIGATION

Mr. ADERHOLT. Let me switch topics just a bit. Alabama ranks third in broiler production, right behind the chairman's home State of Georgia, and then of course Arkansas. And my district in Alabama is the most broilers produced in the state.

Of course, avian influenza has had a terrible impact on the poultry growers in Alabama, and Alabama Farm Credit went out of its way to work with products that were impacted by the last outbreak that occurred in our State. Did your associations have a similar problem? And how did you work with producers who experienced losses like those that are in Alabama?

Mr. TONSAGER. Again, the information that I receive is there is significant effort by the System to work with any party in these kinds of difficulties. And I think the many years of experience. Avian influenza is not new. It has been around a while. It has come and gone.

And I think that that experience helps the loan underwriting within the System and making sure that when they look at these cases, they know that there is a coming out, that you get over it, you get on, and you can go on to the next thing.

So that experience, I think, has given them a confidence in being able to work with producers to help make sure we can keep moving forward and keep financing them and help them make some money, hopefully, along the way.

Mr. ADERHOLT. Thank you. I yield back.

Mr. BISHOP. Thank you. Let me just follow up on the rural development discussion that we had a little earlier. As I had indicated, one of my priorities is investing in and giving renewed focus to rural development; and for rural America to thrive, we have to close the digital divide between urban America and rural America.

We have got to invest in critical infrastructure, which includes roads, bridges, water, wastewater, and we have got to improve rural health and rural education. And much of that focus, of course, is within the jurisdiction of USDA. But the Farm Credit System has to play an integral part there.

In addition to providing credit to agriculture producers, the system also makes loans for rural housing and for rural utilities. You had mentioned it is to ensure a safe, sound, and dependable source of credit and related services for all creditworthy and eligible persons in agriculture and rural America.

PILOT PROGRAM—LESSONS LEARNED

It is my understanding that in 2014, the Farm Credit Administration ended the pilot programs associated with investments in the rural America. What lessons did FCA learn from these pilot programs? And are there any plans for establishing similar projects in the future?

Mr. TONSAGER. Yes. The pilot program went on for several years, and we did learn some issues, and we—of course, during that time, there was strong debate among many about their participation. I think that we chose to take a route that we felt very secure about going forward.

And we feel very confident that there is the ability for the System to participate in these kinds of investments. At this point, we have chosen to do it through individual approvals by the board and these institutions. So they continue.

We have developed a much more efficient process for improvements at the agency on these approvals, and generally we strive for trying to do them in two weeks. Sometimes it goes a bit longer. We are continuing to look at processes that might allow us to accelerate those investments. But we have come to no conclusions on what might be the process for that.

As I mentioned earlier, I believe that it is critical, in providing credit to institutions in rural America, that as many partnerships can be made as possible; many institutions in the System like to be engaged in those partnerships. So I appreciate your interest in that, and we are diligently looking for ways to continue to grow that.

I would like to add also that Congress authorized the Farm Credit System to invest in what are called Rural Business Investment Corporations. And many institutions have taken advantage of that. There has been, I think, six or seven new investment companies created, and the Farm Credit System has invested significantly in those. And it is out there involved in investments this way as well.

Mr. BISHOP. The key to it is a real robust investment in broadband and the internet because connectivity is going to mean everything for quality of life in rural communities.

DISASTER ASSISTANCE

Let me switch gears for a moment and go back to the impact of the lack of passage of the Disaster Bill, which has been pending now in the Senate since January 16. We had volcanoes and the damage done in Hawaii, the cyclones in the Mariana Islands, wildfires and mudslides in California, hurricanes and tornadoes in the Southeast, the Gulf Coast, the Eastern Seaboard, the floods in Nebraska and the Midwest.

What is the impact of the slowness, the inability allow assistance for farmers and rural communities from the lack of passage of this? How is that impacting the Farm Credit System, and what are the prospects that will come out of that?

Mr. TONSAGER. Well, any assistance that can be provided by the Federal Government or other parties to these people that are affected by this is helpful. And it is not only helpful in the giving of a grant. It also gives lenders comfort in seeing that help occur. So

I think any time the resources of the Government are provided or other parties, it has a positive effect.

And I cannot measure the effect of the lack of approval of a statute.

Mr. BISHOP. My time is expired. Mr. Fortenberry.

FARM CREDIT SYSTEM ADVANTAGES

Mr. FORTENBERRY. Thank you, Mr. Chairman.

I want to go back to a question that Congressman Aderholt hinted at. Many of us receive complaints from the commercial banking sector that the Farm Credit System has an unfair advantage. Just a rough calculation: You have had about a 20 percent increase in assets over the last 5 years. Are they correct in saying that the Farm Credit System has an unfair advantage?

Mr. TONSAGER. I understand the arguments that occur. But I would mention a few things.

The Farm Credit System has roughly 40 percent of the agricultural credit. The banking industry has roughly 40 percent of the agricultural credit; the Farm Credit System—

Mr. FORTENBERRY. Is that a recent statistic, or that has remained the standard article?

Mr. TONSAGER. It has been pretty close. It has varied a few percentage points over time. The System was established 100 years ago as a cooperative System, so there are 500,000 farmer owners of the System that are the beneficiaries of the Farm Credit System.

The cooperative structure generally allows for the profit of the System to be given to the producers, who in turn pay the tax on it. Many of the banking industry participate in a subchapter S structure that also allows the profits to pass through to them.

The profits of the long-term credit lending for particularly real estate are not taxed. The banking industry has access to the Federal Home Loan banking system as well, and gets some advantages that way.

So I would argue yes, there are debates that occur. But by and large, this is a 100-year-old institution that benefits producers, and there are offsetting issues in some cases. And I am not aware of any analysis that has been done in recent times that would compare the two.

Mr. FORTENBERRY. Thank you. Regarding beginning farmers and ranchers as well as small farmers, you have credit available as part of your portfolio to persons in this category. Would you unpack some specifics?

One of the things that I am hinting at here—I will just tell you the pretext here—we have something exciting going on, actually, in the agricultural family. Now, while we only have a certain amount of land, and the barriers to entry for someone entering without connection to perhaps a family or some other institution to obtain a larger-scale production agriculture farm with all of its land requirements, while its capital requirements are diminishing. That is reality.

But the interest in agriculture, particularly among young people, is growing, particularly as there is a convergence of different fields of science, whether that be environmental quality, conservation,

international development, are all components of providing the necessary means toward food security and environmental security.

What is happening is niche markets are developing, small farms that maybe direct market to consumers, reconnecting the rural to the urban and the farmer to the family, as well as all types of value-added opportunities, even increasing significant revenue on traditional production agriculture farms.

So one of the entryways into the agriculture family again is through some of these value-added opportunities or unique niches. Is farm credit involved in that type of issuance of credit for those types of entities?

Mr. TONSAGER. Yes. There is a strong recognition of that, the growth of that. The Farm Credit System does provide assistance in some cases to help getting farmers markets going. We are all examining closely the LAMP program that was recently provided for in the farm bill, and see some opportunity there.

Mr. FORTENBERRY. Well, yes. I am glad you raised that because I think you are not in front of this dynamic yet, that might be an important on-ramp to leveraging the Farm Credit System to again participate in what is already organically happening, and expansion of the agriculture family creating exciting new opportunities.

Mr. TONSAGER. Yes. I have always been a strong believer in the value-added producer grant program. I think that has been a great tool. And I have seen projects where the institutions have been involved heavily in it. I think they make contributions, and you can speak to them in the next panel, of course, about efforts they have seen in their own areas about the evolution of that. And I think it is exciting as well.

Mr. FORTENBERRY. Yes. So that was half a question and half a speech. I think you understood the intention of my speech.

Mr. TONSAGER. Yes. Sure.

Mr. FORTENBERRY. Thank you.

Mr. BISHOP. Dr. Harris.

NAVIGATING CBD REGULATION

Dr. HARRIS. Thank you very much, Mr. Chairman. And I apologize, but we have concurrent hearings. And one of the topics I am going to ask about, actually, is—we just discussed at the hearing with the NIH, and it is the CBD issue.

I understand that my colleague has brought it up already. But I need to dissect this a little further because we just had the head of the National Institute of Drug Abuse testify three doors down that we do not know what CBD does on developing brains right now. A 10-year-old can go in and buy CBD items at a store.

And it is a little disconcerting to understand that now we may be loaning money to farmers who might find out six months from now, when the FDA regulates it, that there is—the vast marketplace goes away. Because the amount of CBD raised or grown for the licensed drug is minuscule compared to this huge, overwhelming market that could come under tight regulation.

So you have got to walk me through this. Why, when this is completely up in the air—I mean, the FDA—I spoke to the Commissioner about this. They are very close to regulating this industry. If they regulate it, it can fall under the scheduling, the DEA sched-

uling, and could eliminate the market, not for all hemp—obviously, you still have the fiber product—but the CBD market.

So how are you going to factor that in when you make this loan? Because that crop, I have got to tell you, if you are raising it just for the rope, for the fiber, it is probably not a profitable crop for a lot of farmers. And yet the credit association is going to be advancing or suggesting that credit be advanced for it.

Mr. TONSAGER. Of course, it is a combination of issues that we are struggling with. And that is, this is now a legally available product, crop, to be produced.

Dr. HARRIS. OK. That, of course—and I am going to interrupt you right there because you know, of course, that is questionable because the raising of that crop for other than use to make the FDA-licensed drug is actually of questionable legality.

I understand there is an issue of disagreement on this. But in that setting—and let me take it back one step. There are other places a farmer can get a loan to grow hemp. Is that right? They do not have to do it through the Farm Credit Administration. Right?

Mr. TONSAGER. Of course. Yes.

Dr. HARRIS. So why would the Farm Credit Administration wade into that in a period of regulatory uncertainty? Because, you see, the trouble is that my farmers who do not grow it now are subject to risk because we have the coop system and all now. They are subject to risk because of a decision made in Washington that farm credit ought to be advanced to a product that is of questionable legality.

Mr. TONSAGER. My understanding is the statute provides for any hemp that is to be grown of TH3, of—excuse me—.3 THC or less, which is obviously a very low level involved with it.

Dr. HARRIS. I fully understand that. That is only the definition of hemp. That is a botanical definition that separates it from other cannabis products. It does not say that you can sell the CBD legally. That is not a corollary of that.

So again, my question is: Why would FCA wade into this area of uncertainty? I do not get it. There are other ways—these farmers want to get loans; there are other ways to get it. I know there are because the marijuana growers in my State certainly do not get farm credit advanced to them. Is that right?

Mr. TONSAGER. That is correct.

Dr. HARRIS. Because of the questionable legality. Right? Because in Maryland, it is legal to grow the drug in Maryland. It is just not legal to grow it in the United States. Right?

Mr. TONSAGER. We are—well, we are—

Dr. HARRIS. How is this not analogous? Is the next thing that someone in your shop is going to say, “You know what? Some States approve it. It is a profitable product. Let’s go ahead and lend money for marijuana growth.”

Mr. TONSAGER. Well, certainly with marijuana we are a Federal agency and we comply completely with—marijuana is still on the contra substance list and we are not touching it.

Dr. HARRIS. I am going to interrupt you once again. Cannabis is still on the list, on DEA Schedule 1. Read what it says. Read what it says. Cannabis is on the list. Hemp is a cannabis plant. So again,

I am going to say—and again, so I just want to—you and I understand that there is a disagreement, and there is question about this going forward.

Why would a banking institution—which is what the FCA is, for all intents and purposes—take a risk on this, on this remaining legal?

Mr. TONSAGER. The guidance we provide will allow the institutions to set their portfolio standards. So they will evaluate the risk for themselves, for their institution, and for the people that might be financing it. So they are going to look at the market, which may become overwhelmed with hemp availability, and they will have to assess that risk. They will look at the marketplace to see if there is a market for it. And they will look at the overall issue that occurs regarding the hemp.

I was unaware of this particular argument. It is new to me. It is part of the struggle. And it is probably why USDA is moving slower. They are talking about implementation of the program in 2020. So I suspect there are real considerations going on of that all as well.

I would also like to allow my colleague to comment, if he would like to.

Dr. HARRIS. My time is up.

Mr. TONSAGER. I am sorry.

Dr. HARRIS. Thank you.

Mr. BISHOP. Thank you, Mr. Tonsager and Mr. Hall. Thank you all for being here today. I appreciate your honesty and your genuine assessment of our rural agricultural economies. And I want to thank you for your testimony. We look forward to working with you to meet the challenges that we have discussed today. They are significant, to be sure, but we remain hopeful.

With that, we will take a brief recess to set up for our next panel, which I hope we can do quickly. Thank you. We will stand in recess for 3 minutes.

[Recess.]

Mr. BISHOP. All right. The hearing will now come to order. And I would like to now introduce our second panel.

Mr. Hebrink is the president and CEO of Compeer Financial in Sun Prairie, Wisconsin. Mr. Jensen is the president and CEO of Farm Credit Services of America in Omaha, Nebraska. And Mr. Pointevint is president and CEO of Southwest Georgia Farm Credit in Bainbridge, Georgia.

As you can tell, the panel represents a diverse geographic area. We welcome your insight, and we are pleased to have you appear before the committee today and to give us a sense of what you are seeing back home.

Let me ask Mr. Fortenberry if he has any remarks before hearing from the panel. Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman, again for calling this important hearing. I would rather proceed right to the witnesses. Thank you very much.

Mr. BISHOP. Thank you. Let me now recognize our guests for brief oral statements, and then we will proceed with questions. Note that each of your entire written traumas will be included in the record.

Mr. Hebrink, please proceed.

TESTIMONY BY MR. HEBRINK

Mr. HEBRINK. Chairman Bishop and members of the committee, thank you for the opportunity to testify. My name is Rod Hebrink, and I am the president and CEO of Compeer Financial. We provide financing, risk management, and financial services to farmers and rural communities in Illinois, Minnesota, and Wisconsin.

You are well aware of the economic challenges facing farmers. The crop and livestock sectors we serve are best described as struggling, impacting farmers of all ages, experience levels, and sizes. In our region, dairy is the most significantly affected, with hundreds of dairy farmers exiting business this past year.

While commodity prices have always been cyclical, the current downturn has been prolonged. We work with producers through all economic cycles. Our team is actively meeting one-on-one with farmers to review their financial information, to help them better understand their cost of production and ways they can improve their operation. We strive to assist farmers in managing through the downturn, to position them to succeed when the agriculture economy improves.

Each of us have farmers who have been impacted by recent weather-related disasters. Heavy snowfalls this winter resulted in structural damage to farm buildings. We have responded quickly, providing 140 farm families immediate grants through the Compeer Fund for Rural America. We want them to know we have their backs as they begin the process of recovery.

Compeer supports the next generation of farmers through our young, beginning, and small farmer programs. We are proud with farmers such as Emily, a young organic dairy farmer in Illinois who I described in my written testimony. Compeer has a strong commitment to minority farmers. We have created effective partnerships with community and immigrant organizations who recruit farmers and provide training while we focus on lending and technical assistance.

We are proud of our successful work with the Hmong American Farmers Association that has resulted in more than 20 new families growing and selling food to area restaurants and farmers markets. Many of these Hmong families live in Congresswoman McCollum's district.

Our focus in championing the hopes and dreams of rural America goes beyond our farmer customers. We are concerned about the continued decline in the health of rural communities. Strong rural communities help agriculture thrive. Fresh thinking is needed to sustain these rural communities and agriculture.

Fulfilling our public mission includes enhancing the vitality of rural communities. Compeer has taken a proactive approach through partnerships with the USDA Community Facilities Program and Rural Business Investment Companies.

Among the rural areas we have helped is Renville County, Minnesota, which has a very personal connection. Compeer partnered with local banks, AgCountry Farm Credit, and CoBank to rebuild the outdated hospital where I was born, and provide rural families a \$24 million state-of-the-art facility.

Residents now have access to the quality of care previously available only at great distances. But we did not stop there. Farm credit grants purchased telemedicine equipment, allowing cardiologists in Minneapolis to diagnose life-threatening heart conditions real-time. This investment will save lives.

Compeer is one of USDA's key community facility partners, with \$760 million of projects across 17 States. We thank the committee for your past support of USDA's programs, and request your continued support in this year's budget.

Finally, a significant challenge to the future prosperity of rural communities is the lack of equity capital. Developing new approaches to attracting investments into rural communities is essential to creating opportunities for agriculture.

Compeer began partnering on RBICs to address the shortage of equity capital for rural America. Nearly 1500 potential investments have been identified, representing \$7.2 billion in opportunities.

On behalf of Compeer Financial and, more importantly, on behalf of the farmers and communities we serve, thank you for your time today. As a partner in their success, it is a pleasure to share their stories and the impact they are making each and every day.

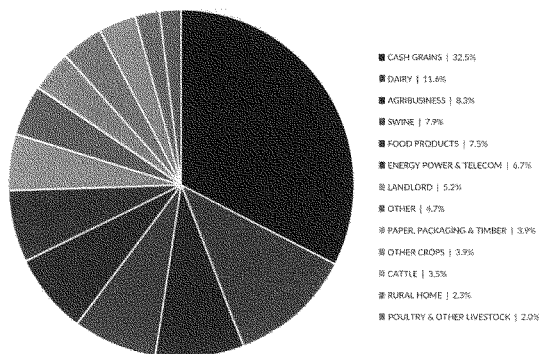
We are honored to partner with them to champion the hopes and dreams of rural America.

[The information follows:]

**Testimony of Rod Hebrink, President and CEO, Compeer Financial
on behalf of the Farm Credit System before the U.S. House Appropriations Agriculture,
Rural Development, FDA & Related Activities Subcommittee
April 2, 2019**

Chairman Bishop and members of the House Agriculture Appropriations Subcommittee, thank you for the opportunity to testify today. My name is Rod Hebrink and I'm the President and CEO of Compeer Financial. Compeer is a proud member of the Farm Credit System. Compeer provides loans, leases, risk management and other financial services to farmers and rural communities throughout most of Illinois, Minnesota and Wisconsin, with headquarters in Sun Prairie, WI. As a cooperative, we're owned by our farmer customers and focused on championing the hopes and dreams of rural America. Whether a dairy farmer in Wisconsin, a vegetable grower in Illinois or a rural hospital in Minnesota – our mission drives the passion for all we do.

Compeer serves over 43,000 member-owners and customers focused on feeding and fueling the world, representing the diversity of Midwestern agriculture ranging from dairy, swine, grain, and renewable energy to pumpkins, potatoes, cranberries and timber. We also have farmers focused on emerging markets – local foods, niche crops and organic production, just to name a few. Ranging from critical access hospitals to assisted living facilities, Compeer also invests in the communities that keep agriculture thriving because agriculture and rural communities are interdependent.



I'm sure this subcommittee is well aware of the current economic challenges facing many farmers. The crop and livestock sectors we serve in agriculture are best described as volatile. While commodity prices have always been cyclical due to the influence of weather and markets, the current economic downturn facing agriculture has been prolonged. This downturn has impacted farmers of all ages, experience levels

and sizes. Certainly the ongoing tariff and trade disputes have contributed to the volatility and we're hopeful these challenges will soon be resolved. We're grateful for the support of Congress in passing a new Farm Bill, which will provide much needed financial support and maintain important risk management tools such as crop insurance.

At Compeer, we're taking a number of proactive steps to help farmers navigate through challenging economic times. While the year-end financials from many of our farmer customers have been slightly better than anticipated, our team is actively meeting with customers one-on-one to review their financial information to help them better understand their costs of production and ways they can improve their operations. We've provided a number of educational seminars for our farmer customers on topics such as risk management, marketing, financial analysis, and benchmarking their operations with their peers. When appropriate, we're also working with farmers to re-amortize loans and make other adjustments to their loan payments.

Arguably one of the most serious challenges right now is dairy. The impacts of multi-year losses are being felt by our clients everywhere. The best way for me to bring this to life is with a client story. A Wisconsin dairy farm family with a multi-generational history of working with Compeer is questioning their ability to transfer their dairy to the next generation. They aren't alone. They operate 50 acres of crop land with a 350-head dairy, partnering with Compeer on operating, equipment and land loans, as well as record keeping and tax services, monthly payroll and crop insurance. A hard-working family, their long term production has been good. Unfortunately, multi-year losses have hit them hard. Their liquidity is severely challenged and payables at the local feed co-op are rapidly building. But this family isn't facing these challenges alone. Our philosophy is to work with producers in all the industries we serve, under all economic conditions. We've invested in a team of experts to help guide them through their circumstances, so they can achieve optimal outcomes and see promise in their future. We offer perspectives that can widen the lens of opportunity, looking at situations in different ways to attain goals that may have previously seemed out of reach. But counseling isn't easy. Farmers willingness to revise plans, consider new approaches and be open to alternate financial strategies are all critical responses to a shifting economy. They're faced with the reality of making tough choices to determine their future. Together, however, we're optimistic.

The diversity of Compeer's portfolio, solid financial performance and a strong balance sheet are key strengths as we respond to market volatility and support our member-owners. As a cooperative, strengthening our financial performance translates directly to an increase in patronage paid to our

member-owners. At a time when this Wisconsin farm family is struggling, our diversification has allowed us to provide them with an increase in patronage – cash in their pockets – to support their efforts to withstand a downturn. In real terms, Compeer increased patronage payments in 2019 by more than \$42 million, returning over \$150 million to farmers across our territory.

As this committee is aware, farmers in many regions of the U.S. have faced weather-related disasters in recent months. While most of our farmer customers have not experienced the recent flooding currently impacting parts of the Midwest, we've had an exceptionally long winter with heavy snowfall, resulting in a number of farmers in our territory having barn roof damage or collapses. Through Compeer's Fund for Rural America, we were able to quickly respond by providing a \$1,000 relief payment (\$117,000 in total payments) to customers who sustained substantial structural damage to their buildings. We want them to know their cooperative has their back as they begin the process of recovery.

As part of our mission, Compeer is also committed to helping support the next generation of farmers, such as Young, Beginning and Small (YBS) producers. One such client is Emily, a 24-year old graduate of Kansas State with a Food Science degree, employed by Crest Foods as a research and development manager in Rochelle, IL. Emily also milks 15 head of dairy cattle and sells organic milk. Emily is an innovative and passionate small, niche dairy farm. Along with her father, Compeer Financial guided Emily through her first purchase of a 70-acre farm in 2018 using the YBS program and USDA's Farm Service Agency's Direct Down Payment Farm Ownership Program. Combined with her incredibly hard work, guidance from her family and expertise and education from Compeer, Emily is actively making her dreams come true. Over the next two crop years, Emily plans to transition her farm to organic and plans to produce her first certified organic crop in 2021. As her partner, we're thankful for the chance to support Emily – and others like her – through their ag journey.

Compeer has a strong commitment to support minority farmers. We partner with government agencies, community, and immigrant organizations to provide training, lending and business support services for minority farmers. We've created effective programs through genuine partnerships; our community and immigrant organization partners recruit the farmers, provide training classes and ongoing support to the farmers, while we focus on lending and technical assistance.

The Hmong American Farmers Association (HAFA) is a great example. HAFA purchased a farm south of the Minneapolis/St. Paul area and leases plots of land to individual farmers. More than 20 families rent five to

10 acre parcels on which they grow food sold directly to area restaurants, CSA's and farmers markets. Compeer and other partners in the Farm Credit System contributed \$70,000 to help HAFA build the infrastructure on the 155-acre farm. In addition, Compeer continues to support HAFA's agriculture program through annual grant. Compeer employees provide business training, technical assistance, and micro-loans to these farmers. As a result of this successful project Hmong American farmers are today leading the Twin Cities local food economy, making up more than 50 percent of all the farmers in metropolitan farmers markets.

Beyond the current economic challenges facing farmers, we continue to see a decline in the health of rural communities as a whole. The ongoing decline in rural population is problematic but strong rural communities help agriculture thrive. We need a new approach for sustaining rural communities because of this integral interdependency. Fully serving our mission includes our commitment to enhancing the vitality of rural communities. Compeer has taken a proactive approach to solving these issues through partnerships with the USDA community facilities program and Rural Business Investment Companies (RBIC). There is a shortage of capital in rural communities to meet all of the infrastructure needs. We understand government funding alone will never fill that void. Rural communities need partnerships between community banks, Farm Credit institutions, and others. Compeer today is working closely with community banks to find unique solutions to regional needs.

Among the many rural communities we've been able to help is, Renville County, Minnesota, which happens to have a very personal connection. Compeer partnered with both community banks, as well as Farm Credit partners AgCountry Farm Credit and CoBank to rebuild the outdated hospital where I was born and provide rural families access to a \$24 million state-of-the-art facility. Combined with the updated equipment and technology, residents now have access to the quality of care previously available only at great distances. We didn't stop there. We partnered again with AgCountry and CoBank to bring Renville telemedicine equipment and training for local staff, allowing cardiologists at Abbott Northwestern in Minneapolis to diagnose life threatening heart conditions in real time. This equipment has allowed rural families' access to specialists by video link instead of having to travel two hours to the Twin Cities, providing immediate access when time is essential. This investment will save lives and improve health.

This is a great example of how Compeer partners with USDA. In fact Compeer is one of USDA-RD's prime partners in the utilization of community facility financing programs. We've partnered on nearly \$760

million of community facility projects across 17 states; Compeer is one of the most active financial institutions in the country in leveraging the USDA Community Facilities Guarantee program for financing health care, senior living and public safety buildings in rural communities. USDA community facility guarantees provide critically important credit enhancements for private lenders. These credit enhancements mitigate risk through a public-private partnership, allowing more non-government dollars to be leveraged and more capital to be invested throughout rural America. More than 75 percent of the community facility projects in which Compeer has participated have involved partnerships with local community banks or credit unions. The public-private partnerships that are forged through the use of community facility guarantees helps ensure that rural communities' needs can be better met, creates jobs and provides an overall economic benefit; resulting in a stronger rural communities. Overall, the investments aid in providing a higher quality of life and a desire to live, work, and raise families in rural communities; as well as off-farm employment opportunities. We thank this Committee for increasing funding for guarantee programs in recent appropriation bills, and urge your continued support of these important programs.

Finally, a significant challenge to the future prosperity of our rural communities is the current lack of equity investment in rural America. Compeer strongly believes that new approaches to attracting investments into rural communities is absolutely essential to help drive innovation and to create new market opportunities for agriculture. One way Compeer is working to attract new investments into rural communities is through RBICs. An RBIC works like a private equity fund: a fund manager raises money from a group of investors and then invests that money in a variety of private businesses. While the fund is supported by the USDA, it is non-leveraged, which means no taxpayer funds will be utilized. We began partnering in this effort after research told us there's a shortage of equity investment capital for rural America. In fact, nearly 1,500 transaction opportunities have been identified in the last five years representing more than \$7.2 Billion in opportunities coast-to-coast, as well as Alaska and Hawaii.

In closing, on behalf of Compeer Financial, I want to thank you for the opportunity to share a snapshot of our business with you. More importantly, on behalf of the farmers and communities we serve, I want to thank you for your time today. As a partner in their success, it's a pleasure to be able to share their stories and the impact they're making each and every day. We're honored to partner with them to champion the hopes and dreams of rural America.

Mr. BISHOP. Thank you.
Mr. Jensen.

TESTIMONY BY MR. JENSEN

Mr. JENSEN. Mr. Chairman, Ranking Member Fortenberry, and members of the committee, thank you for the opportunity to testify today. My name is Mark Jensen, and I am the president and CEO of Farm Credit Services of America and Frontier Farm Credit, with our service territory covering Nebraska, Iowa, South Dakota, Wyoming, and the eastern third of Kansas.

I will refer you to my written testimony, and I am happy to add a few opening remarks to give you more insight into the challenging economic environment the farmers and ranchers in our territory are working through.

Located in the middle of the country, our portfolio is reflective of Midwestern agriculture. Half our lending is committed to producers concentrated on grain production, and another 25 percent on the protein industries, primarily beef feed lots, swine, poultry, dairy, and cow-calf production. I will focus my comments on the grain sector.

Make no mistake—grain producers in the U.S. are world-class when it comes to raising a crop. Above-average yields have helped some producers, but increased volatility in commodity markets has given them a very narrow window for marketing grain at or above the break-even levels. Barring unforeseen events, there are no signs indicating a significant change to projected profitability levels.

Grain producers with higher debt levels and/or those having higher costs to raise their crops have generally experienced losses over the last 4 or 5 years. For many producers, these losses have more than offset profits they may have experienced from 2010 to 2013, during a time of higher gross prices.

Some producers are running out of options to make adjustments to their operations and are at risk of continued price and weather volatility. The financial outlook for 2019 does not look favorable for crop prices relative to the cost to produce these crops, and we anticipate an additional number of producers experiencing credit challenges.

This is the time of year that we work with farmers to establish their credit needs for the upcoming growing season, and this is what we know: Profit margins for producers continue to be tight. We also know the projected crop prices for 2019 are at or below break-even level for many producers.

What we do not know is when trade agreements may be completed which would bring needed stability to grain price levels. Of course, we also do not know the weather. And speaking of the weather, across much of the Midwest major weather events over the last two weeks have taken lives, ruined machinery and equipment, caused substantial livestock deaths, destroyed critical infrastructure, and damaged homes and livelihoods. It will likely take months to fully assess the damage, but the need for assistance is immediate.

We are mobilizing staff and resources to help farmers and ranchers and the rural communities in which they live. We have a stand-

ard disaster assistance program that is tailor-made to work at times like these. Producers impacted by the floods and winter storms will qualify for this program. The program includes more lenient credit standards, deferment of payments, reamortization of loans, and interest rate relief.

Our staff is and will be spending a significant amount of time helping individual producers think through their options. We are grateful for the committee's support of the pending Disaster Bill, and urge you to include assistance for Midwest producers devastated by these storms, and pass the bill immediately. With spring planting season just ahead of us, the timing of disaster assistance is critical. We urge fast action.

Let me close by saying the agriculture industry is very dynamic and has always adjusted. There remains confidence in the future of agriculture and that market volatility will improve. In this environment, agriculture needs Congress's continued support for the farm bill, the ethanol industry, and the Federal crop insurance program. Providing access to the world markets through strong trade agreements is also critical to the viability of U.S. producers.

The U.S. agriculture industry is positioned better than anyone to feed the world for decades to come, and we are excited to be a part of that future. Thank you, and I look forward to addressing your questions.

[The information follows:]

**Testimony of
Mark Jensen, President and CEO
Farm Credit Services of America/Frontier Farm Credit
before
the House Appropriations Committee
Subcommittee on Agriculture, Rural Development, Food and Drug Administration,
and Related Agencies**

April 2, 2019

Mr. Chairman, Ranking Member Fortenberry, and members of the committee, thank you for the opportunity to testify today on behalf of the Farm Credit System. My name is Mark Jensen and I am President and CEO of Farm Credit Services of America and Frontier Farm Credit, headquartered in Omaha, Nebraska, and Manhattan, Kansas, respectively.

We are a part of the Farm Credit System, a nationwide network of cooperatives providing credit and affiliated services to farm and ranch operators across the United States. As cooperatives, Farm Credit Services of America and Frontier Farm Credit are owned by our more than 57,000 customers. We work through a network of 48 retail offices serving farmers and ranchers in Iowa, Nebraska, South Dakota, Wyoming and 41 counties in Eastern Kansas.

The Committee's hearing today is timely. Farmers and ranchers in our territory continue to grapple with a very challenging environment. Commodity prices have fallen and remained low for the past several years, while the costs associated with raising crops has remained high. Many row crop farmers have found profits elusive and face multiple years of losses, with similar circumstances projected for the 2019 crop year. Forecasters see little chance of a quick commodity price rebound barring unexpected changes in commodity demand, supply or both.

We are working hard to support our customers through this cycle, and despite the current situation, we continue to have a positive long-term outlook for U.S. agriculture.

Financial Strength to Fulfill Our Mission

Financial strength is critical to ensuring that we can help our customers work through the inherent cycles in agriculture. Like the producers we serve, we have built financial strength over the past two decades in anticipation of an economic cycle like today's. This financial strength is critical to ensuring that we fulfill our mission of serving agriculture through its inherent cycles.

As financial cooperatives that are 100 percent owned by the farmers and ranchers we serve, every dollar our associations earn is either retained on our balance sheet to ensure we have the financial strength to serve our customers through industry cycles or is returned to our customer-owners in the form of patronage dividends. In December 2018, the Boards of Directors approved an increase in our patronage dividend and we distributed approximately \$245.5 million in cash-back dividends to our customer-owners this past week.

Disaster Response

Across much of our service territory, major snowstorms and historic flooding have taken lives, ruined machinery and equipment, destroyed critical infrastructure and damaged homes and livelihoods. Unfortunately, there is risk of more flooding in the days and weeks ahead as significant snowmelt continues and we experience spring moisture.

It likely will take months to fully assess the damage, but the need for assistance is immediate. In keeping with our mission to serve agriculture and rural communities in both good and bad times, we are mobilizing the financial strength and committed, expert staff to help producers and their communities. Producers affected by the floods will be qualified for restoration assistance including, but not limited to, interest rate discounts, interest-only payment programs and installment loans for refinancing working capital losses from operating loans created by the weather-related disaster.

Our associations are also responding by providing \$175,000 in direct relief to charitable organizations supporting the farmers, ranchers and rural communities impacted by this disaster. Recipient charities include the American Red Cross, the Nebraska Farm Bureau Disaster Relief Fund, the Nebraska Cattlemen Disaster Relief Fund, and the Farm Credit System Employee Relief Fund. We have also expanded our employee match donation program, increasing to \$250 the amount our associations will match employees who contribute to these relief efforts.

We are grateful for the committee's support of the currently pending disaster bill and urge you to include assistance for Midwest producers devastated by these storms and pass the bill immediately. With spring planting season just ahead of us, the timing of the disaster assistance is critical. We urge fast action.

Current Environment

Grain production profitability over the past five years continues to be challenged as the industry reconciles slowing U.S. demand and high domestic and world inventories. At the same time, there is increasing volatility in the evolving trade environment. For many producers, multiple years of financial losses have exhausted some of the typical options such as restructuring debt, deferring payments, and lowering production costs.

The winter and early spring are the typical busy seasons in terms of producers completing financial analysis and working with lenders to arrange financing for the upcoming year. So far it is best to describe the 2018/2019 season as a “mixed bag” of results. Producers who have reduced production costs and operate in areas that had strong yields this past year have fared better and either made some financial progress or at least came close to a breakeven profit. For others who weren’t as fortunate or are involved in certain livestock production (e.g. dairy), it was another year of losses and financial challenges. Smaller farming operations are particularly challenged due to tight margins combined with increasing living expenses and the cost of today’s farming equipment.

Barring a significant drought or other unforeseen event, there does not appear to be anything on the horizon that would suggest the commodity prices will increase significantly and “fix” the profitability challenge facing many producers. The financial outlook for 2019 does not look favorable for commodity prices relative to the cost of production (seed, fertilizer, chemicals, etc.), and we anticipate an additional decline in credit quality decline for the year. In this environment, agriculture needs Congress’ continued support for the ethanol industry, the farm bill and the federal crop insurance program. Strong trade agreements are also critical to the viability of U.S. producers.

In summary, while the short-term outlook remains concerning due to the sustained period of high grain inventories and market volatility (weather, trade, etc.), the position of the industry is not at the same level as the last agricultural crisis in the 1980’s. The financial position of the industry going into this period was much stronger due in large part to the lessons learned by producers and lenders during that period. There is plenty of reason to be optimistic about U.S. agricultural and having the most productive and efficient food supply in the world.

Land Values Soften, Remain Stable

Farmland values in much of our service territory softened slightly in the last half of 2018 but have remained stable overall. This was expected and, in fact, better aligns farmland values to profitability in the grain sector. Stability in land values give producers the option of restructuring their operations to shore up operating capital and sustain production. This strategy improved liquidity, but we can all agree that it is not a sustainable practice for an operation when facing rising interest rates and multiple years without profitability.

While producers in many areas of our territory benefited from strong yields in 2018, the industry continues to be challenged by compressed margins. For producers who rent farmland, softening in the market places downward pressure on cash rental rates which will help their bottom line.

Serving the Needs of Young, Beginning and Small Producers

Supporting the next generation of agriculture is an important part of our mission. We are committed to meeting the unique financing needs of young, beginning, and small (YBS) producers. In fact, despite the downturn in agricultural prices, our lending to young, beginning, and small farmers reached an all-time high earlier this year with more than \$6 billion of credit extended to 25,104 YBS producers.

Our “YBS Producer Program” meets the evolving needs of today’s young, beginning and small producers through long-term relationships and a proactive focus on sound financial services, advice and educational opportunities.

While most YBS producers qualify for credit using conventional underwriting standards, we established special outreach credit programs called AgStart and the Development Fund to support those YBS producers not quite ready for credit on commercial terms. These two programs serve 2,960 YBS customers with \$759 million in loan commitment, including \$113 million in participation loans with the FSA – most commonly farm ownership loans. We are very grateful for this subcommittee’s support of FSA guaranteed and direct farmer loans. These programs are critical to farmers – especially in this economic climate – and we strongly encourage you to continue to support them.

Working with Customers

Farm Credit Services of America and Frontier Farm Credit have been working for some time to help customer-owners plan for the current environment. Part of our philosophy as a cooperative is to be conservative in good times so we can be courageous in bad times. Well ahead of the price downturn, we took specific steps to ensure we weren't encouraging farmers to overextend their operations. As Midwest land values soared, we put hard caps on the amount we would lend on any given acre. As commodity prices spiked, we worked to ensure borrowing decisions were based on more realistic price projections. And, we emphasized the use of crop insurance as a key risk tool. Well over 90 percent of our customers participate in the crop insurance program.

In 2018, we took the extraordinary step of offering our real estate customers the opportunity to defer payments one year to help bridge the cash flow gap due to revenue and expense challenges. More than 7,000 customers took advantage of the program, including more than 30 percent of our customers in the highest risk category.

Dependability

Our job is to be a dependable lender in good times and bad times. Our customers know that we understand the impact of industry cycles. We leverage our long experience and deep expertise in agriculture to work with customers to help them identify risks and encourage them to make proactive adjustments to their operations.

As an example, fourth generation corn and soybean farmers (4,000 acres – half owned, half rented), who bought their family's operation when prices were good and profits were less dependent on strong financial management, credit their relationship manager with putting them on a path to viability.

"When we started, we had a budget, but we weren't tracking each expense... this past year, we have looked at our operation with a microscope, right down to repairs and... our household budget."

Their breakeven is higher today because it accurately reflects the full cost of operating and spreads costs over fewer acres. Now, they are managing to their true breakeven.

"When you know your breakeven and, if you can save \$10 an acre on this, it makes a difference. All those little ten dollars add up. Pretty soon, if you can get your breakeven down \$40, \$50, that's huge in this kind of market... same with marketing. If we can gain 10 cents on basis, that makes you stand up and listen."

The couple still considers themselves farmers first and foremost. But, because of their work with their relationship manager, they say they commit time every day to managing the financial side of their operation.

“Like it or not, that’s what we have to do in today’s market. More money is made in here than is made out there.”

We aren’t just asking our customers to make adjustments. We are making them as well. We are restructuring customer debt to spread out their payments and are providing other loan structuring options when necessary and appropriate. We are making available modern technical resources to help our customers have the best information for managing costs and building their risk-bearing capacity.

As price forecasts stay low, most producers’ only option is to very closely manage the cost structure of their operations. We are seeing many producers eliminate non-essential expenses, scale back expansion plans, and delay new equipment purchases.

Despite our best efforts, we understand that being dependable does not mean we can save every operation. Credit can never be a substitute for income for farmers. We are, however, working with our customers to find the best possible outcome for them.

Conclusion

We are grateful for the opportunity to testify today and update the Committee on our associations’ ongoing effort to fulfill the mission you have given us. Our customers face a challenging economic environment, and we stand ready to confirm our commitment to continuing to fulfill our mission of supporting America’s rural communities and agriculture.

While the market today has its challenges, we remain optimistic. Farmers, ranchers and rural Americans remain enterprising, entrepreneurial and committed to their way of life. We pledge to continue to fulfill our mission and work in the best interest of U.S. farmers and ranchers, agribusinesses, rural homebuyers and companies that provide vital infrastructure services to rural America.

I will be pleased to respond to your questions.

Mr. BISHOP. Mr. Pointevint.

TESTIMONY BY MR. POINTEVINT

Mr. POINTEVINT. Mr. Chairman, thank you very much for what you do for Southwest Georgia, especially as it relates to agriculture and rural America. Ranking Member Fortenberry, my thoughts and prayers are with you and your constituents back home during this time.

Members of the subcommittee, I am Paxton Pointevint, CEO of Southwest Georgia Farm Credit, which is headquartered in rural Bainbridge, Georgia. On behalf of the association's boards of directors, my colleagues, and especially the resilient farmers and rural communities of Southwest Georgia. I would like to thank you for allowing me to be here today.

I would also like to thank each of you for the countless hours you have spent on the disaster assistance package for the farmers and communities that are suffering from recent storms and wildfires.

In my home State of Georgia, agriculture contributes more \$72 billion each year to the State's economy. One in seven Georgians work in agriculture, forestry, or a related field. Agriculture is the lifeblood of our local economies. Our farmers create jobs that support local business and industry.

They buy food in their local grocery stores. They purchase tires from the family-owned tire stores. They seek and receive care at our small hospitals. They send their kids to local schools, and the list goes on. It is safe to assume that when our farmers struggle, our rural communities struggle.

Southwest Georgia farmers are fortunate to grow a diverse mix of row crops, including cotton, corn, peanuts, soybeans, and a variety of vegetables. This is primarily due to soil types, climate, and a consistent supply of well water for irrigation. Such diversification and access to water has historically provided risk mitigation for both farmers and creditors.

However, after several years of suppressed farm income, rising input costs, volatile trade conditions, and catastrophic weather events, many of the customers are now suffering. The benefits of irrigation, excellent soil types, and mild climate cannot overcome these other factors.

Since Hurricane Michael, approximately 10 percent of our loan portfolio's credit quality has deteriorated due to financial-related stress on our borrowers. We expect to see more of this deterioration as we continue to work through the annual operating loan renewal cycle.

On the morning of October 11, 2018 our crops were at their most vulnerable state for wind damage. Cotton plants were full of fiber, and pecan trees were loaded to the hilt with quality nuts and foliage. Much of the peanut crop had been harvested, so most of the farmers had turned their attention to the harvest of what appeared to be a very strong cotton crop, one that would allow farmers to take advantage of an uptick in cotton prices while improving their production history for crop insurance purposes.

Unfortunately, we were quickly reminded Mother Nature has the ultimate say in a crop's fate. By nightfall, Hurricane Michael had swept through our area and decimated most of the cotton and

pecan crops. The storm also damaged agriculture-related infrastructure and equipment like poultry houses, grain elevators, and center-pivot irrigation systems.

Not only had Hurricane Michael created tremendous adversity for the current production cycle, for some farmers the struggle will continue for many years to come. Hurricane Michael's devastating impact on cotton and pecan farmers was felt immediately. Unable to harvest their crops in many cases, some farmers did not make enough money to pay creditors or make necessary repairs to equipment and infrastructure.

Fortunately, crop insurance and farm support programs have provided many of the legal farmers with the ability to repay some of their annual input costs. At the end of the day, however, some farmers are still faced with significant cash shortages, meaning there simply is not enough earnings from their operations to repay all their obligations.

Regardless of the situation facing our farmers and rural communities, Southwest Georgia Farm Credit remains committed to fulfilling our mandated mission. We are currently working with our borrowers to finance their operating losses when justified, provide funds to repair equipment and infrastructure, and renew operating lines for the 2019 production cycle.

As you can imagine, many of the farming families in our area have depleted their equity and liquidity as they have tried to salvage their operations. Given lower projected commodity prices, lower projected farm income, and volatile trade markets, farmers in rural communities will continue to struggle.

Therefore, strong crop insurance programs, farm support programs, and trade agreements remain critically important. But more importantly, it is time to help our farmers. The time for Federal disaster assistance is now.

Thank you very much for the opportunity to testify, and I will be happy to answer any questions from the committee.

[The information follows:]



**Testimony of Paxton W. Poitevint
President and Chief Executive Officer
Southwest Georgia Farm Credit, ACA
Before the Subcommittee on Agriculture, Rural Development, Food and Drug
Administration, and Related Agencies
U.S. House of Representatives Committee on Appropriations
April 2, 2019**

Mr. Chairman and Members of the Subcommittee, I am Paxton Poitevint, Chief Executive Officer of Southwest Georgia Farm Credit, which is headquartered in Bainbridge, Georgia. On behalf of the Association's Board of Directors, my colleagues, and especially the resilient farmers and rural communities of southwest Georgia, I would like to thank you and the Committee for allowing me to be here today. More importantly, I would like to thank each of you for your dedication to agriculture and the countless hours you've spent on a disaster assistance package for the farmers and communities that are suffering from recent storms and wildfires.

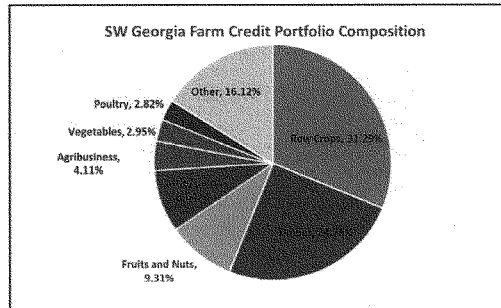
Congress established the Farm Credit System more than 100 years ago to provide a safe, sound, and reliable source of credit and related services to farmers and rural communities. Fulfilling this mission requires a strong focus on the credit needs of young, beginning, small, and minority producers, and a commitment to help ensure there is a next generation of farmers and ranchers. Preserving the many farming operations across America is necessary for the survival of our rural communities, and why I firmly believe Farm Credit's existence is just as critical today as the day the Farm Credit Act was passed in 1916.

In my home state of Georgia, agriculture contributes close to \$72.5 billion each year to the state's economy. With more than 40,000 farms encompassing more than 9.3 million acres of land, one in seven Georgians works in agriculture, forestry, or a related field. Agriculture is the

lifeblood of our local economies. Our farmers create jobs that support local business and industry. They buy food in our local grocery stores; they purchase tires from the family owned tire stores; they seek and receive care at our small hospitals; they send their kids to local schools; and the list goes on. It is safe to assume that when our farmers struggle, our rural communities struggle.

Southwest Georgia Farm Credit serves more than 1,350 customers and maintains approximately \$918 million in committed loan volume. Like the other Farm Credit associations around the country, we strive to meet the financing needs of all credit worthy farmers—big or small. More importantly, we seek to build lasting relationships by serving as a trusted resource. We provide training opportunities to develop the skills pertinent to a farmer's success, including leadership, marketing and risk management. We support their respective trade associations. We invest our time and resources into efforts that benefit the communities in which they reside and raise their families. Such a partnership is necessary to support the delivery of a safe and consistent supply of food and fiber to our country.

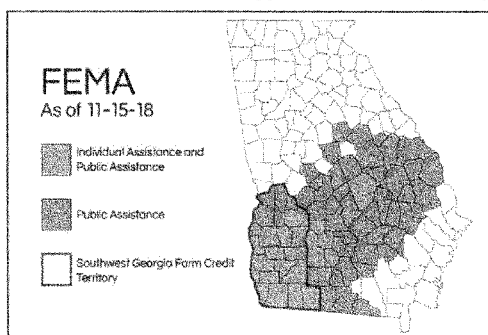
Southwest Georgia Farm Credit's loan portfolio primarily consists of row crops, timber, pecans, and cattle. Our farmers are fortunate to have the ability to grow a diverse mix of row crops, including cotton, peanuts, corn, soybeans, and a variety of vegetables. This is primarily due to soil types, climate, and a consistent supply of well water for irrigation. Such crop diversification and access to water has historically provided significant risk mitigation to both farmers and creditors. However,



after several years of suppressed farm income, rising input costs, volatile international trade conditions, and catastrophic weather events, many of our customers are now suffering. The benefits of irrigation, excellent soil types, and mild climate cannot overcome these other factors. Since Hurricane Michael, approximately 10% of our loan portfolio's credit quality has

deteriorated due to financial related stress on our borrowers, and we expect to see more of this deterioration as we continue to work through annual loan renewals.

On the morning of October 11, 2018, many crops throughout southwest Georgia were at their most vulnerable state for wind damage. Cotton plants were full of fiber and pecan trees were loaded to the hilt with quality nuts and foliage. Much of the peanut crop had been harvested, so most of the farmers had turned their attention to the harvest of what appeared to be a very strong cotton crop; one that would allow farmers to take advantage of an uptick in cotton prices, while improving their production history for crop insurance purposes. Unfortunately, we were quickly reminded Mother Nature has the ultimate say in a crop's fate. By nightfall Hurricane Michael had swept through our area and



decimated most of the cotton and pecan crop. The Category 4 storm also delivered significant damage to ag-related infrastructure and equipment, like poultry houses, grain elevators, and center pivot irrigation systems. According to FEMA, fifteen of the twenty-one counties in which we operate were declared Individual Assistance Disaster Areas, with the remaining six declared Public Assistance Disaster Areas. Not only had Hurricane Michael created tremendous adversity for the current production cycle; for some farmers, the struggle will continue for years to come.

Hurricane Michael's devastating impact on cotton and pecan farmers was felt immediately. Unable to harvest their crops in many cases, some farmers didn't make enough money to pay creditors or make necessary repairs to equipment and infrastructure. Fortunately, crop insurance and farm support programs have provided many of the local farmers with the ability to repay some of their annual input costs. At the end of the day, however, some farmers are still faced with significant cash shortages—meaning there simply isn't enough earnings from their operations to repay their input costs and their debts on land and equipment, not to mention annual living expenses. As an example, a cotton and peanut farmer in our area with a thousand

acre operation experienced significant cotton loss as a result of the storm. The farmer maintained multi-peril crop insurance coverage, but the proceeds received from the insurance claim and his peanut harvest were still insufficient to pay off his operating line of credit and his open accounts maintained at the local farm supply businesses. Therefore, the farmer had to secure an additional loan for the shortage in order to renew the operating line of credit and continue farming in 2019. Doing so further eroded the farmer's equity and placed additional stress on his balance sheet, all the while heading into another year of uncertainty based on projected commodity prices and average farm net income.

Many of our farmers have vertically integrated their production operations by acquiring ownership in downstream processes like peanut shelling plants and cotton gins. As a result of the storm, the cotton gins in our area had significantly less product to run through the operation causing severe cash shortages. Some of the gins in our area are ginning less than 25% of their normal annual throughput. Given such a reduction in production, gins are unable to generate the profits needed to pass supplemental income back upstream to their farmer-owners. Even worse, the gins are also challenged to make their debt obligations. In cases like these we are restructuring debt and offering additional working capital loans to carry these borrowers through the 2019 ginning season.

The long-term implications to our pecan producers are severe. Many of these operations have supported multiple generations—but their future succession plans may be at risk due to the amount of lost income as a result of tree loss. There were thirty to seventy year-old stands of pecan trees blown to the ground. Considering it typically takes seven to ten years for a pecan tree to produce a crop, one can see how difficult it becomes to satisfy any debt associated with the property. For example, one of our pecan producers was within a couple weeks of harvest when Michael came through the area. The annual production costs had been incurred and the trees were prepared to deliver the best yield historically for the grove. The storm destroyed approximately 60% of the trees and blew all the nuts on the ground. In order to harvest the crop on the ground, the downed trees would have to be removed using heavy equipment, which would ultimately destroy most of the nuts. There was crop insurance and grant funding available to cover some of the production costs and cleanup, but these funds were insufficient to cover all the

irrigation repair and replant new trees. With approximately 40% of the trees left standing and land debt to repay, earnings coming from the battered orchard are projected to be insufficient to repay the debt. We are working with many of these producers to find the best possible outcome, so they can continue to farm.

As for the timber in our area, the Georgia Forestry Commission estimated approximately 2 million acres were impacted by the storm, resulting in total losses of approximately \$763 million. More than 7,000 Georgia forest landowners were impacted, many of which were farmers that were dependent upon this income to contribute to their living expenses or to diversify their farming operations.

Regardless of the situation facing our farmers and rural communities, Southwest Georgia Farm Credit remains committed to fulfilling our congressionally mandated mission. As a cooperative, we return our profits to our customers over time. Recognizing the immediate need following Hurricane Michael, we made two early dividend distributions totaling more than \$5.2 million. We also made significant contributions to local charitable organizations, such as United Way and a local food bank, to assist with community-wide recovery efforts. We are currently working with our borrowers to finance their operating losses when justified, provide funds to repair equipment and infrastructure, and renew operating lines for the 2019 production cycle.

As you can imagine, many of the farming families in our area have depleted their equity and liquidity as they've tried to salvage their operations. Given lower projected commodity prices lower projected farm income, and volatile trade markets, farmers and rural communities are struggling. This further supports the need for a strong Farm Bill, especially as it relates to crop insurance, farm support programs, and trade agreements. But more importantly, farmers in southwest Georgia need federal disaster assistance now.

Thank you very much for the opportunity to testify and I will be happy to answer any questions from the Committee.

Mr. BISHOP. Thank you very much, Mr. Pointevint, Mr. Hebrink, Mr. Jensen. Thank you again for being here. As I said, the written and oral testimony is heartfelt, is compelling, and is honest.

Can each of you just take a moment to respond to, reiterate, or emphasize any of the testimony that you heard from our first panel? Are there any stories or anecdotes that you can share that will help the subcommittee get a sense of the mood of farmers from your respective regions? And I think we just got a taste of that from Mr. Fortenberry.

FARM DISASTER AID FROM THE PERSPECTIVE OF THE PRIVATE SECTOR

Mr. POINTEVINT. Mr. Chairman, I think I would add that the best way I know to describe it is there is very little room for error in our area, Southwest Georgia. Given the history, the recent history, I would say the 5-year history of suppressed commodity prices on top of the storm, it is a very critical situation at this time in our territory.

So I think it is important for lenders like Farm Credit to be there for their customers to try and work through these times, and we are committed to doing so. We are looking at loan restructures, providing additional working capital loans, financing irrigation repairs and infrastructure repairs and things like that, to get ready for the 2019 production cycle.

Mr. BISHOP. Mr. Jensen. Mr. Hebrink.

Mr. JENSEN. Mr. Chairman, I would just make a comment. As we have dealt with both a decline in income, net farm income across the Midwest, particularly in grain production, as well as dealt with a disaster or two over the last few years, I think I would call out the consistency in philosophy between FCA, Mr. Tonsager and his testimony, and what we execute on every day in working with our customers.

In terms of—they have been encouraged to work with customers, or the agency has been encouraging to work with customers through these challenging times, both in terms of the disaster and what we have seen of the grain industry. So I would call that out. It is important, as we work with customers every day, which is our focus.

Mr. BISHOP. Mr. Hebrink.

Mr. HEBRINK. Mr. Chairman, both Chairman Tonsager's testimony and some of the follow-up questions he had referenced broad statistics from USDA and overall farm income. And while accurate and indicative of the challenges and the stress within the financial sector, it is important for us to keep in mind that on individual producers, the impact can be very, very different.

And for those individual producers who are exiting the business and as I referenced, our why statement, our position statement, that we exist to champion the hopes and dreams of agriculture in rural America, we understand that when individual farm families suffer, that is a suffering and a death of one of those hopes and dreams of individual families. And that is what we are there and who we are there to serve on an ongoing basis, to help them through those challenges and hopefully see the uptick in the agricultural economy.

SOUTHERN STORM DAMAGE

Mr. BISHOP. Mr. Pointevint, as you know and as most people probably know, Georgia is famous for peaches, peanuts, pecans, and cotton. But a lesser-known fact is that Georgia is consistently ranked at the top of the forestry industry in terms of privately owned forestry.

In 2017, the forestry industry contributed \$18.7 billion to the Georgia economy and supported 82,800 jobs. And the University of Georgia has estimated that Hurricane Michael resulted in nearly \$800 million in direct losses to the Georgia timber industry.

Can you give the subcommittee a sense of the damage to the Georgia forestry industry? And can you tell us from your perspective how three consecutive years of hurricanes have impacted our Georgia farmers, and to reiterate the impact of not having passed the Disaster Bill?

Mr. POINTEVINT. Mr. Chairman, you are exactly right. The timber industry is extremely important to the State of Georgia. And I can tell you, if you took a trek across our territory on October 10 and took that same trek, about a 40-mile stretch across our area, you would see the landscape looks totally different. And that is due to the significant timber damage in our area.

Much of the timber, unfortunately, at this time is done by private individuals. And a lot of our farmers have diversified their operations through their timber operations. So much of that timber was put in place as an investment for retirement purposes, or to pass along to future generations.

One description I like for timber and pecans is the fact that we consider it to be a generational crop, meaning it takes many years to grow. It is typically 10 to 12 years before you can generate any material income from a pecan tree, and it is 10, 12, or 15 years before you can generate any type of income from a timber operation. So it has had a significant impact on our area.

As for the three hurricanes, you are exactly right, Mr. Chairman. 2016, Hurricane Matthew came across the southeastern part of Georgia, and really at a bad time, just like Hurricane Michael, really damaged the cotton and pecan crop in that area. 2017 we had Hurricane Irma that came through southwest Georgia, not quite as severe winds but did significant damage to the cotton crop; again, it was at a very bad time.

And then obviously in 2018 with Hurricane Michael and the significant damage that it did on our cotton and pecans in October.

Mr. BISHOP. My time is expired.

Mr. Fortenberry.

NEBRASKA FLOODING

Mr. FORTENBERRY. Thank you, Mr. Chairman. Thank you for your questions and your vivid description. Sometimes when we are talking balance sheets and debt ratios and deferred interest and loan consolidations, we are in the realm of the abstract. So stories that point to the significance of the problem out there are always very helpful. Let me give you an idea of what happened in the area which I represent.

So we had three 500-year events along three rivers where they basically converged: the Platte, which runs from west to east, flowing into the Missouri; the Elkhorn, from the north down to the south end of the Platte near the convergence of the Platte and the Missouri.

So you have rain on top of frozen ground on top of snow, with rising temperatures, causing a slurry of soil and ice that is not absorbed into the ground smashing against flood control barriers, levees and other designed systems to protect our communities.

So when it hit the Missouri, this wave, this tsunami of sorts, couldn't not go anywhere except backwards, upriver, which then came over the top of the levee system designed to protect Offutt Air Force Base, which is a significant part of our Nation's military infrastructure, which houses, by the way, Strategic Command, which is the most—the place of the most powerful command of weaponry in the world. Going back upriver, all along the Platte as well as the Elkhorn where you had levee systems failing, it looks like Swiss cheese, according to the Corps of Engineers.

The town of Fremont was largely spared except in the southern portion of it, when the Platte River decided to take a new course, going back to the 1940s route that it once had, blowing out 400 yards of levee that I saw. The little town of North Bend had water just coming like fingers straight through the streets.

And then going further west, south of the town of Columbus, which is 25,000 people, there is a little truck stop called T-Bone Cafe. Well, I saw the initial pictures of T-Bones, which had water and mud four feet high. By the time I got there, a lot of that mud was out, and I looked at the manager, Fred, and he said, "We don't mess around. We're Nebraskans. We get it done."

The point of all this is, there is a real cooperative spirit where I live. And in America in general, the disasters tend to bring about the best of us. Neighbor helps neighbor. Local governments have done an extraordinary job of responding. Our role here is to provide the backup mechanisms, which when local responses are overwhelmed, we are here to help.

So can you speak to any specifics in regards to some things that you have done? You talked about the grain sector, but the livestock sector is also significantly impacted.

Back to T-Bones. They have two boots, large six-foot or so cowboy boots that greet you on the outside. One was found about 300 yards away in Mitulka's Garage, and the other one about half a mile away on Highway 81. These are big, concrete boots, big boots sunk in concrete that were just tossed about like toys.

So that's kind of amusing. But at the same time, when you see a bloated cow right next to that area on the side of the road, who knows where it comes from? It points to the issue that the agricultural losses are going to mount. It is almost easier, in a way, to identify the losses in the urban communities because they are dense and the resource mechanisms are right there to begin to count. It is a little bit harder in the agricultural community.

HANDLING LOSS AND PREDICTING CASUALTY

So two questions, Mr. Jensen. What specific examples of what you have already done with persons who are benefitting from your

credit portfolio? And second, how intense do you see the agricultural losses rising, or how intense will the rise be?

Mr. JENSEN. Congressman, thank you for the question. And it has been an interesting week or two, has it not? It is a disaster that I do not think any of us were ready for or anticipated.

I am going to start off my response to your question with a letter I received, actually, from one of our customers. And this is the letter that was received on March 25, so within days after this occurred. And it was after one of our loan officers had already been out to meet with the customer and look at some of the extent of the damage they have seen and start talking about, "What about next steps?"

And this is how we kicked off—this customer happens to be from the Columbus area, which you just mentioned. "I am one of the victims of the terrible flooding across the State of Nebraska. It is going to be a long road to recovery." So that is how he kicked it off.

So we are in the process right now of meeting with many of these customers in these affected areas. We know that there will be many that would be impacted. We also had many employees impacted. I think we identified 11 employees that had significant damage to their homes; four of them may lose their homes. So we are dealing with it both in terms of customers and employees.

There were a couple of unique aspects to what happened there, and you mentioned many of them and how all those things converged at one time. The extent of this flooding is probably something we had not seen; this flooded outside of what would typically be some of your river typical flooding areas if you were to get some mild flooding.

And then how quickly it happened—it converged all within a day or two. A lot of our customers did not have time to get out there and remove grain from bins, remove livestock from those areas, move machinery and equipment out. The impact is significant, and there are all kinds of estimates, and I know you have seen them, too, how broad this could be. Clearly it is in the hundreds of millions of dollars, if not billions.

What we are doing immediately is, when an event like this occurs, what we find is the customers need some time just to get their arms around what has happened and deal with what is ahead of them. And then one of the first conversation was to start to work with their loan officer, their banker, to start talking about what options they have.

So the things that we have done so far is this is not only, as you mentioned, impacted a lot of farm producers. But their communities to some degree have been devastated. So the Nebraska Farm Bureau immediately set up a relief fund. You have got to give them a lot of credit for how quickly they responded to that.

So we have made a significant financial obligation to them, to the Nebraska Cattlemen's, to the Red Cross, and then also the Farm Credit system has an employee relief fund that we have donated a significant amount of dollars to. Add that up, we have donated about just under \$200,000.

In addition to that, as I mentioned, we are starting to have conversations with our customers. And we have what is called a dis-

aster assistance program that is built for these types of situations that—unfortunately, we see them from time to time, and we pull that off the shelf, which starts to lay out options for customers to look at—a lot of the cases, they need to buy a little time. There might be payments coming due here in February—excuse me, in April or May.

So there are ways that we, under that program, defer payments, reamortize some loans, advance some additional dollars under a low-interest loan program to help them. So those are some of the things that we are doing immediately and some of the things we have done for the community. And I realize I am running out of time, too.

RURAL DEVELOPMENT INTERACTIONS AND EXPERIENCES

Mr. BISHOP. Thank you. I am interested in learning a little bit more about your rural development activities. Rural communities and agricultural are interdependent, and the Farm Credit Association has played an important role in financing and supporting rural hospitals, housing, and infrastructure. As you know, our committee oversees rural development at USDA.

From what you see on a day-to-day basis, what are the greatest needs that you see in rural America? Do any of you have experience working with the Rural Development Agency, USDA? And have those interactions been positive? Because what you have to do is, whether it is housing, whether it is infrastructure, whether it is education or healthcare, you have got to help make it affordable and accessible in order for the quality of life in those rural communities to be improved.

Can you comment on that? Each of you?

Mr. HEBRINK. Yes. Thank you, Mr. Chairman. Your observations and insights are correct. In order to retain population in rural areas, we need many of these amenities, whether it is access to healthcare, jobs, education, and other infrastructure, such as broadband in rural communities, to be able to retain the rural population that exists in the young families, your younger generation.

Compeer has been one of the most active Farm Credit Associations within rural development. We have participated very actively with the USDA in those rural development programs, particularly the community facility programs. We have been involved in the development of 40 projects over the Midwestern part of the United States across 17 States, largely rural, critical access care facilities, senior living facilities, and other community living facilities.

We have had a strong partnership with the USDA. Those programs have been essential to put into place the financial structure that allows those communities to move forward and finance those projects. It has been a public-private partnership between Farm Credit, community banks, and the USDA programs. And we look forward to continuing to work on those USDA programs on future projects.

Mr. BISHOP. Mr. Jensen.

Mr. JENSEN. In addition to those type of programs, at more of a local level we are involved in promoting various different agricultural programs, include 4-H programs, the county 4-H level. We have a Hands On Learning agriculture initiative that we partici-

pate in. We provide scholarships for 32 individuals for \$2500 each scholarships last year, and also local farmers markets, like the Fallbrook Farmers Market in Lincoln, Nebraska.

So those are various different types of opportunities we take advantage of to help rural America.

Mr. BISHOP. Mr. Pointevint.

Mr. POINTEVINT. Mr. Chairman, I would echo the comments. But I would say that job creation is an absolute must in the rural areas, especially in southwest Georgia. And the only way to create jobs and lure those industries to our area is to ensure we have access to quality healthcare, access to quality education, and obviously, as you mentioned earlier, the infrastructure, including broadband, to create the connectivity we need to thrive.

But that is definitely the biggest challenge for our rural area in Southwest Georgia.

Mr. BISHOP. Well, thank you. I want to thank all of you, all of our witnesses, Mr. Hebrink, Mr. Jensen, and Mr. Pointevint. And on behalf of the committee, we truly appreciate your willingness to come to Washington today to discuss a rural economy and to provide personal, on-the-ground insight of what is going on and what is needed from Congress.

The work that you do is extremely important, and I am glad that we were able to have you to assist us and discuss this important topic today.

Again, I want to thank you all for your testimony. And with that, the subcommittee is adjourned.

QUESTIONS FROM THE SUBCOMMITTEE

Subcommittee: Please provide a list of all Farm Credit Administration (FCA) field offices and indicate the number of staff associated with each office.

Response:

Number of FCA staff by office location	
Office location	Staff number
McLean field office (headquarters)	167
Sacramento field office	23
Denver field office	48
Bloomington field office	38
Dallas field office	29
Rest of U.S.	8
Total	314*

*As of April 12, 2019, this number represents all staff, including part-time employees.

Subcommittee: Please provide a table showing the agency's FTEs by office for the past 10 fiscal years and include the estimated levels for fiscal year 2019.

Response:

Full-time equivalent staffing levels by office, FYs 2019

Office	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	Celling FY 2019 Est.
Board	8.9	8.6	9.8	9.3	9.4	10.0	9.9	10.2	8.9	9.7	10.0
Chief Executive Officer	1.9	1.7	2.0	3.0	2.8	2.3	2.3	3.0	3.0	3.0	3.0
Congressional and Public Affairs	5.0	6.1	6.6	5.0	5.1	5.0	5.2	5.0	5.7	6.6	6.2
Examination	149.8	163.6	171.2	172.6	163.7	166.9	162.4	173.0	175.7	173.5	178.4
General Counsel	13.6	12.9	13.6	13.1	13.5	13.8	13.7	12.0	12.5	13.6	14.3
Management Services ¹	48.8	50.7	49.9	50.4	48.1	48.9	48.3	25.5	—	—	—
Chief Financial Officer	—	—	—	—	—	—	—	—	7.8	7.8	10.2
Agency Services	—	—	—	—	—	—	—	—	19.2	18.5	20.6
Information Technology ²	—	—	—	—	—	—	—	24.1	26.6	29.5	31.1
Inspector General	4.6	4.6	4.6	4.6	4.0	4.2	5.7	5.5	5.6	5.0	5.8
Secondary Market Oversight	4	4.0	3.7	4.6	4.2	4.7	5.0	5.0	5.0	5.7	6.4
Regulatory Policy	24.2	24.3	25.0	25.0	22.6	22.1	24.2	26.4	26.3	25.3	28.2
Total	260.8	276.5	286.4	287.6	273.4	277.9	276.7	289.7	296.3	298.2	314.2

¹ As the result of a reorganization in May 2016, the Office of Management Services was divided into two offices: the Office of Agency Services and the Office of the Chief Financial Officer. The two new offices divided between them the FTEs of the Office of Management Services.

² The Office of Information Technology was established in May of 2015. It had been part of the Office of Management Services. All FTEs for the Office of Information Technology were part of the Office of Management Services before FY 2016.

Subcommittee: Please provide a table showing FCA obligations by office for the past 10 fiscal years and include the estimated levels for fiscal year 2019.

Response:

FCA obligations by office, FYs 2009 – 2019 (dollars in thousands)

Office	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	Ceiling FY 2019 Est.
Board	\$1,966	\$2,172	\$1,990	\$1,926	\$1,897	\$2,090	\$2,251	\$2,445	\$2,280	\$2,466	\$2,699
Chief Executive Officer	346	405	505	730	677	628	690	775	897	904	1,063
Congressional and Public Affairs	946	1,237	1,440	1,219	1,239	1,306	1,444	1,481	1,605	1,764	1,941
Examination	23,270	26,469	27,987	27,698	27,072	28,862	29,184	31,154	31,264	32,485	34,890
General Counsel	2,752	2,756	2,976	3,029	3,275	3,511	3,652	3,395	3,566	3,939	4,403
Management Services ¹	10,174	11,210	11,669	11,696	11,145	12,539	14,420	7,740	–	–	–
Chief Financial Officer	–	–	–	–	–	–	–	–	3,751	3,277	3,665
Agency Services	–	–	–	–	–	–	–	–	4,571	4,658	5,467
Information Technology ²	–	–	–	–	–	–	–	8,348	10,691	10,834	10,641
Inspector General	985	1,038	1,067	1,096	948	1,006	1,312	1,400	1,514	1,517	1,716
Secondary Market Oversight ³	1,002	1,078	966	1,074	1,038	1,280	1,447	1,417	1,530	1,710	1,906
Regulatory Policy	4,246	4,545	4,777	4,720	4,522	4,599	5,122	5,897	5,959	6,083	6,969
Total obligations	\$45,687	\$50,910	\$53,377	\$53,188	\$51,813	\$55,821	\$59,522	\$64,052	\$67,628	\$69,637	\$75,360

¹ As the result of a reorganization in May 2016, the Office of Management Services was divided into two offices: the Office of Agency Services and the Office of the Chief Financial Officer. The two new offices divided between them the budget of the Office of Management Services.

² The Office of Information Technology was established in May of 2015. It had been part of the Office of Management Services. The budget for the Office of Information Technology was part of the budget of the Office of Management Services before FY 2016.

³ Excludes costs of certain offices, such as Examination and General Counsel, that assist in the examination and supervision of Farmer Mac.

Subcommittee: Please provide a table showing FCA unliquidated/ open obligations by office for the past 10 fiscal years.

Response:

FCA unliquidated/open obligations by office, FYs 2009 – 2018 (dollars in thousands)

Office	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
Board	\$84	\$186	\$104	\$117	\$58	\$60	\$79	\$91	\$74	\$103
Chief Executive Officer	20	26	29	50	38	30	40	31	117	46
Congressional and Public Affairs	94	185	253	133	106	146	218	217	181	119
Examination	1,718	1,792	2,025	1,741	1,229	1,282	1,443	1,408	1,538	2,001
General Counsel	201	209	227	220	154	208	167	145	229	209
Management Services ¹	1,623	1,788	1,400	1,780	1,321	2,631	3,612	1,488	–	–
Chief Financial Officer	–	–	–	–	–	–	–	–	1,047	494
Agency Services	–	–	–	–	–	–	–	–	553	601
Information Technology ²	–	–	–	–	–	–	–	2,634	3,706	3,311
Inspector General	87	110	81	82	43	66	70	82	114	94
Secondary Market Oversight	134	145	153	86	65	155	230	118	215	186
Regulatory Policy	233	332	294	311	179	193	256	258	252	266
Total unliquidated/open obligations	\$4,194	\$4,773	\$4,566	\$4,520	\$3,193	\$4,771	\$6,115	\$6,472	\$8,026	\$7,430

¹ In FY 2017, the Office of Management Services was reorganized into the Office of the Chief Financial Officer and the Office of Agency Services.

² The Office of Information Technology was established in May of 2015. It was previously part of the Office of Management Services. All obligations for the Office of Information Technology were established in the Office of Management Services before FY 2016.

Subcommittee: What is the cost of operating the agency to Farm Credit System and Farmer Mac?

Response: The FY 2019 appropriations bill limits the agency's administrative operating expense paid from System institution assessments at \$74.6 million. The estimated FY 2019 operating costs of the agency are \$71.85 million for the Farm Credit System, and \$2.75 million for Farmer Mac.

Subcommittee: Please provide a table showing the total carryover available at the end of each fiscal year beginning in 2015, including an estimate for 2019.

Response:

**Total carryover at end of each fiscal year,
FYs 2015 – 2019**

Fiscal year	Assessment carryover amount (in millions)
2015	\$5.2
2016	\$0.9
2017	\$1.7
2018	\$1.9
2019 Est.	\$2.0

Subcommittee: FCA also receives funds from interest earned on investments with the Treasury and uses the interest earned to build and maintain an Agency reserve. Please provide a table showing the balance in the reserve for each fiscal year since it was established.

Response:

FCA reserve	
FY	Balance (in millions)
2007	\$8.0
2008	\$9.0
2009	\$9.5
2010	\$10.0
2011	\$10.6
2012	\$11.1
2013	\$11.5
2014	\$11.8
2015	\$12.1
2016	\$12.3
2017	\$12.6
2018	\$13.15

Subcommittee: Please provide a list of recommendations from FAC's Inspector General for which management decisions are pending as of May 1, 2019.

Response: There are currently no recommendations pending management decisions. We have six open recommendations that have been agreed to and that management is in the process of implementing.

Subcommittee: Please provide tables showing the loan volume and net income of Farm Credit System institutions for fiscal years 2011 through 2018.

Response:

Gross loans and net income for the Farm Credit System (dollars in millions)								
	2011	2012	2013	2014	2015	2016	2017	2018
Gross loans	\$174,664	\$191,904	\$201,060	\$217,054	\$235,890	\$248,768	\$258,777	\$271,944
Net income	\$3,940	\$4,118	\$4,640	\$4,724	\$4,688	\$4,848	\$5,189	\$5,332

Subcommittee: Please update the Committee on FCA's opinion of the financial health of the Farm Credit System. Provide an explanation of the top five risks to the System and what factors work to mitigate this risk and what factors can increase this risk. What is FCA doing in **Response** to any protentional increased risk.

Response:

FINANCIAL HEALTH OF THE FARM CREDIT SYSTEM

The FCS is fundamentally safe and sound and is in a strong position to carry out its mission to provide American agriculture with a dependable source of credit. Factors supporting the financial strength of the System include favorable earnings, a strong capital base, and reliable access to the debt capital markets.

The System's strong capital position enhances its risk-bearing ability at a time when many agricultural producers face significant financial challenges. As of December 31, 2018, System capital totaled \$58.4 billion, up from \$55.4 billion a year before. The System's capital-to-assets ratio at December 31 was 16.7 percent for 2018 compared with 16.8 percent for 2017.

Strong earnings have continued to support capital growth. For 2018, the System reported full year consolidated net income of \$5.3 billion, up from \$5.2 billion in 2017. Net interest margin was 2.46 percent compared with 2.48 percent for 2017. Overall, almost 80 percent of total capital is in the form of retained earnings.

While U.S. farmers and ranchers face significant financial challenges in 2019, System institutions are in a strong position to support agricultural producers. For 2018, System gross loans increased by \$13.2 billion or 5.1 percent to \$271.9 billion. Real estate mortgage lending was up \$5.4 billion or 4.5 percent because of continued demand for cropland from new and existing customers. As the largest loan category, real estate mortgages account for almost 46 percent of the portfolio.

Overall, the System's loan portfolio is performing well, and credit quality continues to be good. For 2018, nonperforming assets totaled \$2.3 billion, or 0.84 percent of loans and other property owned, compared with \$2.0 billion, or 0.78 percent, at year-end 2017. Loan delinquencies (accruing loans 30 days or more past due) were 0.31 percent of total accruing loans, up from 0.25 percent at year-end 2017.

While asset quality declined in 2018 from relatively strong levels in 2017, credit stress in the loan portfolio is well within the System's risk-bearing ability. At December 31, the System's allowance for loan losses was \$1.7 billion, and equaled 75 percent of nonperforming assets and 91 percent of nonaccrual loans. Capital and the allowance for loans losses totaled \$60.2 billion or just over 22 percent of System loans outstanding.

The System continues to have reliable access to the debt capital markets. In 2018, investor demand for all System debt products remained positive, allowing the System to issue debt on a wide range of maturities at competitive rates. Risk spreads and pricing on System debt continued to be favorable relative to corresponding U.S. Treasuries.

With a balance of \$5.0 billion at year-end 2018, the Farm Credit Insurance Fund further strengthens the financial integrity of the System. Administered by the Farm Credit System Insurance Corporation, this fund protects investors in Systemwide consolidated debt obligations. System banks also maintain liquidity reserves to ensure they can withstand market disruptions. As of December 31, 2018, the System's liquidity position equaled 182 days, significantly above the 90-day regulatory minimum required for each FCS bank.

Although the FCS is financially sound, a small number of individual institutions displayed some weaknesses in 2018. As the System's regulator, FCA addressed these weaknesses by increasing our oversight and supervision of these institutions.

TOP FIVE RISKS TO THE SYSTEM

1. **The duration of low commodity prices and weak margins** — The potential for borrower operating losses in 2019 following several years of losses or minimal profits creates an uncertain operating environment for both borrowers and lenders. Market prices are weak for key commodities, including corn, soybeans, and wheat. Dairy margins are also under pressure, a situation that will likely accelerate ongoing structural changes as smaller and mid-sized producers exit the industry. At current price levels, many farmers will remain under financial pressure in 2019.
2. **Continued deterioration in the international trade environment** — Uncertainty in trade policy continues to be a major risk for U.S. agriculture. Currently, retaliatory tariffs on many agricultural products by major importers have reduced the competitiveness of U.S. exports, such as soybeans, pork, dairy, almonds, and citrus. Over time, a resurgence of trade protectionism among our trading partners would reduce the U.S. market share in export markets and, in turn, the profitability of U.S. farmers. In this environment, farm prices and profitability are expected to remain subdued, increasing financial pressure on farmers; this situation could, in turn, lead to additional deterioration in credit quality.
3. **A severe recession in the general economy** — A severe recession, if this should occur, could have an adverse effect on the agricultural economy and the financial condition of the System. A recession in the United States would likely slow economic growth globally and ultimately lead to lower demand for U.S. farm exports. Also, agricultural sectors, such as timber and horticulture, that provide inputs for housing and landscaping are frequently hard hit when the country goes into recession. More generally, off-farm income is an important source of repayment for many System loans. An increase in unemployment could lead to reduced off-farm income and credit quality problems at some Farm Credit institutions.
4. **A substantial correction of farm real estate values** — Farm real estate serves as the primary collateral for almost 46 percent of System loan volume. Therefore, a substantial correction in farm real estate values could leave a significant portion of these loans with insufficient collateral. Surveys of lenders and real estate professionals indicate these experts foresee stable to somewhat lower cropland prices for the balance of 2019.

5. **Effect of rising interest rates on credit risk** — Relatively low interest rates in recent years have supported farmland values and kept borrowing costs low. Rising interest rates would have the opposite effect. A higher interest rate environment would be challenging for farmers with debt who are already struggling to break even because of low commodity prices; higher interest rates would put additional pressure on their bottom lines. Borrowers seeking to acquire additional debt as a substitute for income could be severely affected. They can mitigate this risk by using fixed-rate financing where possible to lock in current relatively low interest rates.

FCA'S RESPONSE TO RISK AREAS

FCA maintains strong examination and supervision oversight of all System institutions. We are very aware of the changing risk conditions addressed above, and we have factored these risks into our Office of Examination Operating Plan, our National Oversight Plan, our examination oversight program, and each institution's examination plans.

In the 2019 National Oversight Plan, we emphasized that lenders, because of continued low commodity prices, may need to be more proactive in servicing loans over the planning horizon. Institution servicing and borrower actions to date have minimized any significant effect on the System's credit quality and condition. However, we are increasingly concerned that many borrowers have already used most of the readily available servicing options and more significant actions may be required if risk conditions do not improve.

We have cautioned FCS institutions to be proactive and responsive in counseling financially stressed customers and restructuring debts; at the same time, we have urged them to establish stronger credit controls. We have also cautioned institutions that, in the more severe cases, they will need to strengthen their ability to handle increased credit risk. They can strengthen this ability by adding resources to their special credit departments and by continuing to administer all FCA borrower rights requirements properly.

During examinations, we are emphasizing the importance of the following:

- Portfolio management practices
- Loan-servicing strategies
- Frequent dialogue with association management teams and boards
- Loan-review activities in high-risk areas

We are having discussions with institutions about accurately identifying the risks on individual credits. We are also encouraging them to work with customers who are cooperative and have options for regaining profitability. We have been stressing the importance of neither underreacting nor overreacting to the long period of low prices. We believe the portfolio management practices we have emphasized to the System institutions during the good times have put them in a good position to withstand the current down cycle.

Our examiners and many institutions are also emphasizing appropriate risk-management practices, including the use of crop insurance and marketing strategies. For individual farmers, lowering the cost of production is key for the survival of cash grain and dairy operations, and many institutions offer benchmarking information to help producers make better decisions. Finally, FCA has prepared for more credit and collateral risk by updating our examination programs and plans and by hiring several highly experienced mid-career credit specialists.

In summary, we issued the System an appropriate cautionary message before risk conditions began to erode and have continued to emphasize the importance of timely risk identification and proactive servicing. We have also stressed the need to work with borrowers to find solutions that are in the best interests of both the borrowers and the shareholders. We have also maintained a strong and flexible supervisory program that requires institutions to take corrective actions when needed. While we expect some increased credit risk in the coming year, we believe the System continues to be well-positioned to both manage and absorb these risks.

Subcommittee: Are there any System institutions that are under heightened scrutiny or examination by FCA? Please provide summary of each situation.

Response: Currently there are no institutions under enforcement supervision. Five institutions with combined total assets of about \$6.5 billion are operating under special supervision. In each of these cases, the institution is financially sound but has experienced operational or managerial weaknesses. The Office of Examination has issued direction to each agricultural credit association to address the identified issues, and each is progressing toward compliance.

- In the first institution, the largest branch experienced operational and managerial breakdowns. The board and management have taken the necessary corrective actions, and we are currently evaluating the effectiveness of those actions.
- In the second institution, an employee was convicted of bank fraud. The board and management are implementing corrective actions to address certain operational weaknesses exposed by the event.
- In the third institution, the board is seeking a strategic business combination to help it address weaknesses in its management depth and economies of scale.
- In the fourth institution, significant management turnover and an information technology breach created the need for special supervision. The institution has made significant operational enhancements, and FCA is assessing the adequacy of those actions.
- In the fifth institution, a borrower fraud event exposed weaknesses in the institution's internal controls. The institution is implementing appropriate corrective actions to prevent a recurrence.

Supervisory levels as of March 31, 2019, and assets as of December 31, 2018

Supervisory classification	Number of System banks and associations	Assets under examination (dollars in thousands)	Percentage of assets under examination
Normal supervision	68	\$507,476	98.7%
Special supervision	5	\$6,521	1.3%
Enforcement supervision	0	\$0	0.0%
Total	73	\$513,997	100.0%

Note: Supervisory classifications as of March 31, 2019, and assets as of December 31, 2018, and before intra-System eliminations.

Subcommittee: Please list any System institutions that have not filed any financial reports in over a year.

Response: At present, no System institution has failed to file any financial report in over a year.

Subcommittee: Please update the Committee on FCA's opinion of the financial health of Farmer Mac?

Response: Farmer Mac is fundamentally safe and sound. During 2018, Farmer Mac demonstrated the financial capacity to meet its obligations and fulfill its mission. It experienced steady growth in its Farm & Ranch loan purchases and its AgVantage products.

Farmer Mac's total program activity increased to \$19.7 billion as of December 31, 2018, from \$19.0 billion a year earlier, which is an increase of 3.8 percent. Credit metrics remained favorable, and credit quality in all program business lines remained satisfactory. Delinquencies greater than 90 days declined to \$26.9 million as of December 31, 2018, or 0.37 percent of Farm & Ranch loans, compared with \$48.4 million, or 0.71 percent, as of December 31, 2017.

Financial measures indicate continued good financial health and risk-bearing capacity. Core capital (the sum of the par value of outstanding common stock, the par value of outstanding preferred stock, paid-in capital, and retained earnings) remained above the statutory minimum requirement. As of December 31, 2018, core capital totaled \$727.6 million, exceeding the statutory minimum capital requirement of \$545.0 million by \$182.6 million.

For the year ended December 31, 2018, Farmer Mac also experienced increases in reported net income available to common stockholders, core earnings, and net interest income. Overall interest rate sensitivity remained manageable. Balance sheet liquidity as measured by days of liquidity totaled 205 days as of December 31, 2018, and was well above the regulatory minimum. Access to the capital markets also remained favorable.

Subcommittee: Please describe how the Tax Cuts and Jobs Act of 2017 (P.L. 115-97) effected the Farm Credit System's tax rate and any other changes from the Act compared to traditional banks.

Response: Tax Cuts and Jobs Act (TCJA) lowered the federal corporate tax rate from 35 percent to 21 percent. As a result of the act, the System's provision for income taxes declined by \$16 million in 2018 and by \$162 million in 2017. The act caused a decline in the System's effective tax rate from 3.5 percent in 2016 to 0.7 percent in 2017; however, it caused an increase to 2.3 percent in 2018.

Disclosures by commercial banks indicate they received significantly greater benefits from the enactment of the TCJA than the System did. This is primarily because, as a cooperative under Subchapter T of the Internal Revenue Code, the System is partially exempt from federal and other income taxes as provided in the Farm Credit Act. As reported in the press, the TCJA caused a significant decline in the effective tax rate of most commercial banks (e.g., KeyCorp's effective tax rate decreased to 15.5 percent in 2018 from 26.9 percent in 2017, and Bank of the West's rate decreased to 22.5 percent in 2018 from 50.7 percent in 2017).

Subcommittee: Does FCA anticipate any System institution mergers in 2019 or 2020?

Response: FCA anticipates the possibility of two business combinations in 2019. In each case, the goal of the merger is to address the long-term viability of a small association. FCA is not aware of any potential mergers in 2020, although one of the business combinations anticipated in 2019 could have an effective date of January 1, 2020.

Subcommittee: On average, as of January 1, 2019, how many days of liquidity do System Institutions hold?

Response: Farm Credit banks are the only FCS institutions required to hold days of liquidity to meet debt obligations coming due within the next 15, 30, and 90 days. The days of liquidity are provided by each bank's respective investment portfolio. FCA's regulations establish the criteria for the quality of these investments. Based on the quality of the investment, a discount factor is applied with a resulting investment value assigned for each investment. These values are compared to the debt obligations coming due to assess the days of liquidity an FCS bank has available to meet upcoming debt obligations if the bank's investment portfolio is needed for that purpose. The combined average days of liquidity for the four banks during 2018 was 195 days. For each individual bank, the average for 2018 was as follows:

- AgFirst Farm Credit Bank – 223 days
- AgriBank, FCB – 152 days
- Farm Credit Bank of Texas – 229 days
- CoBank, ACB – 176 days

Subcommittee: What percentage of the System's loan portfolio is urban agriculture. What is FCA doing to ensure urban agriculture is adequately served by FCS.

Response: The Farm Credit Act mandates that the System serve all types of agriculture and agricultural production. To help ensure the System meets this mandate, we issued a booklet (066) on October 11, 2012, that provides guidance on how FCS associations can meet the credit and related service needs of producers who market their goods through local and regional food systems. Urban agriculture is within the scope of this booklet. However, we are considering supplementing this guidance with a discussion of issues specific to urban agriculture, such as requirements for securing urban-based collateral for mortgage loans.

The System does not currently track the numbers of loans extended to urban agricultural producers. Nevertheless, urban agriculture is an area of significant interest for some System institutions, and FCA is studying it. We are currently reviewing our regulations and guidance to ensure that we clearly communicate to the System that, even though the Farm Credit Act has a specific focus on rural America, the financing of urban agriculture is not only permitted but encouraged for creditworthy borrowers engaged in the production of agricultural and aquatic products.

In 2012, we enhanced our regulation pertaining to FCS association business plans. The revised regulation requires each association to be responsive to the credit needs of all types of

agricultural producers having a basis for credit within its board-approved marketing plan. FCS associations must include the following:

- A description of the institution's chartered territory by market segment, including demographic and geographic characteristics and types of agriculture practiced
- Strategies and actions to market the institution's products and services to all eligible and creditworthy persons, with specific outreach toward diversity and inclusion within each market segment

Each institution must report annually to its board of directors on its progress in accomplishing the strategies and actions required by this section of our regulation.

Subcommittee: Please provide the number of loans, the dollar volume of those loans, and the average size of those loans made to Young, Beginning, and Small farmers in 2018?

Response: The Federal Farm Credit Banks Funding Corporation issued the 2018 Annual Information Statement of the Farm Credit System on March 1, 2019. This information statement includes unaudited financial information on the number and volume of loans to young, beginning, and small (YBS) farmers, as well as the average loan size. See the table below for the data for each category.

YBS loans made in 2018 by number, dollar volume, and average loan size

	Number of loans	Dollar volume (in billions)	Average loan size
Young	46,682	\$9.8	\$209,931
Beginning	62,330	\$13.4	\$214,985
Small	114,817	\$12.5	\$108,686

FCA prepares an annual report on the quantitative and qualitative results achieved by the System through its YBS programs and submits this information to Congress when the agency submits its annual report on the condition of the System. Members of our staff annually prepare and present the System's YBS farmer mission performance to the FCA board in the summer of each year. This presentation occurs after FCA staff has reviewed and analyzed the reported YBS data. The attainment of the goals of the YBS programs, as reflected in the collection and reporting of YBS data, is important to a wide range of stakeholders and the public as a whole.

At its monthly meeting on February 14, 2019, the FCA board approved an advance notice of proposed rulemaking to address System programs for serving YBS farmers and ranchers. The notice seeks comments on methods and practices that could be used to improve the collection and reporting of YBS data and the oversight of these activities. We are also seeking comments on whether our definitions of YBS farmers still accurately describe these farmers.

Subcommittee: While not included in the statutory reporting requirements on Young, Beginning, and Smaller Farmers, please provide any available information on Farm Credit lending trends to socially disadvantaged farmers?

Response: Under the Equal Credit Opportunity Act, FCA and the System are limited in the type of demographic data that may be collected from applicants and borrowers. Unlike USDA, neither FCA nor the FCS has statutory authority to require the collection of information that could be used to categorize borrowers under the USDA definition of socially disadvantaged farmers and ranchers. Therefore, we do not have the specific data to respond to this question. However, FCS institutions, consistent with the Equal Credit Opportunity Act, have outreach and other programs to ensure they meet their obligations to serve all eligible borrowers within their chartered territory. FCA, as part of its examination of FCS institutions, reviews these programs.

Subcommittee: In 2013, the Farm Credit Board voted to conclude all pilot programs approved as part of the Investments in Rural America Program. Though these pilots ended on December 31, 2014, FCA can consider investment requests on a case-by-case basis under the existing investment regulations. Please provide a list, by year since the 2015, of the investment requests approved by FCA, the FCS institution that made the request, and a brief description.

Response:

- **Cook County North Shore Hospital** — Bonds to be issued by a rural health care facility, located in Grand Marais, Minnesota, to finance facility improvements and expansion. Requests made by AgStar (8-25-15) and CoBank (9-25-15).
- **Belstra Milling Co., Inc.** — Bonds to be issued by a feed mill, located in the Town of Demotte, Indiana, to refinance existing debt and fund the expansion of the existing mill. Request made by Mid-America (10-07-15).
- **Lakeview Biodiesel, LLC** — Bonds to be issued by a biodiesel facility, located in Moberly, Missouri, to restart the operations of the facility, which were discontinued by the previous owners. Request made by Ag Credit (3-08-16).
- **Winner Regional Healthcare Center** — Bonds to be issued by a rural health care center, located in Winner, South Dakota, to finance the renovation of the existing facility. Requests made by AgStar (3-04-16) and CoBank (3-15-16).
- **Modoc Medical Center** — Bonds to be issued by a rural hospital, located in Alturas, California, to replace and relocate the existing medical center. Requests made by AgStar (6-24-16) and CoBank (6-24-16).
- **Park View Homes** — Bonds to be issued by a continuous care facility, located in Woodville, Wisconsin, to finance the construction of senior independent living units on the existing campus. Request made by AgStar (1-10-17).
- **Lutheran Sunset Ministries** — Bonds to be issued by a continuous care facility, located in Clifton, Texas, to finance the construction of a new skilled-nursing facility and 24-bed assisted living facility. Requests made by AgStar (4-07-17) and CoBank (6-05-17).

- **Lincoln Community Hospital** — Bonds to be issued by a rural health care facility, located in Hugo, Colorado, which would finance the acquisition of an existing facility in Limon, Colorado. Request made by CoBank (6-29-17).
- **Minnewaska Lutheran Home** — Bonds to be issued by a continuous care facility, located in Starbuck and Hoffman, Minnesota, which would expand an existing campus in Starbuck and build a new facility in Hoffman. Requests made by Compeer Financial (8-10-17) and CoBank (8-24-17).
- **Bowdle Hospital Center** — Certificates of participation to be issued by a rural health care center located in Bowdle, South Dakota, to finance the construction of a new medical clinic and to renovate the existing hospital and nursing home facility. Request made by Compeer Financial (12-21-17).
- **Midwest Medical Foundation** — Bonds to be issued by a health care foundation located in Galena, Illinois, to finance the acquisition of, and make minor improvements to, an existing medical campus. Request made by Compeer Financial (3-20-18).
- **AgFirst Farm Credit Bank RHMS Investments** — Allowed AgFirst to purchase and hold rural housing mortgage-backed securities. Request made by AgFirst (6-4-15).
- **Cumberland Memorial Hospital** — Bonds to be issued by a rural hospital located in Cumberland, Wisconsin, to construct a new hospital and refinance existing debt. Requests made by Compeer Financial (1-11-19) and CoBank (1-11-19).

Subcommittee: Given the number of employees that will become eligible to retire within the next three years, please provide a table by office where these retirements are expected.

Response: The following table shows the number of employees who will become eligible to retire in each office for the next three years.

Retirement eligibility by FCA office for 2019 – 2021

Office	2019	2020	2021
The Board	6	0	1
The Chief Executive Officer	1	0	0
Congressional and Public Affairs	0	1	1
Examination	30	11	9
General Counsel	9	0	0
Chief Financial Officer	3	0	0
Agency Services	4	2	3
Information Technology	9	0	1
Inspector General	1	0	0
Secondary Market Oversight	3	1	0
Regulatory Policy	10	3	1

QUESTIONS FOR THE RECORD FROM CHAIRMAN SANFORD BISHOP OF GEORGIA

Chairman Bishop on behalf of Representative Bustos: Since 2013, net farm income has fallen by 50%, and farm debt has increased 30% from the same year. There is concern about rising debt levels among grain farmers in the Heartland and talk of bankruptcies that could approach levels not seen since the 1980s.

In your testimony, you pointed out that 12% of Illinois grain farmers have a debt to asset ratio of at or below 1.0, and that if returns again drop below the breakeven point in 2019, there will be further deterioration.

I'm wondering how the trade war is complicating this situation, and what policies the FCSIC will be implementing to prevent a mass exodus of grain farmers from the profession?

With the President's budget asking for more cuts to USDA programs, and now new flooding across grain growing regions in the Heartland, I'm very concerned that we're approaching a point of no return.

How do you see this situation unfolding in the next couple years? What can the institutions you regulate do to help assist these producers? And what steps could Congress take to be most helpful?

Response:

ECONOMIC SITUATION

Current retaliatory tariffs by major importers have increased price risk and affected trade flows. Reduced U.S. exports have led to higher supplies and lower prices for major commodities, particularly soybeans and pork. Given the current trade environment, expected farm prices and margins for the next several years suggest that pressure on farm profitability will continue, particularly for crop farms. Domestically, a shift in plantings of crops with large supplies to other crops can reduce prices and profits for those commodities. Globally, as trade flows shift toward other suppliers and the United States loses market share, longer-term prospects for U.S. agriculture will decline.

BORROWER AND LENDER RESPONSES TO CURRENT CONDITIONS

While the full impact of recent flooding will not be known for some time, stress from low commodity prices has been ongoing, and this situation adds further pressure. There are various methods institutions can use and are using to help producers who are dealing with natural weather disasters, including small grants and principal deferrals. Principal deferrals and other loan actions may provide short-term relief, but if industry conditions do not improve, it will be more difficult to ensure long-term viability for producers affected by flooding.

In addition, grants do very little to help the producer recover and rebuild, and options for customers with a marginal financial position are limited when there is a loss of a structure without property insurance. For example, it is difficult for lenders to finance rebuilding a dairy barn in the current low-price environment and uncertain future for the industry. Property and

business loss insurance play a key role in these situations. Federal crop insurance and livestock disaster assistance programs can be critical.

For cash grain producers affected by continued low prices, institutions have been assisting producers by restructuring debt and providing additional financing at more lenient terms or lower interest rates. However, those options are becoming somewhat limited since some borrowers are in the fifth year of operational losses and some restructuring or rebalancing has already occurred. In those cases where borrowers do not have the capacity or sufficient equity for further restructuring, asset sales or other avenues are more likely solutions.

HELPFUL STEPS

It is helpful when Congress encourages all segments of the farm lending community (Farm Credit System, commercial banks, other lenders) to work together to ensure farmers have credit to meet today's challenging operating environment and tomorrow's opportunities. Also, subsidized federal crop insurance products are critical to agriculture and lenders to address some of the risks that are beyond producer control such as weather and prices.

WEDNESDAY, APRIL 3, 2019.

FOOD AND DRUG ADMINISTRATION

WITNESS

SCOTT GOTTLIEB, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION

INTRODUCTION OF WITNESS

Mr. BISHOP. The subcommittee will come to order.

Good morning. I want to welcome all of you to today's hearing. Our primary objective this morning is to examine the Food and Drug Administration's fiscal year 2020 budget request. Our witness is the Commissioner of the Food and Drug Administration, Dr. Scott Gottlieb.

Commissioner, welcome back.

Dr. GOTTLIEB. Thank you.

Mr. BISHOP. I remember well your first appearance before the subcommittee. I think you had only been in office a few weeks then. And now you appear to be—you are, unfortunately, appearing before us, which will probably be your last time and with just a few days left in your service at FDA.

I think I can speak for many people when I say that you have been a fierce advocate for public health, tackling critical issues such as reducing youth tobacco use, addressing the opioid epidemic, reducing drug prices, and approving generic drugs. You have taken on these issues during a time of sharp partisan divides on many issues, and yet you have earned broad bipartisan support. I congratulate you on that.

It has always been a pleasure to have you here, and I wish you the best in your future endeavors. I hope you enjoy spending time with your family back in Connecticut. But your efforts and leadership as Commissioner are greatly appreciated.

Dr. GOTTLIEB. Thank you.

OPENING STATEMENT—MR. BISHOP

Mr. BISHOP. Prior to your departure, we are going to take one last opportunity to discuss the impacts of your agency's fiscal year 2020 budget request.

As in past years, the FDA's request is in stark contrast to much of the Federal Government. Many administration officials have appeared in the recent weeks defending steep cuts to their budgets. That is not the case here. Your request totaled \$6.1 billion, an increase of 7 percent from fiscal 2019. The increases include nearly \$176 million in budget authority and \$241 million in user fees. These additional resources are on top of a significant increase for fiscal year 2019.

On the medical product safety side of the agency, you requested \$254 million more than last year's enacted level, an increase of over 7 percent. For the food side of the agency, the FDA is requesting almost \$56 million more than fiscal year 2019, which is an increase of 4 percent. I should also note that you are requesting authority to increase tobacco user fees by \$100 million from the e-cigarette industry.

Again, I want to thank you for being with us today, and I look forward to today's discussion.

My ranking member, Mr. Fortenberry, has been delayed, but I will yield to Mr. Aderholt, the former chairman of the committee, for any comments that he might wish to make.

OPENING STATEMENT—MR. ADERHOLT

Mr. ADERHOLT. Thank you, Mr. Chairman. It is good to be here. It is good to be the ranking member for a few minutes here while we are waiting on the real ranking member to get here.

As you know, I had the privilege to chair this committee for 6 years. And after 6 years, I am now over at the Commerce, Justice, Science Subcommittee. But I am glad I am able to maintain a seat on this subcommittee and to work with everyone that is on this subcommittee, including the chairman and his great work.

But, Commissioner, welcome. It is good to have you here. I would like to take a moment to congratulate you on your tremendous productive tenure at the Food and Drug Administration. I have enjoyed working with you to address a number of issues that we have worked with on this subcommittee. And, quite honestly, it is really rare in a town that someone is able to accomplish quite as much as you have over the last 2 years. And I believe I speak for many as we appreciate your service to the country and the fact that you are leaving FDA in a strong shape speaks well of you as your successor takes over. I applaud the work of the agency that it has done over the last few years to bring increased competition to the market in order to lower the drug prices and expand access. I know that this has been a priority for you and the administration, and I look forward to working with your successor in that regard.

I also appreciate your leadership to curb the tide of the opioid epidemic, between enforcement measures against companies that are violating the law to helping speed alternative nonopioid-based pain medication to the approval process to your efforts to reduce misuse and abuse of opioid drugs, the FDA, under your leadership, has been a leading partner in fighting the scourge on many of our communities across the Nation, and particularly in my part of the country where the Appalachian region has been hit hard. And, of course, I say the commission because I just, the last couple weeks had the co-chair of the Appalachian Regional Commission down to my district. And we were able to discuss some ways that we can try to fight and help this scourge that has been on a lot of the States and particularly the Appalachian region.

And, finally, I am encouraged by your work to curb the epidemic of youth e-cigarettes by addressing youth access and youth appeal to these type of products. And so, again, we are sorry to see you go, but we look forward to seeing you in your next chapter of your life, and I know you will have great success. So, again, thank you

for being here, and I look forward to following up with you in the future.

And thank you, Mr. Chairman, for having this hearing today and having the Commissioner here in his last week in office. Thank you.

Mr. BISHOP. Thank you, Mr. Aderholt.

Mr. Gottlieb, without objection, your entire written testimony will be included in the record. I will now recognize you for your statement, and then we will proceed with questions from the subcommittee.

OPENING STATEMENT—DR. GOTTLIEB

Dr. GOTTLIEB. Well, thank you, Mr. Chairman, for your kind comments at the outset. They mean a lot to me and to my colleagues at FDA.

And I want to thank you as well, Congressman Aderholt, for the work that we have done together over the last 2 years.

And I want to thank all the Members of the Subcommittee and the chance to appear before you today.

As was mentioned, this is the last time I will appear before the Subcommittee as the 23d Commissioner, and I am grateful for the opportunity to have worked with you. I am proud of what we accomplished together on behalf of the FDA's public health mission. We are especially thankful for the funding increases the Subcommittee provided to FDA in 2019. That new funding comes at a critical time. It is going to help FDA modernize our approach to medical product manufacturing and make product review more efficient and safer and help us protect our food supply. The funding request in the President's 2020 Budget will allow FDA to advance our work to ensure the safety of food and medical products that we regulate.

Today I want to focus on one of my priorities, and one of my biggest priorities and my biggest concerns right now is the youth vaping epidemic. This is one of the most significant public health crises facing FDA and also facing our Nation. And it is one of the most significant problems that we are trying to address.

To help address that concern, the President's 2020 budget requested \$100 million in new tobacco user fees. These new user fees are critical to ensuring that the FDA can continue to fight the youth epidemic and, at the same time, create a modern regulatory framework for the appropriate oversight of e-cigarettes. It is key that we have the resources to continue standing up a framework to put e-cigarettes through an appropriate series of regulatory gates and that we aggressively confront kids' use of these products to make sure children don't become addicted to nicotine.

Last month, FDA proposed to end our current compliance policy as it relates to flavored electronic nicotine delivery system products other than menthol-flavored e-cigs. We put all manufacturers and retailers on notice that we expect to see heightened age verification requirements in place for these flavored products sold online and at retail. And if rates of use among kids don't come down, we will need to take additional steps.

Our concern about kids' use of these products isn't just based on the potential for kids to become addicted to nicotine from the e-cigs

and then transition to combustible tobacco products. It is also based on the direct risks posed by the e-cigs. While e-cigs could be less harmful than combustible tobacco for currently addicted adult smokers who can fully transition off of cigarettes, they are not safe. For one thing, nicotine is especially problematic because of the impact it can have on a still-developing adolescent brain. But there are other risks as well.

And while we are still learning about the long-term potential benefits and health risks of e-cigs, existing scientific research offers some clear evidence that several of the dangerous chemicals in tobacco smoke are also present in aerosol of some of these products. And we know that this exposure is a major health concern due to the ability of e-cig particles penetrating deep into the respiratory system. Some of the toxic chemicals and other substances contained in e-cigs can go deep into lungs and may pose the risk for disease not usually seen in smokers.

This isn't idle speculation. And studies have shown that e-cig vapor contains chemicals that can damage cells and cause illness and aging. Research we have reviewed shows substances found in e-cig vapors can pose a risk for decreased lung development, breathing difficulties, lower defense against bacterial and viral pathogens, and vaping-induced inflammatory reactions. We are especially concerned about evidence from animal studies that vapor and e-cigs can cause changes to tissue in the airways that could induce cancer or be a precursor to cancer.

Today, I am announcing that the FDA has initiated a comprehensive research plan to fully evaluate these risks, and we will report our results publicly. The FDA Center for Tobacco Products and the Center for Drug Evaluation Research are already leading these research efforts. Four distinct types of Electronic Nicotine Delivery Systems products are being tested, each with three different flavors. We need to fully evaluate the potential risks that we have identified to inform the public as well as our own regulatory decisionmaking.

We also have other safety concerns about e-cigs. Today, FDA is notifying the public of a potential emerging safety issue. We have reports indicating that some people who use e-cigs, especially youth and young adults, are experiencing seizures following their use of e-cigarettes. While seizures or convulsions are a known potential side effect of nicotine poisoning, they are more commonly encountered with intentional or accidental swallowing of nicotine-containing e-liquids. But our review of voluntary adverse event reports for these products submitted to the FDA and to poison control centers has identified 35 reported cases of seizures following use of e-cigs between 2010 and early 2019. We believe this signal warrants full investigation.

We want to be clear that we don't know yet if there is a direct relationship between the use of the e-cigs and a risk of seizure. We are sharing this early signal information just as we would share similar information with other products we regulate. We have identified it as a goal to communicate early about potential safety concerns and to share when a safety signal is under active investigation by the Agency.

As we work to evaluate these potential risks, we will remain especially committed to preventing kids from using any tobacco products. Any policy steps to advance innovations that could be alternatives to smoking can't and won't come at the expense of addicting a generation of kids to nicotine through these same products and exposing kids to all these potential risks.

I look forward to answering your questions today, and I am grateful for the opportunity to be here. Thanks a lot.

[The information follows:]

**Statement by
Scott Gottlieb, M.D.
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Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

Good morning Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee. Thank you for the opportunity to appear before you today to discuss the President's Fiscal Year (FY) 2020 Budget request for FDA.

First, I would like to thank the Subcommittee for your continued support of the Agency. FDA has received strong bipartisan support throughout the appropriations process in recent years and FY 2019 was no different. I believe this support reflects our shared commitment to the vital role FDA has protecting and promoting the public health. The funding this Subcommittee provides is essential to the Agency fulfilling its mission. The professional staff of FDA is grateful for your support of their work and the funding increases the Subcommittee provided FDA in FY 2019.

Last year, FDA accomplished a broad array of scientific advances and regulatory actions across our broad portfolio. Our work included promoting generic drug entry as a way to foster drug competition and lower drug prices through the implementation of the Drug Competition Action Plan, a record-setting year for approvals of novel medical devices and advanced several meaningful initiatives to continue enhancing the safety of medical devices. The Agency also continued advancing food safety and nutrition, launching our Nutrition Innovation Strategy to leverage nutrition as a tool to reduce the burden of chronic disease, and we took steps to empower consumers with nutrition information by supporting retail food establishments in meeting menu labeling requirements. We also furthered implementation of the Food Safety Modernization Act (FSMA) which builds proactive safety approaches into the production of human and animal foods. With your continued support, we have more opportunity to deliver on the promises of promoting the health of the public we serve.

The funding requested in the President's FY 2020 Budget will allow the Agency to sustain its current work—protecting the safety of the food and medical products consumers use every day—and build on these efforts by requesting additional resources to make significant progress on several important fronts; including fostering innovation and competition to bring better and more affordable products to market, promoting the development of innovative medical products, combatting the opioid epidemic, modernizing food safety and strengthening foodborne illness response, and implementing the 21st Century Cures Act (Cures).

Overall, the Budget requests \$6.1 billion in total resources for FDA—which is an increase of \$643 million or 12 percent above the FY 2019 Annualized Continuing Resolution (CR). At this total level, the Budget includes an increase of \$362 million in budget authority and an increase of \$281 million in user fees. The Budget requests considerable new resources for FDA and makes significant new investments in advancing critical areas of science, technology, and public health.

As the regulatory Agency responsible for ensuring the safety and effectiveness of more than \$2.5 trillion worth of products used by consumers, I remain steadfast that these funds are critical investments in our public health agency.

I. Efforts to Advance Safe and Effective Medical Products

The FY 2020 Budget request for medical product safety is \$3.8 billion, an increase of \$428 million above the FY 2019 Annualized CR, which includes increases of \$316 million in budget authority and \$112 million in user fees. A few examples of the new medical product initiatives this Budget request supports are described below.

A. Transform Medical Device Safety, Cybersecurity, Review, and Innovation

FDA has been improving policies and processes to address scientific advances and enhance the safety of medical devices. These improvements are critical to protect patients and foster innovation. FDA's fragmented information technology systems are not well-suited to support these activities. The Budget requests \$55 million for an initiative to build an integrated knowledge management system and portal for medical devices to enable safety issues to be monitored, and effectiveness to be evaluated, across the total life cycle of the device and to build out our digital health program. These capabilities will better leverage pre-existing and new data in near real time. This modernization effort is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence and medical device cybersecurity.

B. Medical Countermeasures

FDA works with partners at all levels of government—local, state, territorial, tribal, federal, and international—to support medical-countermeasure-related public health preparedness and response efforts. This includes working closely with federal partners through the Public Health Emergency Medical Countermeasures Enterprise to build and sustain the medical countermeasures programs necessary to respond effectively to chemical, biological, radiological, and nuclear (CBRN) threats and emerging public health threats, such as pandemic influenza, as well as with the Department of Defense to support the development of medical products needed to protect American military personnel. In FY 2018, FDA approved 28 medical countermeasures, including the first drug with an indication for treatment of smallpox.

The Budget includes \$128 million for medical countermeasure activities, of which \$31.5 million is for the Medical Countermeasure Initiative, an increase of \$7 million above the FY 2019 Annualized CR level. This investment will increase FDA capacity to facilitate the development and availability of medical countermeasures to respond to CBRN and emerging infectious disease threats by furthering the establishment of clear, scientifically supported regulatory pathways for medical countermeasures, filling critical scientific gaps, and advancing platform and manufacturing technologies for medical countermeasures.

C. Integrated Pathogen Reduction of the Blood Supply

Advancing the continued safety of U.S. blood supply through new safety innovations is a critical public health priority for FDA. The Agency currently works to

prevent transmitted infections through a combination of blood donor screening and laboratory testing methods. Pathogen reduction technologies, however, are a potentially more efficient method of decreasing the risks posed by viral and other pathogens that may be found in blood. These technologies are currently available for platelets and plasma, but with this new funding, FDA would work to promote innovation and expand their use to improve the protection of our blood supply.

The Budget requests \$20 million to pilot this technology as a tool that could help reduce the risk of transmission of contaminating viruses and other microorganisms from Whole Blood and still allow its subsequent separation into various blood components. This pathogen reduction technology could eventually help protect the blood supply from existing and emerging pathogens and, if successful, could potentially reduce or eliminate certain existing blood donor screening and testing requirements. It is possible that if this technology were incorporated broadly, it could enhance national security by enabling a blood supply that would be safe in the face of a wide variety of emerging pathogens. It may also deliver these protections for a potentially lower cost than those associated with current screening and testing methods.

D. Compounding

FDA's compounding program—including implementation of the Drug Quality and Security Act—is a priority for the Agency. We understand that compounded products serve a critical role for many patients across the country and we are committed to develop new policies for outsourcing facilities, including policies to improve the quality of outsourcing facilities' compounded products. We are also helping address providers' needs for supplies of non-patient-specific compounded medications (office stock). For example, with the new resources provided by Congress in FY 2019, we plan to establish a Compounding Center of Excellence to provide training on good manufacturing practices for outsourcing facilities and develop a specialized group of investigators who would focus on outsourcing facility inspectional activities. By engaging with outsourcing facilities and states, we can help the domestic outsourcing facility adhere to the quality standards needed to protect patient health and support sector growth.

The Budget builds on our efforts and requests \$76 million to support compounding activities. Of this total, \$14 million will be used to catalyze the development of policies and regulations for the outsourcing facilities, including advancement of the list of bulk drug substances that outsourcing facilities may use in compounding and current good manufacturing practice guidance and regulation specific to outsourcing facilities. The activities supported by this funding would give outsourcing facilities tools to better meet healthcare providers' and patients' needs for compounded drugs.

II. Efforts to Advance Food Safety

The FY 2020 Budget request for food safety is \$1.4 billion, an increase of \$67 million above the FY 2019 Annualized CR, which includes an increase of \$38 million in budget authority and \$29 million in user fees. A few highlights of the Budget request are described below.

A. Advancing FSMA

As part of our ongoing implementation efforts related to FSMA, the Budget proposes allocating an increase of \$16 million above the FY 2019 Annualized CR level to provide inspections through the state cooperative agreement programs. These additional resources are essential to the successful implementation of FSMA and are key to protecting public health by ensuring that manufacturing and processing facilities comply with the new FSMA requirements.

B. Strengthening Response Capabilities for Foodborne Outbreaks

Efficient global markets for food production and distribution allow American families access to a wide range of wholesome and affordable food choices that can improve their health. We want to provide Americans the benefits from access to a highly diverse food supply, while reducing risks from foodborne illnesses.

In order to strengthen our response capabilities to foodborne disease outbreaks by improving our capacity to detect early signals associated with foodborne illness and shortening response timelines once human or animal food contamination is detected, the Budget requests an increase of \$16 million above the FY 2019 Annualized CR level. In FY 2017 and FY 2018, FDA's Coordinated Outbreak Response and Evaluation network evaluated nearly 120 potential human food safety outbreak incidents per year. That is nearly double what was reviewed in FY 2015 and FY 2016. The increase requested in the Budget will allow the Agency to add new staff and resources to enhance signal detection, response to outbreaks, and post-response evaluations. FDA will also add staff to oversee its recall process and make the recall process timelier.

C. Promoting Innovation and Emerging Technology While Maintaining Product Safety

Innovations in plant and animal biotechnology offer tremendous opportunities for advancing public health. Promising new technologies have the potential to improve human and animal health, animal well-being, food productivity and food security. FDA will continue to facilitate the safe development of these emerging technologies by investing in continued enhancements to our review capabilities for biotechnology products and other novel products, assessing these products in a risk-based manner to provide predictable commercialization pathways that can foster product innovation and market access in a safe and timely way, and improve consumer nutrition. To these ends, the Budget proposes a new \$28 million user fee for Innovative Food Products, which FDA intends to develop in collaboration with industry and other stakeholders. The Budget also requests an additional \$8 million in budget authority to improve review times and eliminate unnecessary burdens to industry related to the premarket safety reviews of animal food ingredients.

III. **Tobacco**

The Budget requests \$100 million in new tobacco fees, and includes manufacturers and importers of deemed tobacco products, including electronic nicotine delivery systems, and certain other products within the FDA's tobacco user fee assessments. E-cigarettes, in particular, represent an increasing share of the tobacco marketplace. The new resources will support the FDA in its continued efforts to create a

modern regulatory framework for the appropriate oversight of e-cigarettes and in taking continued steps to reduce youth use of all tobacco products. One of our most important public health efforts is to continue standing up a framework to make sure we can put e-cigarettes through an appropriate series of regulatory gates, and aggressively confront youth use of these products to make sure children do not become addicted to nicotine.

IV. Opioids

One of my highest priorities as FDA Commissioner is combatting the ongoing crisis of opioid addiction. The FDA has changed its approach to the opioids crisis and is taking a much more aggressive approach to regulatory action. At the FDA, we've committed to taking more rapid action in the face of new threats, like the growing prevalence of illicit fentanyl that's contributing to overdose deaths, or the continued prevalence of prescriptions being written for durations of use that are too long for the clinical circumstances for which they're intended. We've changed the way we're tackling these issues and stepped up our intervention when it comes to opioids. Going forward, we're going to be looking at the potential for evaluating the comparative benefits and risks of new opioids relative to other opioids already on the market. We've raised the question of whether there should be such a standard for new opioid approvals to offer some advantage over the existing armamentarium. We plan continue to evaluate this concept as we work to modernize the FDA's framework for assessing the risks and benefits of opioid drugs. FDA is focusing its efforts in the following four priorities:

- Decreasing exposure and preventing new addiction,
- Supporting the treatment of those with opioid use disorder,
- Fostering the development of novel pain treatment therapies, and
- Increasing enforcement and assessing benefit-risk.

The Budget requests an additional \$55 million above the FY 2019 Annualized CR level to continue supporting the four main areas of the Agency's work. These funds will continue to build on the tremendous financial investments this Subcommittee has provided to the Agency for our opioids work over the last two fiscal years.

V. 21st Century Cures Act

Implementation of the 21st Century Cures Act (Cures) continues to be a top priority for the Agency. Cures includes provisions that have the potential to impart far-reaching effects on scientific advancements in medical product development. The law complements many efforts underway at FDA. All of these efforts are aimed at transforming the way we support product development and maintaining FDA's gold standard for safety and effectiveness. Toward these efforts, the Budget requests a total of \$75 million to support our implementation work.

VI. Conclusion

The last year was historic for the Agency. We are diligently working on a number of fronts and the vital work we do provides Americans with better ways to improve their health and welfare, empowering consumers to make informed choices about the products they use and the foods they feed to their families. This Budget will help FDA maintain and complement our current efforts, as well as provide a renewed focus and investment in some of the Agency's and the nation's top public health priorities. I look forward to answering your questions today and the Agency looks forward to working with all of you going forward.

Mr. BISHOP. Thank you very much, Dr. Gottlieb.
Let me start the questioning.

APPLICATION DEADLINES FOR E-CIGARETTE MANUFACTURERS

At our February hearing, you and I discussed the issue of small e-cigarette manufacturers' ability to afford to submit product applications to FDA. In response to my question, you said, quote: Our desire to extend the application deadlines on these products and give them until 2022 is to give us the time to put in place the implementing regulations and guidance that would not only provide the rules of the road for how to effectively traverse the application process but also take into consideration the kinds of challenges that you bring up about how we can build into our regulation and guidance accommodations for small manufacturers.

In light of this response, I have to say that I was a bit surprised that you recently decided to shorten the deadline to 2021. I will tell you that your response was somewhat vague. I think that we need to have a robust market for adult e-cigarette consumers with competition and wide product choice instead of a smaller market controlled by the big companies with fewer choices for adult smokers, higher prices, and probably less innovation.

If adult smokers who wish to use e-cigarettes to reduce or to end their use of combustibles cannot find products that they like, they may not make the change, and public health will suffer.

And compounding, FDA has requested funds to help small compounders become outsourcing compounders. While this isn't exactly analogous, do you feel like the FDA should request funds specifically to help small manufacturers navigate the FDA regulatory process regarding e-cigarettes?

Dr. GOTTLIEB. Thank you for the question, Mr. Chairman.

We would certainly use the resources from the user fees that we requested towards that purpose. And, you know, part of the hope by trying to request funding to create a regulatory paradigm for these e-cigarette products and for all the newly deemed ENDS products is that we create a proper regulatory framework that can apply, you know, the right regulatory touch, including making accommodations for small manufacturers.

I would just point out, we shortened the application deadlines for the flavored e-cigarette products as an attempt to reduce the access and appeal of those products to kids, to make sure that we have a proper Premarket Tobacco Product Application (PMTA) process to adequately evaluate the risks of those products, recognizing they are being more widely used by children. It wasn't all of the e-cigarette products that we addressed.

But, you know, make no mistake, we still have to put in place all the foundational rules. We issued the substantial equivalence (SE) rule last week, we should be releasing the PMTA ENDS guidance within a couple of weeks. I was hoping to get that out before I left, but it will be coming out. And we will have the PMTA rule and the Modified Risk Tobacco Products (MRTP) rule, two other important foundational rules, out before the end of year.

So, you know, we are putting in place the elements of the modern regulatory process for these products and, in the context of doing that policymaking, trying to take into consideration exactly

what you are bringing to light here. We do not want a process that is only accessible to three large companies.

OLIVE OIL STANDARDS OF IDENTITY

Mr. BISHOP. Thank you, Dr. Gottlieb.

And I want to applaud and let me you know that I think we all support your efforts to keep e-cigarettes and all tobacco products out of the hands of youth.

Let me turn to a more parochial level for the remaining time I have regarding olive oil standards.

Georgia is home to several small olive farms that produce some small batches of extra virgin olive oil. And, unfortunately, there is no single standard of identity in the U.S. for extra virgin olive oil. In the fiscal year 2019 appropriations bill, the committee directed the FDA to establish a separate U.S. standard of identity for different grades of olive oil, including extra virgin olive oil.

What progress has FDA made in the development of these separate standards of identity for different grades of olive oil? Studies show that the extra virgin olive oil provides certain health benefits that no other grades of olive oil provide.

Do you believe that the U.S. should have one single standard of identity for extra virgin olive oil to ensure that American consumers know exactly what they are paying for when they go to the grocery store?

Dr. GOTTLIEB. Well, unfortunately, Mr. Chairman, with apologies, I am not going to be able to answer the question directly. But I will certainly get an answer back to you.

We have over 300 standards of identity, and we have been fortunate to receive some funding from this Committee to undertake a broad process to modernize those standards, including more than 100 that relate to dairy products.

And so, I will get back to you on this specific question around this specific standard of identity. It is not one that has come across my desk yet, but I will make sure it does before I leave the Agency in 3 days.

Mr. BISHOP. Thank you very much.

Mr. Aderholt.

YOUTH NICOTINE ADDICTION

Mr. ADERHOLT. Thank you, Chairman.

And, Dr. Gottlieb, let me just start in and follow up on the first question that the chairman asked about the e-cigarettes.

I am encouraged by your agency's work to curb the epidemic of these e-cigarettes that are used by the youth. And I will be introducing a bill this week that would, number one, raise the minimum age for tobacco products to 21. Number two, it will require online sellers of vapor products to obtain the name, the birth date, the address of customers, and verify the customer's identity through a third-party database, and it would require an adult to sign for the product on delivery.

My question will be to you is, do you think a bill like this is needed to help address the youth nicotine addiction epidemic that we are seeing?

Dr. GOTTLIEB. Well, I appreciate the question, Congressman. I will just say at the outset, you know, while we take aggressive steps to try to address the youth use of these products, we still believe that these products could offer a viable alternative for currently addicted adult smokers to fully transition off of combustible tobacco on to something that is less harmful, notwithstanding our concerns around the risks associated with these products. And we do believe they have risks. These are not safe products.

We also believe they are less harmful than smoking combustible tobacco. That obviously needs to be demonstrated through a proper regulatory process. We plan to put these products through that process. But we still believe in some public health promise of these products for currently addicted adult smokers, which is why we are trying to strike this balance, even while we vigorously address the youth use.

We do believe that raising—and I believe personally that raising the age to 21 for tobacco products can help address this crisis. A lot of the sales of e-cigarettes that we see to youth are secondary sales of enterprising 18-year-olds going in the store and buying a lot of product and reselling it in a high school.

And as far as online sales of these products, one of the things we plan to address with the guidance that we are promulgating is trying to put in place height and age verification requirements for these products being purchased online. We have seen other products being sold online where there is good age verification. Not 100 percent foolproof but certainly better than what we have today. You look at things like alcohol sales online, wine sales online, we have adult signature on delivery and other kinds of age verification. And they are more foolproof than what historically has been in place with the e-cigarette products. Some companies have voluntarily taken those steps now. But we think a more uniform standard could be helpful in trying to address the youth access issue when it comes to these products.

Mr. ADERHOLT. Well, I know, when you were asked just what you said just now, you have said in the past that you want to preserve access to noncombustible for adult smokers. And a lot of the youth access isn't just 14- and 15-year-olds buying illegally. It is these enterprising 18-year-olds that are selling to minors. And increasing the age to 21 will make it harder for this type of activity.

As I understand, approximately 80 percent of high school seniors will turn 18 by the time they graduate. FDA's past data indicates amongst 15- to 17-year-olds, 74 percent of access to vapor products come from social sources; 57 percent asked for or someone offered a vapor product; and 17 percent gave someone money to buy for them.

If this bill that I plan to introduce, a bipartisan bill, when it is introduced, how quickly do you think we could reverse these current trends that we are seeing?

Dr. GOTTLIEB. You know, I hope quickly. I think that the challenge here is going to be that once you have sort of an epidemic like this under way, we are going to continue to see some increases before we start to see decreases. I am not optimistic that, when you have the data for the National Youth Tobacco survey in 2019, it is going to go down. I think it is going to go up. If it goes up, you

know, 30, 40, 50 percent, we are going to need to be stepping into the market with additional regulation.

So my short answer to the question is I don't know. We need to be vigorous here. And if we continue to see these kinds of increases year over year for an additional year, we are going to have to be very direct.

And the next place we would look is at the pod-based e-cigarettes as a class, because these are the ones that are being abused by kids. And, you know, at some point, there is going to be so much use of these products that we are going to have to conclude that there is not enough redeeming public health value in having these products available for currently addicted adult smokers to offset all that youth initiation.

HANDMADE PREMIUM CIGARS

Mr. ADERHOLT. OK. Let me see if I can sneak one more question in.

FDA last week released nearly 200 pages of proposed framework for the substantial equivalent process. The documents seek input on how process may apply to handmade premium cigars. As you may know, as with all handmade products, no two are actually the same.

Given that FDA remains in the early stages of addressing this process, would it not be appropriate to delay the implementation of the regulations relative to the narrow premium cigar category until FDA has clear guidance for these small manufacturers on how to keep their products on the market.

Dr. GOTTLIEB. Well, as you know, Congressman, we pushed off the application deadlines for the cigars as a category while we issued an advanced notice of proposed rulemaking to collect questions looking at questions specifically related to the premium cigars and whether or not there were different patterns of use associated with those cigars that might inform the Agency about how we might regulate these differently.

We haven't formed any conclusions. We are still going through comments on that Advanced Notice of Proposed Rulemaking (ANPRM). This is a question that is actively before the Agency right now. I would just make note that we did get out the SE rule, which does provide a pathway for these products to come to the market using a predicate. And we have also grandfathered a large number of cigars, more than a thousand. And that pathway is also available to the premium cigars.

And just in conclusion, I will mention that we provided Technical Assistance (TA) back to your office on the legislation that you talked about at the outset and look forward to working with you on that.

Mr. ADERHOLT. Thank you.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you.

Ms. Pingree.

Ms. PINGREE. Thank you very much.

And thank you to Chairman Bishop and the ranking member for holding this hearing. It is bittersweet to have our last hearing with Commissioner Gottlieb.

Mr. Chair, I do want to just, as an aside, I had no idea that olive oil was produced in Georgia. And I don't want to rat anyone out, but there was some grumbling next to me about Italian olive oil.

And I really think the only solution here is an olive oil tasting because I feel convinced that domestic olive oil and buying American must be a good thing to do. So I would be interested to learn more about that.

Sorry. I am just sorry.

But there is actually—you know, olive oil is one of the products with the highest rate of fraud and mislabeling. And so it is an interesting topic in and of itself.

But we are here to speak to you, Commissioner Gottlieb. And I just thank you so much for your service and dedication. The chair said it very well, but you have really worked on a broad range of issues under the FDA's jurisdiction. And I know all of us have enjoyed working with you. And I have in particular. You have been so responsive, so knowledgeable about so many topics and been willing to tackle many of the tough issues that come before us just in a straightforward way. And we are going to miss you. We are grateful that you get some time with your family and look forward to staying in contact. But thank you so much, really, for all you have done.

And, in particular, I want to thank you for a few announcements that FDA made yesterday. First, FDA is working with USDA and EPA on elevating our country's food waste reduction problem during the month of April. Most people don't know that this is Food Waste Month, but we appreciate that you are helping us to do that. The challenges of food waste is something I am focused on quite a bit, and so I appreciate the joint effort.

Second, you announced some updates on finding legal pathways for CBD products including forming a high level working group and setting the public meeting for May 31. So, again, thank you for prioritizing this issue, which is causing substantial disruption in the hemp market in Maine and in States across the country. And it would be good to have some of these things resolved.

But since I have you here, I am going to start with a couple of questions.

CHEMICALS IN FOOD CONTACT MATERIALS

One I wanted to ask you about I don't think I have discussed with you before, but that is chemicals that are in food contact materials. Public concern about food safety due to chemical substances in our food supply continues to grow, and we are currently dealing with PFAS contamination crisis, and phthalates are also widely used in U.S. food contact materials, like packaging and processing equipment.

Does the FDA consider new scientific information once an indirect food additive has been approved? There is some concern that some of these substances in food contact materials were approved years ago and may need to be reassessed. And additionally, does FDA currently coordinate with other Federal agencies, such as the EPA and the U.S. Consumer Product Safety Commission, on chemicals that are used both as food contact substances and/or for other purposes subject to the jurisdiction of these agencies?

Dr. GOTTLIEB. Thank you for the question.

We would evaluate the food contact materials in the same way we would evaluate other food additives. We do a scientific safety assessment of them. If there are historical compounds still in use that your specific question is about, I would be happy to take that back and take a look at what the process was that they went through and whether or not there was updated scientific information that we have taken into consideration.

On the food waste issue, which you and I have talked about a number of times, I will just mention that, and we have discussed this, we are going to be sending out letters to the industry to encourage adoption of best-if-used-by nomenclature on the labels. So, as long as the dating is for quality reasons and not for safety reasons, we find that is the best language to be using to try to discourage food waste.

Ms. PINGREE. That is great. And my understanding, after researching that quite a bit, is that changing that in a way that would bring some sensibility to what a label means, which are, as you know, arbitrary on most things, would be the greatest return on our investment in reducing food waste that, frankly, people just pick it up, and if a label tells them to throw it away, they throw it away, even if it may be just a little bit old.

Dr. GOTTLIEB. Not in my house, but—

Ms. PINGREE. There you go. See.

In most houses, there is an argument, so you clearly have a harmonic household.

PRODUCE SAFETY RULE INSPECTIONS

Let me slip in one other quick question. The FDA's fiscal year 2020 budget request includes an increase of \$16 million above the fiscal year 2019 level for FSMA implementation to provide inspections through the State cooperative agreement programs. It is my understanding that, through cooperative agreements, FDA and most State departments of agriculture will soon begin produce safety rule inspections. FDA has indicated that they will visit farms that are qualified exempt under the produce safety rule, but it is understanding that States will have discretion in whether to conduct on-farm inspections of qualified exempt farms.

Is the FDA planning to show up at farms that are exempt from most parts of the rule? Will it vary from State to State as to whether qualified exempt farms will receive on-farm inspections.

Dr. GOTTLIEB. Well, in that kind of a framework, we would defer to the States unless we had a cause to be on the farm. I mean, there might be situations where we would.

But we are trying to work in a cooperative fashion with the States and leverage their resources. So this is \$16.5 million. It is \$11.7 million in new money on top of 2019. We received some money. We were fortunate to receive money from this Committee about \$2 million, for this effort. But this would go towards, as you mentioned, the State cooperative agreements program.

It would also help manufacturing and processing facilities comply with the rule. Right now there are no resources for those inspections. And so these are important resources for the Agency to help

advance the Food Safety Modernization Act (FSMA). We are grateful for the support that we have received.

Ms. PINGREE. Great. Well, I am out of time. But just to clarify, I think we do realize you have limited funds available. There was some concern that the FDA, not the States, would be making visits to qualified exempt farms, and that doesn't seem like the best use of resources.

Dr. GOTTLIEB. We would agree with that. We are looking wherever we can to leverage the resources to States.

Ms. PINGREE. Great.

Thank you very much.

Mr. BISHOP. Mr. Fortenberry.

Mr. FORTENBERRY. Thank you, Mr. Chairman.

Dr. Gottlieb, welcome back.

You were before our committee maybe about a month ago. It might have been the same day that you announced that you were leaving government.

Was it something that we said?

Dr. GOTTLIEB. It might have been a week or two before, but it was not the same day. But I appreciate the—

Mr. FORTENBERRY. Well, thank you for your service. And you have navigated process and possibilities very well, and we are grateful and wish you all best.

Dr. GOTTLIEB. Thank you.

Mr. FORTENBERRY. You will be with us for another month or so. Is that right?

Dr. GOTTLIEB. Another 3 days.

Mr. FORTENBERRY. I see. Well, we better hurry and get these questions in.

GENETICALLY ENGINEERED ANIMALS

Can you explain the state of the science regarding genetically engineered animals? And then I would like your perspective on the state of the ethic debate in that regard. And then explain your proposed regulatory pathway, which I believe you released a statement yesterday in that regard.

Dr. GOTTLIEB. So I think, you know, when you and I spoke about this, we were speaking about gene editing in animals. We see a lot of promise in this technology right now. And there are indications in the literature. There are public disclosures in literature of where people try to use gene editing Cas9, zinc-finger nuclease. There are other forms of gene editing to try to edit in modifications that can be inherited to try to, for example, guard against certain diseases where there is no effective vaccines or engineer other qualities that could make the animals more advantageous for food production uses and more impervious to disease.

And so this is a field where there is significant promise and ethical considerations across the board. I think where the ethical considerations are most acute, frankly, in my estimation and where I have been outspoken, is when we are looking at doing gene editing on germ line cells for human reproduction. You have seen the National Academy of Medicine (NAM) and other groups come out and talk about the need for potential moratoriums or registries. My concern is that I can't find a good-use case on why you would intro-

duce gene editing in human reproduction. And all the ones that have been brought forward to me as a theoretical basis seem to be things that could be addressed with modalities and through methods that are far less high-risk and raise far fewer ethical considerations.

And so I think, as a society, we need to consider whether or not we just put a moratorium in that kind of scientific inquiry because I think if we cross boundaries that cause deep concern for a large section of the population, we end up potentially besmirching this technology for all the potential beneficial uses, whether it is in animals or whether it is to help cure inherited disease in pediatric patients through gene editing.

So that is where I think the most acute ethical considerations are right now, and I think this issue is very ripe having seen experimentation done in China that tried to—that did edit germ line cells, edited embryos for trying to introduce a heritable trait with, really, I think, not significant enough medical rationale to support the risks that they were taking in that case, and other people proposing other experiments in this regard.

The resources that we are requesting would help stand up a comprehensive program inside FDA to consider all these technologies, particularly on the animal side, where we see a lot of opportunity not just from biotechnology in the context of animals and the use of these technologies, like Cas9, but also continued biotechnology with respect to crops as well. And we think it is time that FDA should have a comprehensive program addressing all these possibilities. We think this could be a significant area of growth for the United States as a new scientific opportunity.

Mr. FORTENBERRY. And that is a part of your proposed budget?

Dr. GOTTLIEB. That is. There was a request, I believe, for \$8.2 million, if I am remembering correctly, of budget authority and then a user fee on top of that.

Mr. FORTENBERRY. Do you think that the FDA is the proper regulatory authority in this regard particularly in response to your thoughtful response regarding the ethics? Because I, frankly, was surprised and pleased by the outcry from the international scientific community about this rogue scientific experiment in China. And I don't know if those persons are now being watched or are part of a database to see what happens to these persons or not or whether, again, this is just some random thing that a scientist does because he can untethered to the larger consequences for all of humanity.

But this question and issue was specifically to animals. But then, of course, there is ethical considerations regarding persons. So will you, as a part of that budgetary proposal, have a very considered structure around the ethical question as well?

Dr. GOTTLIEB. Well, I think FDA is absolutely the optimal place to consider this technology with respect to animals, for a whole host of the reasons, not least of which are the ones you have brought up here today. I mean, we have a deep experience in uses, technology, across human and animal health. I think if we are going to watch these innovations go forward effectively, we have to instill confidence in them. And FDA is the proper authority to

evaluate the safety of these products. And that is our first consideration.

I think, frankly, also, the ethical questions and the other kinds of broader questions, the societal questions and public health questions that we have to consider across our portfolio, and FDA, looking at this technology across an entire portfolio, allows us to make the distinctions between doing something in an animal and putting a heritable trait into an animal versus, why would you ever consider doing that in a human? And so, keeping the technology within the domain of an agency that can make those considerations across a portfolio makes eminent sense for a whole host of reasons, not least of which are the ones you brought up.

Mr. FORTENBERRY. Thank you very much.

Mr. BISHOP. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair.

Before I get into my question, I wanted to share this with the committee because I agree with my colleagues who are concerned about this. This is from Bloomberg News: China is selling genetically modified mice for as much as \$17,000 a pair. Demand for animals that mimic human disease is skyrocketing as President Xi Jinping works to churn the country into a biomedical powerhouse by 2025.

So this is something that we need not only to be addressing here in the United States but something that we need to be addressing with our colleagues and friends, you and around.

REGULATION OF COSMETICS

So good morning. Thank you for being here. And I want to go back to one of our first conversations when I asked about cosmetic regulation, or should I say therefore the lack of regulations. And I asked you about some of the tools available at the FDA to ensure the safety of the millions of cosmetic products on the market today. And I have been learning a little more, and I want to thank your office and others for helping us with this.

Part of the problem is Congress has granted you and the FDA very little authority to even regulate cosmetics. You don't have the ability to order mandatory recalls. You can't inspect facilities or records. You can do that with other food and drug products, but you can't do that with cosmetics. And cosmetic companies don't have to submit safety data before marketing their product. They are not required to register their facilities with the agency or even comply with basic good manufacturing practices.

So, even if you did have mandatory recall, cosmetic companies are not required to even report their adverse effects to you. So, clearly, I think there needs to be more done.

In a 2017 letter from the FDA to Energy and Commerce Chair Frank Pallone, said 2.9 million products were imported. Less than 1 percent were physically inspected. But of the products that were physically inspected, and this is 1 percent, 15 percent had adverse findings. And additionally, where the U.S. has been banned or restrict 11 substances for use in cosmetics, the European Union has banned more than 1,300.

And I point these numbers out because it seems like we might not be giving you all the tools in the toolbox you need to do to carry

out basic functions I think the American people assume even in cosmetics that you are doing. One of the offices of congressional appropriations at the FDA in fiscal year 2019 was \$7.3 million, 27 full-time employees devoted to cosmetics. In 2019, a little increase to \$8 million and 31 full-time employees or plans.

So I am glad to see the trending is going upwards. But at the same time, Congress had tried to pass unsuccessfully legislation that would have expanded your authority over the industry. But short of that happening, and that is something I am going to be working with others on, is there anything that you can point to us in the 2019 budget that you are going to build on to help make it safer for consumers and the role that you are going to have with the extra employees and the extra dollars so that we know the direction to help, due to lack of regulation, to make you more effective in protecting U.S. consumers?

Dr. GOTTLIEB. Well, I appreciate the question. And you and I have had the opportunity to talk about this. And I share your concerns that there are a lot of things that we think we would like to be doing as the industry gets more modern, as more products are on the product, more diversity of products, products with more active ingredients and creating more potential opportunities but also more risks. You know, looking at mandatory recall authority, Good Manufacturing Practices, inspection capacity, reporting of adverse events, looking at issues with metals in tattooings, for example. We have seen a sharp increase and changing patterns of how people use tattoos. It is another area of regulation where we have some questions and things that we would like to be doing.

There is nothing specific in the Budget, to answer your question directly. I hope you don't take that as a reflection of our lack of concern and interest in doing something.

Ms. MCCOLLUM. No.

Dr. GOTTLIEB. What I would say is that if we are unable to try to do something within the cosmetics program itself, my long-term plan, we worked this up internally, would be to move the cosmetics program to the drug center where, you know, more and more of the cosmetics themselves have active ingredients in them where they could be able to leverage some of the resources that we have in our drug center.

I don't want to do that. I would rather see it reside as it historically has resided within the food center. But if we can't get more resources into that program, one way to try to support it better would be to move it into our center for drugs.

Ms. MCCOLLUM. Thank you. Thank you, Mr. Chair.

I think some of the heavy metals that I am finding in some of the cosmetics, I think most women would be taken back, because it is women who are primarily using these products, but more men are starting to go use them too.

Thank you.

Dr. GOTTLIEB. That is right.

Mr. BISHOP. Ms. Lee.

Ms. LEE. Thank you very much, Mr. Chairman. Thank you for this hearing to you and our ranking member.

And thank you for being here, Dr. Gottlieb. I just want to say I wish you well and good luck in this next chapter of your life. It has been great getting to know you.

DIABETES DRUGS

As you know, I am going to bring up again my two favorite subjects: Cuba and cannabis. And, you know, when you were here in February, I mentioned that I care very deeply about reducing diabetes, especially in communities of color. Thirty million Americans—that is about 9.4 percent of the United States population—has diabetes. And for African Americans, those numbers are even worse. African Americans are 80 percent more likely to get diabetes than their white counterparts. And currently 13 percent of African Americans, the entire population, has diabetes. And, unfortunately, in many of these cases, amputations are prevalent.

So it is my understanding that the FDA cannot comment on this possible ongoing approval of a Cuban diabetic drug called Heberprot-P which helps prevent and treat foot ulcers and also prevents amputations. I have visited, I have seen, with members of the American Diabetic Association, Members of Congress, it is used in many countries.

So, while the drug was signed by the Cuban company, it is called Heber Biotec, and the U.S. company, Mercurio Biotec, we still don't know where the FDA is on their approval. And this drug has already been made available in—I believe it is over 20 countries in the world.

So what can you tell us about what is going on? Are you familiar with the companies? How do we get an update if, in fact, we can't just ask what the status is? And what is the regulatory framework for dealing with drugs from other countries?

Dr. GOTTLIEB. I appreciate the question.

I can't comment on a specific sponsor and whether or not that sponsor has filed an investigation or a new drug application and is, in fact, engaged in the regulatory process just because that would constitute commercial confidential information. As much as I would like to answer your question very directly, I would put the question back to the sponsor, and I would hope that they would be responsive to you.

I would say, though, just at a broader level, a drug that met the profile of what you are suggesting and if it showed promise in an early stage clinical study that it could achieve the kinds of outputs, end points that you have suggested here today, that kind of drug would potentially qualify for breakthrough designation with the Agency. It would be something that we would be very interested in.

But as far as this specific drug and whether or not they have engaged FDA, that is a question that the sponsor would have to answer.

Ms. LEE. I understand they have engaged FDA somewhere in the process. We just don't know where it is. It has been there for a year, 2 years.

Dr. GOTTLIEB. Right. I am not sure what they have said publicly, about their engagement with the FDA and whether or not they have an active Investigational New Drug.

Ms. LEE. So we should go back to the sponsor.

Dr. GOTTLIEB. And ask them if they have an investigational new drug application on file with the Agency.

Ms. LEE. And they could tell us the status?

Dr. GOTTLIEB. They should be able to give you some information about that. And, you know, that would give you an indication of where they are and what stage of development they are in.

We could help guide you on the questions to ask them.

Ms. LEE. OK. No, I would like to do that because this has taken much too long, and we need this.

LAWFUL MARKETING OF CANNABIS DERIVED PRODUCTS

You announced steps yesterday that the FDA has advanced in our cannabidiol regulatory pathways for lawful marketing of cannabis-derived products. Since the public hearing, I guess on May 31, an interagency working group is going to explore dietary supplements and conventional foods containing CBD and public website updates. It is a good first step, especially considering we just passed into law the farm bill which has hemp now as a descheduled schedule I control substance.

So I am concerned about the proper interagency communications with this working group. And I wanted to find out who do you plan to include in the public hearings? And are you working with an intergovernmental body to make sure that nothing drops through the cracks and our regulations are consistent and you are collaborating with Congress?

Dr. GOTTLIEB. Right. I appreciate the question.

We have engaged with DEA and USDA around some of these questions. I think a lot of them fall within the purview of the Agency.

You know, we have heard Congress loud and clear that there was an intent to provide a regulatory pathway that allowed for the lawful marketing of products derived from hemp, including CBD. But that bill also preserved FDA's drug authorities. And so what we need to do is craft a framework that allows CBD to lawfully be put into food products, even though it is a drug product and didn't previously exist in the food supply. That is the conundrum here: Because it never previously existed in the food supply and it is subject to substantial clinical investigation and also approved as a drug, we would have to create a separate regulatory scheme in order to allow this to be put lawfully into the food supply. We don't have a really modern proxy for where this has happened. That doesn't mean we can't create such a framework.

But part of what we are going to do—and this is a working group being chaired by Amy Abernethy, who is here with me today, the Principal Deputy Commissioner at the FDA and a physician—part of what we are going to do is also look at potential legislative remedies where you could potentially have, for example, and I don't want to speculate too much, but you could have situations where CBD exists in lower concentrations as a food additive and in a more purified high concentration form as an approved drug.

I will just say, CBD is not entirely safe. We have CBD in the context of some of the drug applications, and there are side effects associated with it. And so, when you think of the cumulative effects of having CBD for breakfast and lunch and dinner in different food

products, you might be getting a dose that could potentially cause public health concerns, safety concerns, including liver damage.

Ms. LEE. Thank you very much.

Mr. BISHOP. We have been joined by the distinguished gentleman from New York, the chairwoman of the Appropriations Committee. And she has an extremely busy schedule, so I ask my colleagues to please indulge me as I recognize her out of turn but, of course, in turn as our distinguished chairwoman.

The Chairwoman.

The CHAIRWOMAN. Thank you very much, Mr. Chairman. But we have several hearings going on at the same time.

I want to welcome you, and I also want to wish you well. And I won't say I told you so.

E-CIGARETTES

But we have had a discussion about what is going on with these kids and the fact that 60 percent of the kids are vaping today. And the now it is going down to junior highs and elementary school. But any event, we have had many conversations about this.

Last month you described a difficult meeting with Altria suggesting the tobacco giant went back on its earlier promise to withdrawal pod-based products from the market all while moving forward on a \$12.8 billion investment in Juul—boy, I saw that in the newspaper, and I was pretty upset—valued at 35 percent stake in the e-cigarette maker. I was so alarmed by this sale. I am not sure that I was surprised, but I was alarmed.

Do you believe that Juul and Altria are working in good faith to reduce youth use of e-cigarettes? By the way, you look at the local newspapers, huge advertise for Juul; in the bottom, “This could be dangerous to kids,” so I don't know if that is the exact word.

Why would Altria publicly say it is so concerned about youth use of the e-cigarettes that it would offer to voluntarily remove flavored products from the market pending FDA review and then shortly thereafter make this investment in Juul? And what can we do about this?

Dr. GOTTLIEB. Well, Mrs. Chairman, you did warn me. And, sadly, you were right about the epidemic that ensued with respect to these products and kids.

You know, you ask about, can we rely on their good faith? I am not dependent upon their good faith. That is why we have a regulatory system in place, and that is why we have been taking regulatory action.

I will take voluntary action where I can get it. And if these companies want to voluntarily comply with our rules and take other steps to try to thwart this epidemic, I welcome that. But we are not dependent upon that.

Unfortunately, I can't answer your question. I invited Altria and Juul in to answer that specific question. And I can't say that I walked away from my meeting with them with clear insight into why they would send me a 15-page letter saying that they believe that the pod-based products are so concerning with respect to, you know, stoking this youth epidemic, and the flavored products in particular are so problematic that they are going to voluntarily withdraw their entire portfolio from the market pending either a

successful PMTA application or otherwise the abatement of the youth addiction crisis and then, several months later, make an investment to extend market access to the flavored pod-based product that happens to be, the top selling product with adolescents.

And so, those two don't seem to square with me. I thought maybe they would come in and tell me they thought the youth crisis had abated and met one of their criteria in the letter. But, clearly, they are not going to be able to say that. So I am not sure what their rationale was from a public standpoint.

The CHAIRWOMAN. Let me just ask you, because time is limited. We have had many ongoing conversations, and I appreciate your concern, and I wish you good luck in your future.

What kind of advice do you have for your successor? Do you have any recommendations or cautionary tales, particularly regarding tobacco regulation and enforcement? Are you free to really share with us whether you think—never mind could have—what can be done now to possibly prevent this spread?

It is just widespread, as you know, everywhere.

Dr. GOTTLIEB. I appreciate the question.

I have had a lot of advice for him. I have to temper some of my advice for him because I want him to show up for work on Monday. But, I think a lot of this is going to depend on what we see with the 2019 National Youth Tobacco Survey, which we are doing in the field right now. We will have the results probably late July or early August given the fact that we will probably try to take an early look at them.

I think the policy that we announced several weeks ago, that we will fully implement shortly to try to put in place significantly heightened age verification requirements for the flavored products and the pod-based products at retail settings, is going to impact this. But unfortunately, our regulatory action in the setting of any epidemic—and this is the lesson we learned from the opioid crisis—you are always sort of one step behind a burgeoning epidemic. And that is why we are trying to act so aggressively to get in front of this one.

The CHAIRWOMAN. Thirty-three seconds. One thing that you would like him to do?

Dr. GOTTLIEB. So, if the 2019 National Youth Tobacco Survey shows another substantial increase, I think we need to look at the potential market withdrawal of the pod-based products as a category because those are the products that are being abused by the kids and particularly the flavored products. That is what we are going to have to start to look at, the cartridge-based, pod-based products. If we see another 30, 40, 50 percent increase and we see youth tobacco use rates of this country hit 40, 45 percent, which is where we will be if the increase in cigarettes continues to go up.

And I will just add, we are not going to see an increase in e-cigarette use among kids without also starting to see a corresponding increase in cigarette use among kids. So all the dramatic gains that we have made in recent years from a public health standpoint, abating smoking among kids, will have been reversed.

The CHAIRWOMAN. Well, thank you very much, Mr. Chairman. And I wish you good luck. And I just hope, as you leave, based upon—we all have could have, should have, would have. I do hope

you leave a very clear directive and perhaps encourage us to work with the FDA in place—putting in place some really stringent, stringent actions.

So thank you very much and good luck.

And thank you, Mr. Chairman.

Mr. BISHOP. Thank you for your patience.

Mr. Moolenaar.

Mr. MOOLENAAR. Thank you, Mr. Chairman.

And, Commissioner Gottlieb, thanks for being with us, and thank you for your service and all you have done at FDA and the work you have done to advance the mission and protect public health. I really have appreciated the time I have had to get to know you briefly and just see your passion for your work. So thank you for being here today.

OPIOIDS

I wanted to follow up with you on some of the testimony you have had about fiscal year 2020 budget request, where you have requested an additional \$55 million to support FDA's efforts in addressing the ongoing opioid crisis. And I understand you are focusing on four priorities: decreasing exposure, preventing new addiction; supporting the treatment of those with opioid use disorder; fostering the development of novel pain-treatment therapies; and increasing enforcement and assessing benefit risk.

I wonder if you could comment on what the FDA is doing to expedite the approval of nonaddictive, opioid-alternative treatments.

Dr. GOTTLIEB. So, thank you for the question. We have stated that we are going to withdraw the existing guidances that we have in place as it relates to laying out a regulatory pathway for the development of drugs, particularly to treat chronic pain—acute and chronic pain, but particularly acute pain, and be replacing those with new guidances that are indication-specific. So, outlining a regulatory pathway for pain related to minor post-surgical procedures or pain related to dental pain or bunionectomy or other sort of common places where you see analgesics prescribed, trying to allow for sponsors to come to the market with more targeted studies rather than having to do, five or six studies across multiple indications. We think this will create a more efficient pathway for the development of nonopioid alternatives for the treatment of pain.

So these guidances are going to start to roll out. We have one specifically addressing evidentiary standards for nonopioid alternatives. So, this is sort of a modernization of the overall framework as it relates to the development of these products, and I will just say, in closing, we have also said that we have been very clear that a product that could potentially treat pain, without all of the addictive qualities of opioids, would probably be a product that would qualify for breakthrough designation and all the benefits of all the expedited processes that Congress has legislated over the past several years.

Mr. MOOLENAAR. OK. Thank you. Are there any other lesser known programs or initiatives within the FDA that—maybe that you haven't highlighted in the budget that you are believing that this subcommittee should further investigate, to address the opioid crisis?

Dr. GOTTLIEB. Well, I think one of the things that is sort of embedded in the budget is continued efforts to try to rationalize the prescribing of opioids. I believe that the agency—and we have sort of taken on a view over the last couple of years, that we play a significant role in trying to reduce the rate of new addiction by trying to rationalize prescribing; making sure fewer prescriptions are written; they are only written for appropriate circumstances; and when they are written, it is for a duration of use that comports with the clinical reasons why the prescription was given in the first place.

So a lot of the resources that we got last year are going towards developing evidentiary standards, evidence-based guidelines that can potentially be used by physicians and maybe even eventually be incorporated into drug labeling to try to better delineate what the appropriate dispensing and prescribing should be by indication. Because when we look at our data, if you look at, you know, post-surgical procedures, cholecystectomy, things like that, typically it is a day or two of prescribing of opioids, and yet you still see doctors prescribing 30 pills in those situations. And so we want better evidence-based guidelines that can be used to help guide those circumstances.

We are also going to be implementing, very soon, authority that you gave us to acquire the immediate release formulations of the drugs we put in blister packs, so that more doctors will default maybe to a one-a-day pack of drugs, rather than, again, a 30-day tablet fill. So that whole area of activity, I think, continues to be exceedingly important in a place where FDA plays a unique role and perhaps a singular role in trying to address this crisis.

THERAPEUTICS FOR RARE CANCERS

Mr. MOOLENAAR. Thank you. Occasionally, I will meet with people who, in my office, who talk about some of the rare cancers, and I wonder if you are—kind of what you could comment on the FDA doing to help develop more therapeutics for those rare cancers and how the FDA might be able to incentivize or accelerate drug development in these areas.

Dr. GOTTLIEB. I think we have had tremendous success in recent years, trying to target rare and ultra-rare diseases and particularly in the oncology setting. More than 40 of the record 59 approvals that we had last year were in oncology, and some in pediatric oncology and other very, very rare tumor types.

The challenge is, in many cases, recruiting enough patients for these trials. So that is where we look at things like master protocols where you can allow multiple drugs to be tested within the same protocol. We put out guidance to sort of delineate that framework for the development of oncology products; basket trials where you can test multiple indications within the context of the same trial; tissue-agnostic approvals where we might approve a drug that is targeting a rare mutation that might be seen in multiple different types of tumors, but rather than approving the drug in tumors in the pancreas and tumors in the liver, we would approve the drug on the basis of the marker that it is trying to address that drives multiple different types of cancer.

So all of these innovations in the clinical-development process, I think, are having an impact to try to achieve the purpose that you are identifying here to make it more efficient and to develop products for these very rare cancers.

Mr. MOOLENAAR. Thank you very much. And again, thank you for your service.

Dr. GOTTLIEB. Thanks a lot.

Mr. BISHOP. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman.

And I just want to welcome Dr. Gottlieb. Thank you so much for being here today, but really thank you for your service over the last several years.

You and I have not seen eye to eye on every issue, but I really do appreciate many of the important initiatives that you have spearheaded, and I hope that, moving forward, two things, one, FDA will continue much of the work that you have started, and then, for you personally and for your family, that you move on to another productive chapter in your life. So thank you very, very much, for going back and forth with us.

I just want to mention to my colleague, Mr. Aderholt, who is not here, but the online sales of e-cigarettes—we introduced the Youth Vaping Prevention Act in January 2019, the first section of which deals with online sales and age verification. So we will communicate that to him.

OPIOID LABELING

Let me just ask a question with regard to FDA's role in opioid labeling. Your testimony, you describe the ongoing crisis of addiction, one of the highest priorities. You are familiar with the 60 Minutes report, "Did the FDA ignite the opioid epidemic?" 60 Minutes identified a controversial labeling change in 2001 for Purdue Pharma's oxycontin.

The approval of oxycontin in 1995 was based on science that showed oxycontin to be safe and effective, underscored, only for a, quote, short-term use. 2001, FDA allowed the label to be changed to include terms like, quote, daily, around-the-clock for an extended period of time, end quote.

It later becomes—and this is still true today, as I understand it, that, quote, there is long-term use, which has broadened the drug's use to all chronic-pain patients. If this labeling change occurred without a clinical trial to support it, as has been reported, would that be a violation of the law? And just a yes or no answer on this one.

Dr. GOTTLIEB. The labeling change itself would not. What was a violation of law—and we know that now—was how they marketed off of that label. And they have been criminally convicted for it.

Ms. DELAURO. But only with a short period of time for a clinical trial, which I believe it was about 2 weeks in time—

Dr. GOTTLIEB. It is hard for me to relitigate the labeling change made many years ago, but I am familiar with the history. But the labeling change was made with good intention. The language that they used tried to discourage the use of the long-acting formulations when immediate-release formulations could do. So we were seeing doctors using these long-acting formulations for things like

postsurgical procedures, when you really should be prescribing Vicodin or Percocet for a few days. What we couldn't envision was how the company would inappropriately market off of that language.

Ms. DELAURO. But with regard—my understanding is that the law says that a drug must have substantial evidence of efficacy, that the drug has the effect it purports to have in the label. I really would love to see, and if you can get to us, with getting us the substantial evidence of efficacy, for oxycontin's label of chronic, long-term use.

Dr. GOTTLIEB. Well, I will tell you, we are doing that now. The changes that were made historically were with the best of the intentions by the FDA staff, but we are using the authority that Congress has given us under the SUPPORT Act to require long-term efficacy studies with chronic administration, and require that those studies will be done, that information will be put into the labeling, and we could take additional regulatory action on the basis of what we find. So we are doing that.

Ms. DELAURO. OK. But because, you know, if you look at the label, it shows a single, 2-week efficacy study in the 20 milligrams dose. That was it. And we are talking about a drug whose launch and aggressive marketing, honestly, you would acknowledge, I would, we all would acknowledge, is the most responsible for igniting the epidemic that we have today. In your opinion, is this 1, 2-week study legally enough to justify long-term, chronic-use labeling for oxycontin?

Dr. GOTTLIEB. Yeah, it is hard for me to sit here and comment today on the historical information that they had at the time. I am not familiar with all of the studies that they were evaluating at that time and what the standard was for the decision. I will tell you the company was criminally convicted. They marketed inappropriately off of this label.

Ms. DELAURO. Yeah, I knew that, but I think we have to look at what the labeling change was just as for future use. Now, this is Dr. Woodcock at the FDA on chronic labeling. She says here, in 2013, and I quote: FDA is not aware of adequate and well-controlled studies of opioid use longer than 12 weeks.

Again, the FDA—how does the FDA justify the current labeling for chronic, long-term use? Let me just ask this question because my time is up.

OK, thank you, Mr. Chairman.

And I will get the question to you in the last 3 days of—

Dr. GOTTLIEB. Thank you.

Ms. DELAURO [continuing]. Of your tenure.

Dr. GOTTLIEB. Thanks a lot.

Mr. BISHOP. Dr. Harris.

Dr. HARRIS. Thank you very much.

CBD REGULATION

And, Dr. Gottlieb, I think you are one of the best FDA Commissioners, certainly the most knowledgeable, very responsive. So I congratulate you on your tenure and wish you luck going forward. I do want to just follow up on this—the release—I guess, yesterday about CBD and regulation. And I think it takes—I think it takes

a necessary first step, but I am not sure it goes far enough. I mean, you know, you make the statement that you issued multiple warning letters, and I think you have an example of the three companies, marketing products with egregious and unfounded claims that are aimed at vulnerable populations. What would be a founded claim for CBD, other than for, you know, pediatric seizures?

Dr. GOTTLIEB. Well, right now, it is a good question. There is probably no—

Dr. HARRIS. OK. There is no founded claim—

Dr. GOTTLIEB. You can't make a structure or function claim because it is not a lawfully marketed dietary supplement, so—

Dr. HARRIS. Correct. So my question—and so there are two issues—one is—well, three really because if you go online, and anybody who wants to go, go online and see, you can buy CBD that is supposed to be pure, that is actually at a price about—my calculation, about 40 percent of the list price of the FDA-approved drug. It is claimed to be pure. So I am not sure how the FDA allows an American company to sell, claiming they are selling pure CBD, which is exactly what Epidiolex is, I don't understand why that isn't being stopped, as they are selling a pharmaceutical. OK? Now, then, there are nutritional supplements and food supplements. On the food supplement side, I mean, I am assuming that CBD is not generally recognized as safe. Is that correct?

Dr. GOTTLIEB. That is right.

Dr. HARRIS. And we went to extraordinary levels with trans fat, for instance, to make sure there was zero in any food supplement, zero. Not like minuscule amounts, because it is naturally occurring, just like CBD is naturally occurring, but zero. Why isn't the FDA going as hard a regulatory pathway? Because—I walked into a store, a little country store in my district, and find a CBD food display in the store. Now, it didn't say, you know, show us proof that you are 21 or 18 or something, just like anybody come in, and they are buying a food supplement. So how is the FDA allowing a food supplement, which is not generally recognized as safe, to be put in food products and not regulated?

And then, finally, in terms of nutrition supplement, I think, you know, you hit the nail on the head. The bottom line is that we have a regulatory scheme that basically says that, you know, CBD has been regulated by the FDA as a pharmaceutical product, and as you said, there is no grandfathering in for it being a nutritional supplement.

So I think the FDA has to come down a little hard on these institutions, on these individuals who are making money—and they make a lot of money in this—selling a product that has—that I think we agree has no founded claim except for pediatric seizures, right, in the FDA's mind. Why is it taking so long and we are going to—you know, you are going to study it a little bit more? How do you need to study when CBDs is being sold as a food additive when it is not generally recognized as safe?

Dr. GOTTLIEB. Well, I would just say—and Congressman, I appreciate the question—we are not allowing it. You know, we have taken enforcement action. We are taking a risk-based approach, where we are going after places where CBD is being marketed, in situations where we think the claims are either misleading to the

point of encouraging a patient forego otherwise effective therapy for a medical condition, and are being marketed in a formulation and a dose that is, at a level that creates significant safety concerns.

We expressed concern yesterday, I did, about CVS and Walgreen's stepping into this market. So you now see big box stores seeking to market CBD products for some uses where the claims seem to be potentially, over-the-line claims for the treatment of pain, for example. So we are not allowing this. What is happening is we see a burgeoning market, and we can't boil the ocean, so we are trying to take a risk-based approach to enforcement, like we do in all matters. And we are hoping by taking selective enforcement actions, you are going to see voluntary compliance from the legitimate manufacturers and retailers because they are marketing an unlawful product. Now, that said, I recognize Congress wants there to be a pathway here. So we are trying to work at the same time to expeditiously create a viable pathway that could differentiate between potentially appropriate use of the product if we can have scientific evidence to support its appropriate use, and use of the product that creates safety risks for the consumers.

Dr. HARRIS. Sure. So, again, and I see, you know, your actions basically looked at a therapeutic claim, but as a food supplement, I don't see any action at all. I mean, I am going to walk into that store 2 weeks from now, and it is still going to have a food supplement, CBD food supplement—foods that have it as a supplement. And I wish you would take action. I don't think you have to take much action before everybody gets the message you shouldn't be doing this.

USE OF FETAL TISSUE IN RESEARCH

Just one final question. I know that there was a controversy about the FDA using fetal tissue in research, and I understand the contract has been canceled. Has the research been stopped, or is it just—the contract just been reissued with another entity?

Dr. GOTTLIEB. I don't believe there is any ongoing research right now with fetal tissue at the FDA. That is right, yeah.

Dr. HARRIS. So that contract was canceled, and it just—

Dr. GOTTLIEB. That contract was canceled, and there is no ongoing research.

Dr. HARRIS. Thank you very much. I yield back.

Mr. BISHOP. Mr. Pocan.

Mr. POCAN. Sure. Thank you, Mr. Chairman, and thank you, Commissioner Gottlieb. I want to associate myself with the first 10 seconds of my colleague's remarks on the other side. I don't know if you disassociate with the other 4:50, but I do think you have been an excellent FDA Commissioner. You have improved morale—I mentioned that last time—in the Department, one of the few where I have seen that happen with the change of administration. The companies that work with the FDA have—in my district—have had nothing but praise for working with you and your staff. I have always appreciated your candor when we agree and even when we don't; in fact, even more when we don't agree, because I really have learned a lot in our conversations.

And what I would like to do, almost as more of the exit interview, because I do hate to see you leave the position. Independently, in your opinion alone, when you look at the FDA—and I also really appreciate the three generic-equivalent goal of the FDA, and I hope that continues under the FDA—what would you like to see done differently, you would hope that if you had that ability, that magic wand, whether it be, you need additional funds in some area that the White House and Congress never look at, you are doing something that is idiotic and you think is a waste of your agency's time and takes you off course? I have always appreciated your candor. I hope you will give some candor here, but what would you do—you know, as you are leaving, what would you say would improve the FDA based on your experience?

Dr. GOTTLIEB. Well, I think—I appreciate the question. And I haven't quite left yet, so I probably have to temper it a little bit.

I still have residual concerns about the have and have-nots in the agency, and I have always had those concerns, having been around the FDA now for almost 15 years. And particularly on the food side of our house, you know, we have struggled to fully fund our obligations and have adequate authorities. And so I would be taking a hard look at what we do with respect to cosmetics, dietary supplements and the resources that we have to carry out our food-safety mission. Those are the higher risk parts of the agency, the places where you can wake up one morning and find out that something really bad has happened and a lot of people have been hurt. And so I think that we need to be looking hard at that and how we shore up those parts of FDA.

Mr. POCAN. And what are you doing that you wish you didn't have to do? You look back and you are going, I don't think it serves the public mission and those resources could be allocated towards what you just brought up?

Dr. GOTTLIEB. That is a good question. In all candor, I would have to give that more thought, because I think, you know, everything that hits my desk, and everything that I have been involved in, I think, is really important. The agency has a very vital mission.

Mr. POCAN. Ms. Pingree just said maybe congressional hearings, you would like to—

Dr. GOTTLIEB. I have always—

PRESCRIPTION DRUG COSTS

Mr. POCAN. And just to this point—and I really appreciated it when you said it last time—because the price of generic, when you have that third equivalent, really brings it down. What else could the FDA be doing, again, if you were just in charge, to help bring down the cost of prescription drugs? It is something we all say we want to do, but you don't see the activity. I think the American people aren't seeing the activity. I think that was a good suggestion that you had. What else should the FDA be doing or could it do, with or without additional resources, to help work towards this?

Dr. GOTTLIEB. Well, there are still a lot of areas where we don't see all the expected product competition after exclusivities have elapsed on branded drugs. And the one place is looking at the complex formulations of complex drugs, where sometimes it is, from a

scientific standpoint, hard to develop generic copies of those drugs and demonstrate that they are seen through a conventional regulatory process. I mean, you could contemplate changes to the Hatch-Waxman construct that allow the agency to look at small complements of clinical data in the context of an approval of a complex drug. You would have to go through the difficult job of defining what a complex drug is. I can define what I know it is. It is sometimes hard to define what you know it isn't.

And, you know, I am growing increasingly concerned about the lack of second-to-market—timely second-to-market competition for novel drugs. And we see more and more drugs that are approved for these very rare disorders where, once the drug is approved and the population that has the disease is treated, the financial incentive to approve a second drug for the treatment of the same condition has gone down significantly. And the market is so small, it might not support second-to-market innovation. And we literally see companies slowing down the development of products if they think they are going to be second to market. That is going to be a problem when you get into things like gene therapy. If the market is only big enough to sustain one product, then you get monopoly pricing in perpetuity and no competition, and it forestalls access. And so that is a concern of mine. I think there are things we can do to make the development of second-to-market innovation more efficient. It has been a focus of mine.

Mr. POCAN. I have 27 seconds, and we have NATO coming in. But I really do want to say thank you. You know, the companies—and I have so many that are spinoffs from our University of Wisconsin network—with you, have had nothing but praise. We appreciate that. We look forward to the Department continuing, and, you know, I think maybe it is bad luck when you are like my favorite Trump appointee. The next one may go down as well. But thank you for your service, I appreciate it.

Dr. GOTTLIEB. Thanks a lot, Congressman. I appreciate it very much.

Mr. POCAN. Thank you.

Mr. BISHOP. Mr. Cuellar.

Mr. CUELLAR. Mr. Chairman, thank you so much.

Commissioner, I really appreciate the service that you provided to our country and give you God speed to your next endeavor. Again, thank you so much.

COMPOUNDING

I want to follow up on what we talked about last time you were here, and I want to talk about compounding. The center—you are looking at establishing—you have plans to establish a compounding center of excellence, to provide training on manufacturing practices, as well as establishing investigators for inspectional activities. And my two questions are: Can you explain how this compounding center for excellence will help decrease costs for those in need of compound medication? And number two is, how is the FDA taking small pharmacist issues with regulations regarding distribution and dispensing of medications into consideration? And I want to thank you for doing this. I really, really want to because I have been to different parts of the country, and this issue is

something that we certainly have to look at. So I want to thank you for your leadership on this.

Dr. GOTTLIEB. All right, thank you for the question, and thank you for your comments. I appreciate them very much.

The \$12 million that we received in 2019, to establish this compounding center for excellence, is focused exactly on some of the challenges that you have identified. How do we help small pharmacies get into a regulatory framework where they can engage in a wider scale of activity, particularly some manufacturing engaging in potentially office stock, shipping to hospitals? And so what we want to do is make it easier and less expensive for the 503A pharmacies to become 503B pharmacies, outsourcing facilities. And what we believe is by developing a center that can work more directly with pharmacies, help train them on how to meet GMP requirements, provide a high level of touch, train them on how to be inspected. We believe we can help actually provide sort of almost consultative-type services to these pharmacies to try to get them over that transition and also promulgate policies and guidance that adjusts the amount of regulation that we are going to impose based on the size of the pharmacy and what they are doing, so take a much more risk-based approach. So, if a 503A pharmacy wants to compound relatively lower risk products and do it on a small, local scale, we shouldn't be applying the same level of regulation as someone who is going to ship hundreds of thousands of vials of a sterile product nationally because that is more risk.

And so the resources are going to allow us to develop a center that is going to be focused on that and help develop this domestic industry. I believe, and I still believe, that if we can get more 503A pharmacies to more less expensively convert to 503B pharmacies, we also offer them a tremendous economic opportunity to expand their businesses. Because if they remain a 503A pharmacy, they are always going to be capped in terms of what they can do. If they become a 503B pharmacy, a much broader range of opportunity becomes accessible. Those resources are different than what we requested in 2020. We were asking for \$13.5 million. That is to help expand the 503B opportunity set to finalize the bulks compounding list and develop guidance from regulation that is going to further clarify how the 503B pharmacies can operate in a regulatory, compliant fashion.

This is a relatively new industry, and we envision that this should be a robust industry, but we want to be more actively engaged in making that come to fruition.

Mr. CUELLAR. Thank you. I do want to say, thank you so much for—on this forward thinking on this. So thank you, thank you so much.

Dr. GOTTLIEB. Thanks a lot.

Mr. CUELLAR. Thank you, Mr. Chairman.

Mr. BISHOP. OK. Thank you, Mr. Cuellar, for that last question. You saved me from having to explore that.

FUTURE OF FDA

Dr. Gottlieb, I want to take a moment to discuss the future of FDA and where you would like to see it in the next 5 years. As you know, too often a regulatory agency is forced to spend most of

its time responding to various issues that arise, and sometimes without any warning, rather than to help build a foundation for the technological innovations that would drive the industry forward.

Regarding the medical side of FDA, where do you see the industry moving forward, and what are the most important things that FDA is doing to help safely and effectively guide it there? And on the food safety mission side, tell us the same thing about that mission area.

And, finally, is there an area of FDA's work that deserves a bigger spotlight moving forward?

Dr. GOTTLIEB. I appreciate the question. I think that there are things in the 2020 budget—and I would come back to that—that I think can be sort of the foundational elements of a modern transformation of the agency. And I would point to what we are trying to do to try to develop knowledge management systems and more structured approaches to medical product review across the entire continuum to make more of the application review process, a structured, templated approach to review, where we are not receiving paper applications from industry anymore, but we are actually receiving information that is in a cloud-based environment, pulling that information down, and then populating templates and applications that are standardized from review to review to review, to help standardize the review, make it far more efficient, and having our team sort of collaborate around single applications that are in a virtual environment.

What I have just described probably exists inside every corporation that deals with data and makes decisions based on information, but it is not the way FDA has traditionally done business because we haven't had the resources. So the money that we are asking for to fully develop the new data enterprise is focused on that. It would fundamentally transform how we go about our work.

Another transformational element is the ability to use information from electronic health records to do post-market safety assessments and also look at real-world evidence derived from Electronic Health Records (EHRs) as a component of how we assess, not just safety in the postmarket, but also benefit pre- and postmarket. And so that is another transformational opportunity set for the agency, and those are embedded in that 2020 Budget request, and we received partial funding in 2019.

On the food side of our house, I think there is more work that we want to do to improve the recall process. We have a request in the budget for 26 Full time Employees (FTEs) in our Office of Regulatory Affairs (ORA), for example, to improve how we do on recalls and how we get timely information to consumers. I think we need to contain and make investments there, but I think one of the more transformational things we can do from a technology standpoint, in terms of modernizing the regulatory process, is putting in place modern track and trace. What people want to know is, are they getting an assurance of safety from FDA? And that is where all the tools, the preventative controls in FSMA come into play. They want to know, if something goes wrong, will they find out about it quickly? And that is where everything we are trying to do to modernize the recall process comes into play.

But they also want to know where their food is from, and they want us to be able to trace it right back to the source. And that is where modern track and trace comes into play. And as we have seen, when we have recalls, if we recall romaine lettuce, it takes us a long time to trace it back to the specific farm where it might have come from. We think there is much more we can do with traceability in the system using modern technology like blockchain.

We hired, as a Deputy Commissioner, Frank Yiannas, who is here today, who used to head up food safety for a very large retailer and has deep expertise in this. And he has many purposes in coming to FDA, but one of them is to try to stand up this modern framework. So we have requested resources for that as well. I think these could be transformational elements.

The final thing I will just say—and I will put a plug in for one more thing that is in the budget, if I may, with just 30 seconds—is what we want to do with the blood pathogen technology and basically pathogen reduction technology to improve the safety of our blood supply. I think this is another tool that could be transformative in improving the safety of the blood supply and lowering the costs, reducing the need to defer people who want to donate blood. And it is a technology that exists. It is a technology that we could be adopting, and I think it could be transformative on the blood side of our house.

And if you ask me, in closing, where the biggest risks are, it is the places in the FDA portfolio where you have the potential for latent risks that become widely distributed before they fully manifest, before we discover them. And those kinds of risks only exist in a few places in our portfolio, but one of them is in the blood supply, if there is some undetected pathogen in the blood supply. And another one is on food safety part of our house, where you could have a food contaminant that gets widely distributed very quickly in today's supply chain, has latency associated with the pathogens. So, by the time people start showing signs of illness, it has been out there in the food supply for 5, 6 days, and you could have a lot of people exposed.

Mr. BISHOP. Thank you.

I would like to recognize Mr. Fortenberry.

GENERIC DRUGS

Mr. FORTENBERRY. Dr. Gottlieb, I want to return to the issue of generic drugs that Mr. Pocan brought up. The last time you were here, I had asked for the broad calculation if the full vision that you have for generics was implemented, what would we say? Do you have that number yet?

Dr. GOTTLIEB. I have—

Mr. FORTENBERRY. It doesn't have to be absolutely precise, but you—let's move from the—the problem is, let's move from the abstract to—

Dr. GOTTLIEB. Right.

Mr. FORTENBERRY [continuing]. What is potentially real.

Dr. GOTTLIEB. Well, I don't have the number yet, the aggregated number. What we do have is an updated—and we can make this available to you—we have an updated estimate of what the price reductions are as you get multiple product introductions in a cat-

egory. And it is more substantial than what we have seen historically. We haven't been able to publish that yet, but we could certainly get that data to your office.

Mr. FORTENBERRY. OK, but you are leaving in 3 days.

Dr. GOTTLIEB. Well, I will get it to you before we leave.

Mr. FORTENBERRY. Are you staying?

Dr. GOTTLIEB. She is—yeah. We have it.

Mr. FORTENBERRY. OK.

Dr. GOTTLIEB. We can get it to you today.

Mr. FORTENBERRY. That is all I have. Thank you, Mr. Chairman.

Mr. BISHOP. Thank you.

Dr. Harris.

Dr. HARRIS. Thank you very much.

CBD AS A FOOD SUPPLEMENT

Let me just follow up on, again, the CBD as a food supplement. So what would you need in order to establish regulatory action or, you know, actions against these stores that are selling CBD as a food—put it in food? You know, I don't care what food they have them in. There is one that sells gummies, for God sake, with the stuff in it. Talk about marketing to children. But my understanding is the schedule V, right? Epidiolex is in the schedule V. Is that right?

Dr. GOTTLIEB. I believe it is, yes.

Dr. HARRIS. Yeah. So they obviously move from I to V, but, you know, codeine is in V. So I assume that if I went into that display in that store and it said, you know, "Buy these products with codeine in it," and they were food products, I would assume that the FDA has instant regulatory authority to, you know, stop the sale of those. Does the FDA have authority to stop the sale right now of food products containing CBD?

Dr. GOTTLIEB. We do. And we are taking action.

Dr. HARRIS. What action are you taking?

Dr. GOTTLIEB. We have sent warning letters to a number of companies to ask them to remove products from the market. And when we send a warning letter, that is a legal action, and if the company doesn't comply, we could go to court and seek an injunction against the manufacturer. You know, this has exploded, Congressman, and—

Dr. HARRIS. Oh, I know.

Dr. GOTTLIEB [continuing]. And, you know, we are taking a risk-based approach, but with more resources, we can not only accelerate our policymaking process here to try to create a legal framework that will form the basis of more effective enforcement action but also put more resources behind the enforcement activity.

Dr. HARRIS. Well, so you don't have the legal framework in place to enforce—

Dr. GOTTLIEB. We have the legal framework in place to enforce right now. I think what Congress wants is a framework that could allow us to better differentiate between where this could be permissible and where it is clearly crossing the line. You know, I am hearing a lot of different voices on this issue from a lot of different folks. Right now, they are all presumptively illegal, and we have been taking enforcement action based on risk.

But what I think we would ideally like to do, having heard from Congress very clearly on this, is try to create a framework, that if there are places where CBD can be appropriately marketed as a food product, and safely, perhaps in very low concentrations, whatever the scientific criteria might be—and it would need to be a science-based process that ultimately defines what is permissible—have the framework to do that, and that would make it more efficient for us to then take enforcement action where risks are being created.

I don't know the science on this. It could be, at low levels, CBD might not pose a risk to consumers. And if that is the case, then we need to define what that is and where it could be marketed as a food product and not. Right now, we can't do that. To your point, everything is illegal. We could be taking enforcement action against all of it, and if I do that, that is the only thing that my agency will be doing right now.

Dr. HARRIS. OK. But you can take action and—so you don't believe that you could, just by taking action against a few companies—I don't know, are these the letters in your—in the statement, these are the three companies that got letters: Advanced Spine and Pain, Nutra Pure, and PotNetwork Holdings?

Dr. GOTTLIEB. And we also put out a statement yesterday about other concerns we had, including my statement about the concerns I had with respect to what some of the big box stores, like CVS and Walgreen's, are attempting to do here. And we are going to be calling them up to have a discussion with them about it. I do think this is going to have a deterrent effect. So you don't see a lot of legitimate food packaging companies and large stores putting CBD products into their stores and into their food products right now because they know it is illegal. I think they are all trying to work with us to see what a legal pathway would look like. But they are not doing it right now.

So I do think these steps are going to have a deterrent effect. So we have to see where we are in 6 months. Because to your point, there is a lot of people out there and—

Dr. HARRIS. How about the flavored vaping products that are being marketed online with CBD?

Dr. GOTTLIEB. All of that causes concern to us.

Dr. HARRIS. OK.

Dr. GOTTLIEB. They are all a public concern.

FLAVORED CIGARS

Dr. HARRIS. So just one very brief point, I noticed that—what is the action you are taking on the flavored cigars? I mean, this—because my understanding is the usage is going down, but still it may still be inappropriate. But the usage is going down. So how aggressive is the FDA going to go after flavored cigars?

Dr. GOTTLIEB. Well, cigars are the largest growing segment of tobacco use among African American teens. So I don't know that it is going down overall, but it is certainly not going down in the segments where we have deep public health concerns. The guidance that we promulgated several weeks ago that will be finalized shortly would ban characterizing flavors in all nongrandfathered cigars. We also seek to advance a rulemaking process to ban character-

izing flavors in the grandfathered cigars. We would need to do that if the rulemaking was committed. I don't believe any characterizing flavor should be in any combustible tobacco product.

Dr. HARRIS. OK, but grandfathering is probably the way you will go at first?

Dr. GOTTLIEB. Well, we will seek to ban.

Dr. HARRIS. Right.

Dr. GOTTLIEB. Ultimately, once our full policy framework is in place, there shouldn't be any characterizing flavor in any cigar.

Dr. HARRIS. Yeah, OK, thank you very much.

I yield back. Thank you, Mr. Chairman.

Mr. BISHOP. Thank you.

Dr. Gottlieb, once again, I would like to extend our appreciation for your work. During your tenure, you have been a wonderful advocate for public health, transparency, and you have been willing to take on some very, very tough issues. You certainly have my respect and that of my colleagues as you have heard today. But before we close, I wanted to turn the floor over to you to share with us a little bit about your experiences and any lessons learned as the Commissioner of FDA that might be instructive for us.

Dr. GOTTLIEB. Well, I appreciate that, Mr. Chairman. I will share with you some of the advice that I imparted on my successor, Ned Sharpless, who I think very highly of, and I think is an outstanding public health official, who is going to lead the agency very effectively. And this is a lesson I learned having worked at the agency before and with multiple Commissioners. I think that as a sort of Commissioner coming into this agency, you need to come in with a clear sense of what you want to accomplish from a broad standpoint when it comes to public health and advancing the public health mission of the agency. And I came in with the sense that we needed to be doing things a little bit differently, a little bit more when it came to the opioid crisis. I wanted to try to use the tools of the agency to try to address public health issues related to challenges with access to affordable drugs. There were other areas where I wanted to see if we can use the agency's tools in a more robust fashion to effect certain public health goals.

But how we ultimately address those issues, the idea is the policies, that came from the career leadership. It came from the center directors. It came from the professional staff. If you are going to make enduring policy inside FDA, that is the way you need to go about making policy. You need to have that engagement directly with the scientific and professional staff and respect the policy-making process inside the agency.

And so the very first thing I did was make sure that I meet every week with the center directors, and hardly a day goes by that I don't engage with them directly. Those relationships are among the most important relationships that I have in terms of my ability to effectively lead this agency, accomplish things on behalf of the agency and the public health of the country, and accomplish policy goals.

So that is the advice that I left my successor. I know he took it to heart, and I know that is the way he has operated at the National Cancer Institute (NCI). So I am very confident that the agency is in good hands.

Mr. BISHOP. Thank you, Dr. Gottlieb, for being here today. We really appreciate your taking time to share your knowledge and your experience with us. I think it is safe to say that we have all appreciated working with you and your efforts at FDA, and we look forward to working with your successor. And, of course, we wish you the best in your future endeavors. So, again, thank you.

And, with that, this subcommittee is adjourned.

TUESDAY, APRIL 9, 2019.

**U.S. DEPARTMENT OF AGRICULTURE'S FISCAL YEAR
2020 BUDGET REQUEST**

WITNESSES

HON. SONNY PERDUE, SECRETARY, U.S. DEPARTMENT OF AGRICULTURE
ERICA NAVARRO, BUDGET OFFICER, U.S. DEPARTMENT OF AGRICULTURE

OPENING STATEMENT—CHAIRMAN BISHOP

Mr. BISHOP. The Subcommittee will now come to order. Good morning, and welcome to today's hearing on the Department of Agriculture's fiscal year 2020 budget.

I'm pleased to introduce our witnesses this morning: Secretary Sonny Perdue. The Secretary and I have a three decades-long relationship. He has a deep commitment to our farmers, ranchers, and to our rural communities.

Before we begin, I want to say that we need to get a supplemental disaster bill through Congress. I know that the Secretary shares my sense of urgency about this. The House passed its bill in January, and we are ready to go to conference with the Senators as soon as it passes the bill.

I know that all House Members are committed to ensuring the areas of the Midwest that were hit with monumental floods just a few weeks ago have the funds that they need, as well as the folks impacted by the tornadoes last month in Alabama and Georgia.

Twenty-six of the 29 counties that I represent in Georgia are rural, with average populations of between 10,000 to 15,000 people. These counties are some of the most economically disadvantaged counties in the Nation. They face immense challenges in healthcare, nutrition, rural housing and utilities, broadband and economic development.

As chairman, I am intensely focused on rural development. I believe that the ZIP codes in which a child is born, or a family lives, should not prevent them from realizing their full potential.

The administration's interagency task force on Agriculture and rural prosperity correctly recognized five key indicators of Rural Prosperity: e-connectivity, quality of life, rural workforce, technological innovation, and economic development.

But unfortunately, once again the administration has put forward a woefully underfunded budget request that fails agricultural communities and rural America. Many of the short-sighted proposals contained in the administration's request have been submitted by the Department before and will be rejected by the Subcommittee once again. I am somewhat surprised that the fiscal year 2020 budget request is essentially a carbon copy of the past

few years. The Department submits this at a time when the agricultural and the rural economies of our Nation face significant challenges.

This budget comes to Congress with a reduction of over \$4.2 billion, or 21 percent, in discretionary funding from Fiscal Year 2019, and it seeks to re-open the farm bill with significant legislative requests to change mandatory programs. The proposed elimination of programs such as Food for Peace, McGovern-Dole, the Commodity Supplemental Food Program, Summer EBT, rural watershed protection programs, and nearly all of the rural housing loan and grant programs is wholly unacceptable.

Other programs face drastic cuts. I was extremely disappointed to see that rural broadband funding was cut by \$350 million. One of the greatest barriers to entry into the modern economy in rural America is access to adequate broadband. I have children in my district who go to the local library after school or after football practice, at hours when the library is closed, just to access the internet. They sit in their parents' cars, outside the library, to do their homework. I find that unacceptable in 2019.

I was disappointed that the budget cuts agriculture research by over \$179 million. I was disappointed to see that under this budget there would be significant staffing reductions, specifically in Rural Development and the Farm Service Agency.

There are also, once again, many legislative proposals related to the Supplemental Nutrition Assistance Program, most of them rejected by Congress in the 2018 farm bill. We expect to reject them again.

Finally, the proposed relocation of ERS and NIFA. As the Secretary and my colleagues know, I and most knowledgeable stakeholders of these agencies strongly oppose this, as well as the proposal to move ERS under the Chief Economist. We will discuss this a little bit further today.

Mr. Secretary, I believe that you are honestly trying to bring positive changes to USDA, and we are always looking for ways to do things more efficiently. My concern is that the Administration has not asked for appropriate resources and staffing. I want to ensure that the resources that this subcommittee provides are used as intended.

I also believe that to make rural America a priority, you must invest the necessary resources. You must put your money where your mouth is. While this budget falls short, I pledge to do my best to work with you and Ranking Member Fortenberry to develop a bill worthy of the farmers, the ranchers, the rural communities who rely so heavily on the services provided by USDA.

So hopefully, the conversation today will provide some insight into the disconnect between the budget proposal submitted by the Department and the economic realities that rural America faces.

Again, I would like to thank you for being with us today, Mr. Secretary, and by the way, I would also like to thank you and your cousin, our junior Senator from Georgia, Senator David Perdue, for your presence and the very thoughtful comments you made at the ham and egg breakfast last Friday, at our state's second land grant university, the Fort Valley State University.

Now let me ask our distinguished ranking member, Mr. Fortenberry, if he has any opening remarks.

OPENING STATEMENT—RANKING MEMBER FORTENBERRY

Mr. FORTENBERRY. Yes I do, Mr. Chairman. Thank you so much for convening this hearing.

What is this ham and egg breakfast I didn't hear about? This is the first I've known about this, so maybe we can better coordinate next year.

Anyway, Mr. Secretary, nice to see you. How in the world did you navigate that media scrum out there? I was so excited to see the Secretary of Agriculture attracting 20 national cameras outside of the Appropriations hearing on the budget. It is an unprecedented event, so I hope that went well for you outside.

Secretary PERDUE. "Release the reporters".

Mr. FORTENBERRY. I think that's a pretty good summary.

Anyway, one other quick story before I start my remarks. I was—as we visited about a month ago over at the Department, I had stopped by Ms. Navarro's office. I believe that's the same office, interestingly, that I had when I was an intern in the USDA. So interns had a bigger status back then, but—maybe that is a result of tight budgets, putting Ms. Navarro in that space, but it was a pleasure to see you and thank you for being—again, for being here today.

Mr. Secretary, before we dive into the budget request, I do want to commend you for your leadership over the last few years. The Department's efforts across a vast portfolio of responsibilities is immense. Perhaps not well understood, and USDA touches the lives of hundreds of millions of people in the United States and abroad in one way or another.

And in particular, I want to express my appreciation for what you and your staff have done in providing assistance to farmers and ranchers in my state and neighboring states of the Midwest, who have endured the devastating effects of the flooding. These were three 500-year events along three rivers that converged in a moment, due to rain on top of frozen ground, on top of rising temperatures, on top of melting snow, that created a flurry of ice and sludge that impacted levees and created swiss cheese types of effects all up and down these rivers, devastating many communities. But thank you for your eager and willing response, as we unpack the damage here further.

A natural disaster like this can also, in some ways, create blessings in disguise. In that regard, what I mean is, our Nation will oftentimes put aside politics and other differences in order to simply just lend a helping hand to our citizens, and I think Americans want Congress to actually do the same; to put aside any differences, and find consensus and quickly pass some type of budget supplemental that will provide additional help to my constituents affected, those from Chairman Bishop's district, and many more who have waited and waited for some help.

Let me add, over the past year, your Department has assisted producers in other ways, dealing with the effects of trade disputes, assisting rural communities—communities in rebuilding inadequate infrastructure, and fed those who were hungry, across the

world. So for that, I want to commend you, and as we've all heard you say before, Mr. Secretary, "do right, and feed everyone". What a great summary of your values.

The Department has a number of challenges, obviously, that we are going to discuss today, as well as opportunities. Top on that list is the implementation of the farm bill, enacted last December. And we would like to hear from you about the farm economy against the backdrops of some challenging financial conditions.

I want to also recognize your actions and efforts to streamline certain functions within the Department, in engaging with customers and striving to improve service and enhance engagement. You are trying to, clearly, repair the relationship between the USDA employees and their customers, so efforts to upgrade the effectiveness of websites like Farmers.com should ultimately save farmers and ranchers time, if they don't—can't drive in to the FSA or NRCS county office to process paperwork. Other efforts, such as the proposed relocation, from my perspective, of ERS and NIFA—they may be controversial, but they are based upon good intent, to save our constituents' hard-earned taxpayer dollars.

The subcommittee will need to keep abreast of the Department's actions and planned actions, as it relates to these efforts, including an assurance that any reduced staffing levels are not negatively impacting the delivery of important services.

In turning to the 2020 budget requests, there are some initiatives that will likely receive bipartisan support, and other proposals that I'm sure none of us can get behind, for a variety of reasons. I agree with your proposed increases in rural development for community facility grants, business and industry loans, as well as distance learning and telemedicine grants.

On the other hand, steep cuts to rural housing programs, international food aid and crop insurance cannot find an acceptance right here. When it comes to rural housing, it will be extremely challenging for our rural communities to grow without access to low-cost loans and grants. While this subcommittee has always supported responsible investments, in light of the 22 trillion dollar national debt, it is my perspective that some of these cuts would actually be very counter-productive.

Whether the items in the budget are true policy positions, or just our annual budgetary theater, we are going to unpack that, and I listen—I look forward to listening to your thoughts and rationale for some of these reductions, especially given the challenges of the farm economy and rural America.

So again, I want to thank you for being with us today, and look forward to fullness of discussion with you.

REORGANIZATION OF THE OFFICE OF BUDGET AND PROGRAM ANALYSIS

Mr. BISHOP. Thank you, Mr. Fortenberry.

Secretary Perdue, in my opening statement I failed to mention the—a letter that I had just recently seen. In fact, I saw it just as I was leaving the office to come down to the hearing. It was from you, with regard to a planned reorganization of USDA's Office of Budget and Program Analysis. You indicated in the letter that it is—it would realign the functions and the staff internal to OBPA,

to clarify roles and responsibilities for the four primary business processes.

I read the letter, and my staff had already seen the letter, and it seems as if that is an insightful move, to more efficiently operate and streamline those processes, so I just want you to know that I would personally, and I think our staff would concur in that; you will probably be getting a letter from us forthwith indicating that.

I also failed to welcome your Budget Officer, Ms. Erica Navarro, who is accompanying you, and we want to welcome you both, and at this time I'd recognize you for your statement, and also let you know that your entire written statement will be included in the record.

OPENING STATEMENT—SECRETARY PERDUE

Secretary PERDUE. Well, thank you, Chairman Bishop and Ranking Member Fortenberry and distinguished members of the subcommittee. I really do appreciate the spirit in which we were welcomed here this morning. I think, again, while we may find some differences of opinion, I don't think we have differences of intent in trying to serve the American people. And I very much appreciate that spirit.

I also appreciate, really, the natural tension that our founders created between the executive branch and the constitutional role of budgeting and appropriating and oversight of the congressional role in that regard. And we—our goal, as I have indicated to you before, is to be, where we can, agreeable and compliant, certainly not defiant without reason of defending what our recommendations are.

So I appreciate very much the relationship that we enjoy with you and your members. And we look forward to continuing, even when we can't, maybe, finally agree on the fundamentals of what policy is there. But we understand your constitutional role and responsibility. And we respect that and we want to behave and communicate as transparently as we can our thoughts about budgeting and how we—we use the money that is appropriated.

We stand ready to be responsive in defending and communicating about how that was utilized. So thank you for that opportunity. It is no surprise that you began with a disaster that has been on the minds of our constituents, really, since last fall when you witnessed, in your district, primarily, and I think Representative Aderholt's district in southeast Alabama as well a terrible hurricane, Michael, there, that I've never seen that kind of destruction that far inland with pecan trees, which is a mainstay of your district, and cotton, certainly, destroyed the way it was.

And we are very anxious. Your constituents and constituents throughout those areas and the Carolinas in a previous hurricane and the more recent floods, as far as the wildfires, are waiting anxiously, some of them literally devastated. We have got—as you all know, we have safety net provisions. The Farm Safety Net is alive and well, and you all have appropriated safety net functions like emergency livestock provisions, watersheds and those kind of things, and the Environmental Quality Incentives Program for losses. But it doesn't contemplate utter devastation like we've seen.

So I appreciate both of you mentioning that, and hopefully we can come to a reconciliation. I do agree with Ranking Member For-

tenberry. This is a time where Congress has demonstrated its ability to put partisanship aside and typically respond on behalf of your citizens. And I hope that we can do that as well. Certainly trade is a big issue that we hear about in the agri-economy across the country. And it is never over until it is over. We are seeing some positive signals from China in that regard. But we are not just focusing there. Ambassador Lighthizer will be over tomorrow speaking to a committee about trade responses with Japan as a big market.

Actually, Under Secretary Ted McKinney has been circling the globe since he came on board last year looking for new markets. We don't want to put all of our eggs in the China basket. But that seemed to be progressing, but it is never over until it is over in that regard. You mentioned infrastructure to a certain degree. And I didn't realize our broadband history was as bad as you made it sound, Mr. Chairman. I thought we had been doing better.

In broadband, we are beginning to receive the applications in just a couple of weeks for the money that you appropriated last spring and for the—the rural broadband there, we have gone through a very careful and judicious application process. Since the beginning of last year, we have given technical assistance to many different groups. I am delighted in the fact that various groups are showing a lot of interest from Electric Membership Corporations and rural telecoms and other nonprofits in these different areas, as well as communities themselves over applying for this.

It will be three different tranches of money that we think will absolutely help the connectivity that you describe that I agree with you that is so—is so critical in that regard. Obviously, you all passed a great farm bill in 2018, December 20. And our Department is working feverishly to implement that farm bill. You understand your constituents rely on the rules and regulations of specificity that USDA provides to them. And we are hoping to get those out.

In fact, we focused on dairy particularly. That has been the sector that is under the most stress. And we are on track for the—the dates that I gave the full Committee earlier on those types of things. We will begin to get returning money over previous premiums later this month. And we believe that we will have the full program implemented by that June timeline that we—we indicated earlier in that regard.

So we are working on all those areas of the farm bill implementation. Now speaking to the budget, I look forward to answering your questions and your subcommittee questions over the—over the budget. You know that there is—obviously, it is a time of great risk here. But we believe that our administration has taken the step of providing a fiscally responsible budget that doesn't continue to kick the can down the road on a \$22 trillion deficit.

While no one likes cuts, we at USDA are prepared, if we could implement this across to government-wide, to do our share in returning to fiscal responsibility in all of these areas.

Many are positive things in the—in the budget that—I know you mentioned some negative things. And we look forward to discussing those with you. But there are also many positive things in the budget as well. But we do believe the administration is prepared

to propose a budget that is fiscally responsible and deals with some of the realistic issues that we have here regarding national debt.

And I want to commit to you that whatever resources are provided by you all as the appropriators, we will do our very best to provide the kind of customer service that I think your constituents want and deserve each and every day. In providing for them, we hope that we have been responsive to your members and requests over constituent issues heretofore.

And we look forward to continuing to provide the most efficient and effective customer service to agents in the Federal Government. We, first of all, consider you and your subcommittee and members of Congress as our primary customers with whom we expect to be responsive and responsible for those funds. And I appreciate the opportunity to testify this morning and look forward to your questions.

[The information follows:]

For release only by the
House Committee
on Appropriations

**Statement by
Sonny Perdue
Secretary of Agriculture
Before the Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations, U.S. House of Representatives**

April 9, 2019

Mr. Chairman and distinguished Members of this Subcommittee, it is a privilege to appear before you today to provide an overview of the Department's proposed budget for fiscal year (FY) 2020. Joining me today is Erica Navarro, USDA's Budget Officer.

When I appeared before you a year ago, I laid out my vision for making USDA the best managed department in the Federal government. Since then, USDA made great strides toward becoming the most effective, most efficient, and most customer-focused department in the federal government. USDA has worked to create rural economic opportunities and improve the quality of life for rural Americans. Rural Development invested in new and improved high-speed e-Connectivity and electricity for 7 million residents and improved water and wastewater infrastructure for nearly 3 million rural customers. USDA also launched an initiative to provide comprehensive and timely support to veterans interested in opportunities in agriculture, agribusiness, and in rural America.

USDA played a significant role in helping rural communities and agricultural producers recover from hurricane-related damage and wildfires. USDA assistance has included providing children affected by Hurricane Florence access to free meals, helping Supplemental Nutrition Assistance Program (SNAP) recipients replace food lost due to power outages, helped businesses and utilities by considering requests to defer principal and/or interest payments, and provided emergency farm loans to impacted operations.

In 2018, the Department worked with Federal partners to deliver new and improved trade deals like the United States-Mexico-Canada Agreement and a re-negotiated United States-Korea Free Trade Agreement and provided trade assistance to

farmers due to unjustified trade retaliation. Efforts to break down barriers and pursue export opportunities resulted in new or expanded market access for numerous U.S. farm products in 2018. USDA sponsored six agricultural trade missions in 2018, enabling more than 200 U.S. companies and organizations to engage in 3,000 one-on-one meetings with foreign buyers, generating more than \$140 million in projected 12-month sales. Similarly, USDA organized exporter participation in 19 trade shows around the globe, where more than 900 U.S. companies introduced 4,500 new products to potential customers and reported \$296 million in on-site sales and \$2 billion in projected 12-month sales.

Since we last met, USDA worked with local school officials to explore reforms that will make school meals more appealing by giving control back to local school food professionals who know the children best. Based on the input received, the Food and Nutrition Service (FNS) finalized a rule to allow for more flexibilities for schools to offer nutritious and satisfying meals to children, reduce food waste, and ease operational burdens for the National School Lunch Program and School Breakfast Program. With a focus on the Administration's priority of moving SNAP participants to self-sufficiency through work, FNS proposed another rule to improve and strengthen our efforts in moving able-bodied adults without dependents participants to work.

We refocused USDA to be more customer-oriented, merging where it made sense to maximize efficiencies, while modernizing and optimizing Information Technology (IT) to improve delivery of services. USDA stood up the Farm Production and Conservation (FPAC) mission area. We also launched the FPAC Business Center in 2018 to eliminate redundant administrative support functions. USDA successfully merged the Agricultural Marketing Service, the Grain Inspection, Packers and Stockyards Administration, and the Farm Service Agency's (FSA) Commodity Operations programs to better meet the needs of farmers, ranchers, producers, and consumers while improving customer service and maximizing efficiencies. We continued efforts to optimize and consolidate Enterprise Data Centers by closing 21 in 2018 which together with prior closures is expected to achieve \$21.5 million in cost savings/avoidance by 2021. We also decreased the number of cybersecurity critical vulnerabilities per endpoint by 62 percent and the number of high-risk vulnerabilities by 73 percent in 2018, decreasing USDA's weaknesses in software or hardware that can be exploited by a hacker. After reviewing the motor fleet,

we were able to identify over 4,200 underutilized fleet vehicles (over 10 percent of the USDA fleet) that are being targeted for disposal, which is estimated to reduce USDA costs by \$26 million in FY 2019 and beyond.

2020 President's Budget

The President's Budget recognizes the overriding need to reduce the Federal deficit, and USDA shares in the responsibility of controlling Federal spending. There are proposals in the budget for USDA that will produce real savings in both mandatory and discretionary spending. The Budget includes proposals to cut programs that achieved their goals or do not work, eliminate wasteful or duplicative spending, streamline government operations, and limit spending to achieve deficit reduction goals. The President's 2020 Budget lays out a vision for a Federal government that is efficient, effective, and accountable.

USDA's total budget authority request pending before this Subcommittee, proposes a total of \$143.2 billion in 2020, compared to \$137 billion in 2019, primarily due to an anticipated decrease in SNAP participation and crop insurance payments. The discretionary appropriation request for this Subcommittee is \$15.7 billion, which is lower than the \$20.2 billion under the annualized continuing resolution for 2019.

For 2020, we will continue to prioritize customer service every day for our customers – the American taxpayers. We will strive to conduct the people's business efficiently, effectively, and with the utmost integrity. We will promote the ability of America's agricultural sector to produce and sell the food and fiber that feeds and clothes the world and to reap the earned reward of their labor. By promoting American agricultural products, we will work to remove obstacles and give farmers, ranchers, foresters, and producers every opportunity to prosper and thrive. Through our programs and working closely with our customers, we will facilitate rural prosperity through the expansion of rural business opportunities and improved infrastructure. We will also work to preserve the land. USDA will continue to ensure that all Americans have access to a safe and secure food supply.

Become the Best Managed Department in the Federal Government

For FY 2020, the President's Budget supports new and continuing investments in IT modernization by USDA to improve customer service and streamline and modernize rural and farm program and service delivery. In addition, the Budget continues support for the business functions of the FPAC Mission Area by streamlining service delivery between FSA, the Natural Resources Conservation Service, and Risk Management Agency to improve efficiency, effectiveness, and accountability. To maximize the effectiveness of these customer-focused improvements, the Department must modernize its own back-office technology capabilities. The Budget includes an increase of \$31.5 million to begin the transition to a modernized enterprise network in FY 2020.

In the National Capital Region (NCR), the Department is starting the OneNeighborhood initiative to better utilize office space in the Washington, DC Headquarters Complex. The Budget requests \$266 million for the initiative to increase the occupancy capacity through life and health safety upgrades; space reconfigurations; and the replacement of outdated building systems. The efforts will allow the Department to reduce its lease costs in the NCR that amount to approximately \$40 million annually.

In August, USDA announced we would realign the Economic Research Service (ERS) under the Office of the Chief Economist and would relocate both ERS and the National Institute of Food and Agriculture (NIFA) outside of the NCR. Those changes will improve customer service, strengthen offices and programs, and save taxpayer dollars. USDA received 136 expressions of interest submissions from 35 states. The firm Ernst & Young was retained to evaluate and conduct the site selection process. On March 12, we announced 68 expressions of interest remain under consideration. We recognize there are outstanding questions regarding this decision and are committed to an open process as we move forward together to address concerns. The President's 2020 Budget includes an estimate of the funds necessary to move these agencies outside the NCR, but final costs will be dependent on the location selected.

Create Conditions so Agricultural Operations Can Prosper, Fulfilling Their Mission to Feed, Fuel, and Clothe the World

Over the past year, USDA responded to conditions that tested the resilience of American farmers with initiatives to create economic conditions in which they can

prosper. With the help of crop insurance, natural disaster assistance programs, and short-term trade mitigation programs, many producers are managing the stresses of these difficult times and are indicating increased optimism, particularly with expectations that trade partnerships will strengthen in the near future. As we implement the 2018 Farm Bill we will work toward achieving the primary goal of farm programs: to help farmers and ranchers manage risks and continue producing food, fiber, and fuel in good years as well as bad. The Budget estimates net CCC expenditures of \$6.5 billion which includes all the commodity programs, CRP and CCC funded trade programs. This compares to the estimated \$20.9 billion net CCC expenditures that we anticipate in FY 2019, which includes disaster and trade mitigation assistance in addition to the other programs.

In addition to mandatory funding provided by the 2018 Farm Bill, the President's Budget provides resources to help agricultural operations prosper, fulfilling their mission to feed, fuel, and clothe the world. Funding is requested to support the estimated \$7.7 billion demand for farm loans that provide access to credit to about 48,800 producers, 80 percent of whom are beginning farmers and ranchers, veterans, and socially disadvantaged producers. It provides nearly \$1 billion for the Animal and Plant Health Inspection Service to promote the health of animal and plant resources and facilitate their movement in the global marketplace, as well as the welfare of certain animals. For agricultural research and extension activities, the Budget includes a total of \$2.9 billion, including \$500 million for competitive grants through the Agriculture and Food Research Initiative. The Budget includes a total of \$66 million to take ownership of and operational responsibility for the National Bio and Agro-Defense Facility (NBAF), in addition to funding to transition and expand the Agricultural Research Service and the Animal and Plant Health Inspection Service research and diagnostic programs at NBAF.

Expand Foreign Markets and Promote U.S. Products Around the World

USDA is committed to helping U.S. farmers and ranchers identify and access new export markets and expanding trade opportunities. With around 20 percent of farm income derived from exports, it is critical that USDA work with the American food and agriculture community to ensure farmers, ranchers, and food manufacturers and workers can fairly compete against anyone in overseas markets. To support this mission, the Budget includes \$503 million to reduce trade barriers that disadvantage U.S. agricultural

exports and to open new markets for U.S. farm products. Within this amount, funding is also requested to preserve or expand trade valued between \$6 billion to \$8 billion through resolution of foreign market access issues. To facilitate exports to buyers in countries that may not have access to adequate commercial credit, the Budget includes a program level of \$5.5 billion for CCC Export Guarantee Programs to provide guarantees.

Facilitate Rural Prosperity and Economic Development

American prosperity and well-being are intrinsically tied to rural America's ability to thrive in the new global economy; to build and attract an educated workforce and expand its population base; and to use its diverse and abundant natural resources to provide food, fiber, forest products, energy, and recreation. Through the Task Force on Agriculture and Rural Prosperity, the Department has identified actions to improve the quality of life and expand economic development in rural communities. Many of these actions are supported through investments made in USDA lending activities to rural utilities and communities and to strengthen investments in housing programs.

The President's 2020 Budget for USDA includes investments to increase prosperity in rural America that are in addition to the Administration's \$200 billion infrastructure proposal. For USDA, the Budget proposes over \$2.9 billion in budget authority to support \$38.3 billion in Federal funds to stimulate public-private partnerships needed to build rural infrastructure including broadband, community facilities, safe and affordable housing, health services and facilities, and provide capacity-building to help underserved communities become thriving communities. This includes \$690 million in loans that enhance telecommunications infrastructure and \$200 million to support loans and grants to support high-speed broadband series to communities with populations under 20,000. The Budget supports \$5.5 billion in loans for rural electric improvements, benefiting rural residents through the expanded use of smart grid technologies. The Budget also includes \$1.7 billion to improve water and wastewater services for 1.5 million rural residents and \$3.1 billion to provide access to improved community facilities for over 5 million rural residents. The budget provides \$24 billion to lenders in providing 160,000 low- to moderate-income households the opportunity to own their primary residence through the single-family housing guaranteed loan program. The

budget also includes \$1.4 billion to fully fund multi-family rental assistance grants for about 281,000 contracts.

Provide All Americans Access to a Safe, Nutritious, and Secure Food Supply

A plentiful supply of safe and nutritious food is essential to the healthy development of every child in America and to the well-being and productivity of every family. USDA works to help prevent foodborne illness and protect public health as well as aid access to safe, nutritious, and balanced meals and promote a healthy diet. The Budget includes mandatory funds to support estimated participation levels for SNAP and Child Nutrition programs, and discretionary funds to serve all expected participants level in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). It also includes the funding needed to meet our responsibility for providing inspection services to the Nation's meat, poultry, and processed egg product establishments.

Program Reforms

The 2020 President's Budget includes legislative proposals to reform programs to better target Federal dollars, while contributing to deficit reduction efforts. This includes several legislative proposals that we also included in the FY 2019 Budget to better target commodity conservation assistance, and crop insurance that would generate savings of \$47.8 billion over ten years compared to current baseline spending. In addition, the Budget proposes to delink the Section 32 program from customs receipts, and replace the receipt funding with direct mandatory appropriation direct from the Treasury. Our proposal funds all of the current Section 32 nutrition programs and provides stable funding for surplus commodity donations the Budget's proposals will ensure stable historical levels of funding for all the nutrition programs that have traditionally benefited from these activities while also increasing transparency, improving operational efficiency, generating savings of \$5.1 billion over 10 years.

The Budget also supports a foundational principle that those who need assistance have access to wholesome and healthy foods. The Budget includes an approach to nutrition assistance that combines the use of traditional SNAP Electronic Benefit Transfer cards with a USDA Harvest Box that contains 100-percent American grown products. States would have the ability to provide choice to their recipients, including

innovative approaches for the inclusion of fresh products. In addition, the Budget focuses on innovative administrative reforms on outcome-based employment strategies. The Budget also includes proposals to reserve benefits for those most in need, promote efficiency in State operations, and strengthen program integrity. Specifically, the proposals for SNAP have the potential to reduce waste, fraud, and abuse by limiting opportunities for benefits to be misused or trafficked. Combined, these reforms to nutrition assistance programs maintain the Administration's commitment to ensuring Americans in need of assistance have access to a nutritious diet while reducing the cost to taxpayers by approximately \$216 billion over 10 years.

Disaster Relief

As I mentioned earlier, farmers and ranchers were battered last year by a series of monumental storms, robbing them of their livelihoods and inflicting damage well beyond the financial risks they normally assume in their operations. These are the men and women who dedicate their lives to feeding, fueling, and clothing this nation, and we cannot turn our backs on them when they need assistance. In 2017, Congress provided supplemental assistance for producers who experienced losses not covered by existing forms of relief. USDA stands ready to quickly implement assistance, bolstered by lessons learned, for similar losses in 2018 should Congress decide once again to act.

Conclusion

In the face of a growing national debt, the President has offered a fiscally responsible budget that no longer puts off the tough decisions to future generations. The budget will support a robust economy that created 200,000 jobs in January, with unemployment at 3.8 percent in February. Recent estimates predict Gross Domestic Product will grow at a rate of about 2.5 percent. Nonetheless, according to the US Treasury, the National debt has grown to more than \$22 trillion as of March 15, 2019. The Trump Administration has proposed a budget that is fiscally responsible and no longer puts off the tough decisions to future generations. At USDA, we will do our part to reduce government spending.

I would be happy to answer any questions at this time.

Mr. BISHOP. Thank you very much, Mr. Secretary. We appreciate your efforts. My colleague, Ms. McCollum chairs the Interior Subcommittee of Appropriations. And she has a hearing that she needs to chair very shortly. So with the subcommittee's indulgence, I would like to forgo my opening questions and yield to Ms. McCollum so that she may ask her questions quickly and be able to go on to the subcommittee that she has to chair this morning. So I recognize Ms. McCollum.

MINERAL WITHDRAWAL STUDY

Ms. MCCOLLUM. Thank you, Mr. Chair, and I look forward to repaying the kindness and the courtesy that you've extended to me today. Secretary Perdue, you were talking about taxpayers and our obligation to live up to commitments we make to our taxpayers. You have responsibility over our national forests. And it's shared between Mr. Bishop's subcommittee and the subcommittee I chair, Interior Environment.

And two years ago, you testified before the Interior Environment Subcommittee. And, at that hearing, I asked you whether the mineral withdrawal study, which the taxpayers were paying for, and the watershed of the Boundary Waters Canoe Area would continue.

Your response to me and to the rest of the interior subcommittee was—and I quote, "I think your statement regarding the two-year study over sound science, none must know what to do without the facts based on sound science, and we are absolutely allowing that to proceed. You also know that your state has a shot at that after the recommendation as well. So we are determined to proceed in that effort and to let it run its course. No decision will be made prior to the conclusion of that." And I end your quote, sir.

Secretary Perdue, those were very reassuring words to me at the time because you were following the direction of Congress. But those words were completely belied by your actions. You failed to live up to your words when you announced in September the abrupt cancellation of the mineral withdrawal study, 20 months into a 24-month study review, 20 months of collecting public input, 20 months of science-based assessment.

And all you released was a one-page press release and that is completely inadequate. We still have not seen any of the science behind the science-based decision. I have sent multiple letters, first in November and then again on March 1, along with the chair from the Natural Resources Committee, asking your agency to release the relevant documentation from the 20-month review. Your own press release said the review included, and I quote from the press release, "Mineral resource report, a biological and economic impact assessment, potential impacts to water resources, wilderness areas and cultural resources." Secretary Perdue, were all of those reports completed as part of the environmental assessment?

Secretary PERDUE. I can't answer that question directly, ma'am.

Ms. MCCOLLUM. So if you don't have complete scientific reports to review before making your decision to cancel the withdrawal, one has to ask what your decision was based on. Do you have any idea what your decision was based on, sir?

Secretary PERDUE. Yes, ma'am. I do. Would you like me to describe?

Ms. MCCOLLUM. I would like the documentation that you said that you weren't aware of so you couldn't answer my original question.

Secretary PERDUE. Certainly. We will do our best to provide that.

As stated in USDA's December 11, 2018 letter to you and Congressman Grijalva, the Regional Forester of the Eastern Region submitted an application to the Bureau of Land Management (BLM) for an administrative withdrawal on December 14, 2016. DOI accepted the application and issued a Federal Register notice providing for the 2-year segregation on January 19, 2017. The Forest Service initiated work on a withdrawal package and held public meetings during a 15-month period. On September 6, 2018, I announced the cancellation of the Rainy River mineral withdrawal application. The documents being prepared for the withdrawal application were never finalized. The incomplete application package was not reviewed by agency officials.

Applicable Federal laws, such as the National Environmental Policy Act and 16 U.S.C. 508b, provide for procedural review and considerable discretion regarding new mineral leases. The State of Minnesota likewise has environmental review processes for mineral development for the protection of natural resources. A case-by-case approach, rather than an inflexible 20-year withdrawal, will ensure adequate review of future lease offerings. Should the BLM decide to lease National Forest System land—assuming the requisite Forest Service consent to such leasing—the lease terms and conditions, lease stipulations required by the Forest Service, and the requirements of any operating plan would undergo close review and require approval by the Forest Service. I am confident the processes presently in place preserve the high-quality fishing, wildlife viewing, and recreational opportunities Minnesotans and visitors from around the world enjoy in the Boundary Waters Canoe Area Wilderness.

Ms. MCCOLLUM. Are you aware, sir, that the very same month that the abandoned mineral withdrawal proposal in—you abandoned the mineral withdrawal proposal in Minnesota that the United States Forest Service recommended withdrawal of mineral leases on national forest lands in Montana, which is adjacent to a national park, and in Washington State within a national forest?

Secretary PERDUE. I am aware of that.

Ms. MCCOLLUM. All three of these withdrawals were proposed in response to the serious threat of acid drainage from gold and copper sulfide ore mines. Can you explain to me why the Forest Service has a different standard for withdrawal from the study in Minnesota? Minnesota's withdrawal is international forest. It's adjacent to a national park, and it's adjacent to a national wilderness area.

Secretary PERDUE. When I learned that, I think, Minnesota really has the last vote on this as a State government where the Governor had determined already that he was not going to allow this to go forward, it made sense for me to proceed, there has not been one permit issued. There will not be one permit issued until it's a complete environmental impact statement and study based on that and it looked to me to be duplicative after I realized that after my statement to you in May of 2017 at my first hearing. And, there-

fore, the State of Minnesota has the last vote on this. And I would expect them to do what the citizens of Minnesota would decide.

Ms. MCCOLLUM. Well, sir, I respectfully disagree with your analysis of this. Once the Forest Service didn't go forward on the study, BLM started moving forward on lease renewal. Once the study wasn't completed and I asked for all the information on it, the taxpayers paid for it. I have not received it. So, sir, I feel that—that the Forest Service did not fulfill its congressional obligation by moving forward with the full 2-year study.

And the watershed that the Boundary Waters is in—all water is precious, but it makes no sense to me at all that the Forest Service abandoned its due diligence resource. I look forward to receiving the information from you. But I take this issue very seriously. You are stopping—the study started a roller coaster of events that will lead to, possibly, the destruction of these pristine waters. Thank you, Mr. Chair and thank you, sir.

Secretary PERDUE. Thank you, ma'am.

Mr. BISHOP. Thank you, Ms. McCollum.

Mr. Fortenberry.

DISASTER ASSISTANCE PROGRAMS

Mr. FORTENBERRY. Mr. Secretary, there is a lot of consequences to flooding, some of which are—couldn't be perceived before it actually happens, one of which is the loss of onsite grain that was stored. You know, you're dealing with the immediate aftermath of floodwaters rushing over fields, drowning cattle, covering fields in debris and sediment, making the possibility of planting not only difficult, maybe even impossible in many areas. But another manifestation of this has been the loss of grain stored onsite.

So are—do you—so I want to ask you two questions. Are you looking at that issue through the lens of any flexibility that you have in current programming or as a part of the disaster assistance package that is potentially coming through Congress? And then, secondly, I think it would be helpful, particularly for the public, if you could just tick through a high-level summary of what the USDA is already doing in response to the flood.

Secretary PERDUE. Sure. Unfortunately, I would love to answer in the affirmative that these stored grains would qualify for the safety net that is there. They do not currently. And that is why the disaster appropriation supplemental is so important to cover issues that were not covered in the destruction and devastation by the floods flooding there. But this is an area that is not legally or statutorily approved under our safety net provisions currently.

Certainly, the second part of your question, there is the Emergency Conservation Program where we pay a cost share on practices recovering stream banks and other types of debris/sand removal, regrading the land, filling gullies and restoring other properties in that way as well. Certainly one of the uses is the Livestock Indemnity Program where the cattle or livestock losses can be paid for that—due to the disaster and that is—there is an adult cow rate based on that. It is 75 percent of the national average, fair market average so that helps.

The Livestock Forage Program that is utilized to feed, for cattle feed and livestock feed, also qualifies for grazing losses due to

drought, flood or fire in that regard. And then there is emergency livestock assistance for livestock as well. And that is another program that FSA can advise your producers and farmers about that.

The Emergency Watershed Program is another that, again, helps with debris removal from the streams and culverts and, again, helps to reshape stream banks. And that is—in a flood, that is certainly necessary. Vegetative cover, repairing levies and other conservation practices have been destroyed by the floods. Those are examples of that. And we'd be happy—on our website, farmers.gov, you go if you have had a disaster, see what you qualify for. And I would advise your constituents to take advantage of that.

ONSITE GRAIN STORAGE

Mr. FORTENBERRY. Thank you. One other subset of this is, do you have any idea—and it can be just an approximation of how many farmers actually use private insurance to indemnify on-stored—on-site storage of grain because I am trying to get a handle on just how large the problem is. I suspect that is pretty small but I don't know.

Secretary PERDUE. We don't know, either, the exact number. I expect it is very, very, very small.

Mr. FORTENBERRY. I see.

Secretary PERDUE. Commercial operations, elevators, have that kind of stock coverage for their operations. But typically producers, once it is out of the field and crop insurance is no longer a factor, most of them do not cover the stock within their bins over their—their grain production. So I think it's a very, very small number.

Mr. FORTENBERRY. So in the supplemental disaster package that's being written currently, are there—is there enough flexibility in this regard to potentially help you to help with the problem of onsite grain storage that's been lost?

Secretary PERDUE. We would love to be involved in helping the language as the disaster bill moves along to make sure that gives them the flexibility. The 2017 disaster bill was fairly flexible based on giving the USDA an opportunity to design the program to help the most consumers and the most customers out there. But that was not contemplated or specified. And we would like to probably have some additional language that would ensure that.

Mr. FORTENBERRY. OK. Mr. Chairman, I think this is a very important point, either in terms of the architectural flexibility or some specificity for the Secretary so that he can help with this particularly devastating consequence of these floods, which is a secondary effect that was completely unanticipated. So if we could work directly with you all on the type of language that you are perceiving that you need, either, again, at a high level of flexibility or specifically targeted to this, that would be very helpful to me, Mr. Chairman.

Secretary PERDUE. We would be happy to give technical assistance—

Mr. FORTENBERRY. Thank you.

Secretary PERDUE [continuing]. Over the language we think would give us—

Mr. BISHOP. Thank you, Mr. Fortenberry.

Ms. Lee.

SNAP LEGISLATIVE PROPOSAL

Ms. LEE. Thank you very much. Good morning, Mr. Secretary and Ms. Navarro; right? Thank you very much for being here. First of all, let me just say it's no secret that some of us believe that this \$220 billion cut in SNAP benefits is cruel. And the Harvest depression-era food box for SNAP recipients, it's stigmatizing. I mean, how in the world can this box keep up with families who are unhoused or even low-income families who rely on their EBT card, as they are forced to live—and we know the huge homeless population in their cars or with friends.

And so I just wanted to mention, you know, currently, unhoused SNAP recipients are able to get benefits within three days of onsite application. And it can be also mailed to a homeless shelter. So I don't understand this new Harvest box. I know you say it is to reduce administrative waste. But it seems like you are layering more paperwork on warehouses and what have you. And it is to reduce—you say to reduce fraud. But it seems like it is going to go in the opposite direction. And so can you kind of talk about why you think this is a dignified way to help those who need help?

Secondly, and I will try to do this very quickly, you know, it is no secret that I am a former food stamp recipient. And it is a bridge, really, over troubled water for many people. Three-quarters of a million people would lose their SNAP benefits simply because they can't find work through no fault of their own.

We have waivers now which you want to eliminate in your budget where there—when the unemployment rate is at a certain level. There is significant pockets, in my district, for example, of real unemployment rates by—with people of color and communities of color where workers have been displaced, and yet you are talking about eliminating this waiver in your proposed rule.

And, finally, let me just ask you, with regard to people who have serious health conditions and with disabilities, one in four SNAP recipients are people with disabilities. Your rule claims to only target so-called able-bodied adults without dependents. But individuals with disabilities and serious health conditions who don't receive Social Security Disability benefits would be at risk of losing food assistance if they can't log 20 hours of work per week. So many people face barriers to work, especially those who are disabled and have chronic health conditions. It's mean-spirited. I think it's wrong, and I hope that you would reconsider all of these proposed cuts and rules because people need this program desperately.

Secretary PERDUE. Thank you, ma'am. I'd love the opportunity to visit with you in order to give you more thorough than we can do in this meeting today our thoughts about that. Certainly when you describe them as cruel and stigmatizing in that kind of way, we have proposed the Harvest box again. Grocery shopping is changing. Many of your most affluent citizens get their groceries delivered to their doorstep in that way.

We think it is a very effective way and we'd love—if you all don't want to authorize it at all, to give us an opportunity to have a pilot program to prove the concept in that way and to do that. Regarding the able-bodied decisions, that probably—the definition describing

“able-bodied” may need some fine-tuning on that. Certainly we are talking about people who are able to work. When I think they hear the term “able-bodied,” people who are able to work from ages 18 to 49, not senior citizens, not parents with dependents, not pregnant women, able-bodied adults without dependents.

We think 20 hours a week of either volunteer, training or work is reasonable based on the 1996 law that was still contained in the farm bill that was passed this year. The waiver provisions also, when there are pockets of higher unemployment there in this time of national low unemployment, when a particular region has a localized unemployment rate higher, I think, of—than the national average by a factor, then that qualifies for the waiver. We are not doing away with that waiver at all but localized unemployment pockets for whatever reason will qualify, along with the fact that the states also have a 12 percent—no excuses—12 percent margin that they can designate through their 12 percent waiver that was passed in the farm bill. So I’d love the opportunity to personally visit with you to help really persuade you. We are not trying to be cruel or stigmatize people who are on food stamps.

Ms. LEE. Thank you, Mr. Secretary. I look forward to meeting with you, but I can’t help but say, when you look at one in four SNAP recipients who are disabled with chronic health problems, they are going to have to choose between paying their medical bills or food.

Secretary PERDUE. Well, I wouldn’t consider them able-bodied so, anyway, we will have to define that.

Mr. BISHOP. Dr. Harris.

TRANSPORTATION STOPPAGE

Dr. HARRIS. Thank you very much and thank you, Mr. Secretary, for being here. And, you know, I know the—because Congress has kind of handcuffed the administration in terms of the budget and caps until Congress takes action—and I appreciate the Department had a pretty tough job because you actually have to follow the law, I mean, as set forth by Congress with the caps set under the original Budget Control Act.

Anyway, a couple of things. First of all, you know, I’m glad that the Department did propose the new rule for the able-bodied receiving SNAP benefits. I think that is the right thing to do. And I hope that that—that you are able to go forward with that effort. I think that is important that, you know, we give people a—you know, we help them when they are in need but we also help them get back into the—into the workforce, certainly what we need to do with a full working economy right now.

I also want to indicate my support for the move to relocate NIFA and ERS. I think that there—that—you know, obviously taking into consideration the possibility that geographic proximity may be important, there really is no need for these to be inside the Beltway. And I would hope that, throughout the Department—and I think the Department has one of its—one of the points of emphasis is getting the rural economies going. And certainly moving parts of the government into rural areas provides a stabilizing effect on the local economies, as I am sure you can appreciate the cyclicity of the

agriculture industry and the non-cyclicity of the government in general.

So citing those kind of institutions which are agriculture-related in rural areas, I think, is a good idea. Two areas of concern. One is I—and I'm sure you are aware of it, the hours of service requirement for trucking livestock around. Obviously, in my district, the poultry industry is very important. And, clearly, you know, you can't—if you run into traffic, you can't just stop a truck with a truckload of birds. Bad things happen if that happens. So could you just, very briefly, indicate what is being done to address that issue?

Secretary PERDUE. We have been working with the Federal Motor Carriers, the Department of Transportation, for over a year. And that issue has first become aware that the—the rules on safety, hours of service, were negatively impacting not only livestock transfers but also fresh vegetables. And some of these hours of service were creating some unintended consequences. Fortunately, they've been—they have been reasonable.

We have some proposed rules coming out that will better define agricultural products and agricultural exemptions. So from an interagency perspective, we feel like we've gotten the attention of the Federal Motor Carriers. And, hopefully, by this summer, we can see some resolution of some of those hours of service issues over the electronic logging devices.

ROUNDUP CONTROVERSY

Dr. HARRIS. Good. And I'm glad to hear that.

Finally, one issue is this issue, the Roundup controversy. You know, in my district, as you know, grain is very important. The ability to use a very effective agent like Roundup is exceedingly important in maintaining our high crop yields. And I personally am worried when I hear about multi-hundred billion dollar settlements or jury verdicts when my understanding is that the EPA, the NIH have both concluded that this is not a carcinogen, that—you know that the value of the company has decreased 25 percent due to this, and this is just the tip of the iceberg in terms of the cases. I'm worried that it could disappear. Could you—that the use of Roundup could disappear. They could choose just not to assume the risk of selling it anymore. What would the impact of that be on our agricultural community, especially our grain production?

Secretary PERDUE. I think it would be devastating, Congressman. I think, again, much of the productivity increases you've seen over the last 25 years since these type of crop protection chemicals have been out have been almost exponential in that way. If we're going to nine and a half to ten billion people by 2050, we're going to need all the tools at our disposal. I'm afraid that while the groups that oppose these types of uses have not been able to win on the science side, they've chosen the litigation route. And you go before juries with some sad cases of people having cancer, and they used this product once or twice in the yard and are having multimillion dollar awards. I'm hoping that the appeals court will see through this and make better decisions about that. But it would be literally devastating to our productivity capacity worldwide. What we're seeing in the European Union along this route, I call it a technology-free

zone, and I think, again, they will pay the price for this in the future.

Dr. HARRIS. Well, thank you. Is there anything the Department can do to educate Americans about the importance of cutting-edge technology, like Roundup and the GMO crops obviously that keep our American farmers the best in the world?

Secretary PERDUE. Well, we try to advocate for sound science and good scientific discovery about that, which, as you indicated, NIH and others have indicated, there is no health risk there from these chemicals. This is a topical chemical that does not transfer in the soil. And actually it works on the product that you do not want, the weeds, rather than the crop that's produced. So we are concerned. All we can do is continue to communicate what we think the truth that science does. EPA certainly has the ultimate responsibility of approving or disapproving these chemicals. We work with them in helping them to have the research they need to make the best decisions in that regard.

Dr. HARRIS. Thank you very much. Yield back.

Mr. BISHOP. Thank you, Dr. Harris.

Mr. Secretary, it is now my turn.

Secretary PERDUE. OK. I thought you'd already had your turn. [Laughter.]

RELOCATION OF ERS AND NIFA

Mr. BISHOP. As you know, two weeks ago we had a hearing on the proposed relocation of ERS and NIFA. Like Hallmark, you were unable to attend, but you cared enough to send the best. And you sent your representative, Ms. Kristi Boswell, to articulate the Department's position on why this is a good idea.

However, in my opinion, her best efforts were not sufficient to overcome the well-documented and well-reasoned case against such reorganization and relocation. We heard from four former USDA officials with a total of 70 years of experience in the USDA research agencies. We heard from Dr. Gail Buchanan and Dr. Catherine Woteki, both of whom are former Undersecretaries for the Research, Education and Economics Mission Area. And they served under President Bush and President Obama respectively for 10 years.

We also heard from Dr. John Lee and Dr. Katherine Smith-Evans. Both of them are former Administrators of the Economic Research Service and combined have 60 years of service spanning from President Reagan to President Obama. In total, their experience speaks for itself. The understanding of these agencies' functions and how they fit into the greater research community are what's clear from their eloquent testimony.

Besides those individuals who testified, there's an enormous number of groups and individuals who publicly oppose the plan, including the National Farmers Union; the Association of American Veterinary Colleges; the American Statistical Association; the National Coalition for Food and Agriculture Research; at least another 104 agriculture, science and food-related organizations; at least 24 university departments of agriculture and/or economics; at least 37 deans, provosts, et cetera of university agriculture departments; more than 1,150 individual scientists from 47 states.

On the issue of the ERS specifically, besides those who testified, a list of senior government officials publicly opposed includes two former Deputy Secretaries of USDA, two former Chief Statisticians of the United States, several past Undersecretaries outside of the REE area from both parties, past heads of NIFA and ERS, three former heads of the National Association of NASS, former heads of the Census Bureau, two former heads of the Bureau of Labor Statistics, three former heads of the Energy Information Administration and multiple former senior statisticians at the IRS, the Justice Department, the Commerce Department and the CDC.

I understand the Department's position, but after that hearing, I still do not agree that this is a good decision. It does not make any sense, and it seems to be a solution in search of a problem.

You indicate that you want to move ERS and NIFA to be closer to the stakeholders. But upon close examination, this doesn't hold water. Farmers and ranchers may be informed by ERS reports, but they are not direct recipients or users of most of the ERS products. ERS and NIFA are not regulatory or farm program agencies. These agencies do not implement farm programs like FSA or NRCS or inspect plants like FSIS.

You indicate that this will benefit taxpayers, but we still do not have a cost benefit analysis that was used to make this decision.

Finally, you claim the move will help USDA attract and retain highly qualified staff. This, too, is questionable. The subcommittee has only heard anecdotes about commute times, home prices and Ph.D. lifestyles. We've seen no actual analysis to back up the claim that it will be easier to hire outside of Washington, DC.

Your response, sir.

Secretary PERDUE. Mr. Chairman, I'm just amazed that all those people you mentioned could all be wrong. [Laughter.]

Certainly this is maybe one of those areas where you and I are friends, but we'll have to disagree over the issue going forward.

We are somewhat restrained or constrained right now on a cost benefit analysis, because we have not narrowed that list down to the final few and looking for their final invest proposals over the cost benefit. When that happens, we will present that to you all in the subcommittee, so that you all can evaluate that from the best value perspective. We think those reasons that we've been giving and Kristi so well-articulated that day are bona fide and beneficial to retracting and retaining those type of talents that we want in both of those agencies and organizations.

Mr. BISHOP. Mr. Secretary, we hear the assertion, but we don't see the data to back it up. We don't see the problem. It seems the case of—is—back home in Georgia, they would say if it ain't broke, don't fix it. And we don't see that it's being broken. And all of these experts indicate to us that it's not broken, that, in fact, if we do this relocation and the reorganization as you're proposing, that it will break it as opposed to allowing it to continue doing the work that it's doing. So I—and my time is up. I'll revisit this in my next round. But if you'd like to comment, then I'll allow you to make it—

Secretary PERDUE. I appreciate that.

Mr. BISHOP [continuing]. Your comment, and then I will yield to Mr. Moolenaar.

Secretary PERDUE. Some of the experts you talk about were around in the USDA before the internet was developed and the ability to communicate and get work done today. It's a different day in research and others, and we'll, again, as we narrow these down, have a real cost benefit analysis. We will further communicate our reasons and our recommendations and our value and our decision. So thank you.

Mr. BISHOP. Sir, it seems like the cost benefit analysis should be before the fact rather than after the fact. It seems like after the fact you'll be justifying what you did as opposed to using the cost benefit to make the decision.

Secretary PERDUE. We had a beginning cost benefit analysis of what we estimated. What I want to provide to you are the actual cost benefit of the exact location.

[The information follows:]

USDA received 136 Expressions of interest from 35 States to host ERS and NIFA. USDA has retained a consulting firm to evaluate those Expressions of Interest, which recently narrowed down the list to 67 possible locations. The consultant will provide a benefit-cost analysis during the site selection process, and the results of the analysis will be made available as soon as feasible.

Mr. BISHOP. Thank you.

Mr. Moolenaar.

DAIRY MARGIN COVERAGE PROGRAM

Mr. MOOLENAAR. Thank you, Mr. Chairman.

Secretary, thank you. For your presence here. I wanted to talk with you a little bit about dairy. I'm from Michigan, and dairy farmers make up a large portion of our agriculture industry in my district and in our state. A lot of uncertainty there. The Dairy Margin Coverage Program established in the farm bill is going to help, and last month I joined 76 of my colleagues in a letter to you expressing the importance of implementing the Dairy Margin Coverage Program as soon as possible, and I want to thank you for your response. I'm wondering if you could comment on what you anticipate in terms of enrollees for the Dairy Margin Coverage Program as compared to the old Margin Protection Program and then how long the processing period will last.

Secretary PERDUE. I think, again, the Dairy Margin Protection Program that was designed in 2014 for most everyone didn't perform as they had hoped, and it really got kind of a bad name, the MPP program, and that's one of the reasons you all chose to refund the premiums from that, and those will begin going out very soon, hopefully by the end of the month, in that regard. That kind of makes up for it, and then a new name I think also helps.

I expect the enrollment, certainly from those herds that are under the 250, 300-count herds will virtually be everyone. I can't imagine why a dairy farm would not sign up for the program that you all have designed under this new program. Certainly larger dairies that are over that cap may not find it as beneficial in that regard. But certainly the up to 250, 300 cows, it seems like to me it would be a no-brainer.

Mr. MOOLENAAR. OK. Thank you. And then, as you know, this is a crucial safety net for farmers, and many of us are hoping that we can even move up the start date. Is there a scenario where the

Farm Service Agency might be able to open up prior to the June 17 goal?

Secretary PERDUE. This is a pretty aggressive goal that we are struggling to meet, and it's still on track. I don't think that we can do that any earlier. There are a few steps here to do it. It's a fairly complex program. We had to go back. Unfortunately, the first two years of the Margin Protection Program were kept on paper and spreadsheets, and we didn't have a database.

As you know, the reimbursement program has to go back and find out who the record of owner—the owner of record was in that dairy farm and, make sure the money gets to the right people. There have been some changes of ownership, going out of business and others. So it's a very laborious process to get that done. So I think the June 17 date is a pretty aggressive date to get that done. I'd like to tell you we can get it done sooner, but we're probably not going to be able to meet any sooner than that.

UNITED STATES-MEXICO-CANADA AGREEMENT

Mr. MOOLENAAR. OK. Thank you. And just to follow up on some of the dairy issues, I'm encouraged under the USMCA that Canada has agreed to increase market access for dairy products from the U.S. and ending their class 7 pricing screen. Obviously it's important that we pass the USMCA. One of the questions I get is this use of broad-based tariffs, how that's going to affect the passage of the USMCA. I'm wondering if you feel that some of these—if the Administration might be able to address some of the disputes over tariffs on imports of steel and aluminum before the USMCA either is voted on or goes into effect.

Secretary PERDUE. Well, it's no secret I've advocated to the administration over the resolution of the 232 Steel and Aluminum Tariffs between Mexico and Canada. If the President would choose to utilize potential quotas, tariff-rate quotas in lieu of tariffs, I think that would resolve and make the ratification of the USMCA in all three countries more likely to occur sooner.

BROADBAND PROGRAM/OPIOID CRISIS

Mr. MOOLENAAR. I know we're running out of time, but two other issues I wanted to just touch on. Rural broadband, the fight against opioids, those two issues. I know the farm bill had efforts in both of those areas. Can you make any comments on those?

Secretary PERDUE. Yes, our Rural Development is active in the opioid crisis. In fact, our former Assistant to the Secretary that was in charge of Rural Development, we have lost her to the drug czar to work. She'd done such a good job in the opioid area in RD and USDA that she's working full-time on that now, and she knows our programs in Rural Development, so we'll be able to work more in sync with what the Administration's goal is in eliminating the opioid epidemic.

And certainly broadband is an issue that we look for these applications coming in April—end of April, April 23rd, in order to evaluate and get money out, starting hopefully in the early summer.

Mr. MOOLENAAR. OK. Thank you very much.

Thank you, Mr. Chairman. I yield back.

Mr. BISHOP. Ms. Pingree.

CLIMATE CHANGE

Ms. PINGREE. Thank you very much, Mr. Chair.

And thank you, Mr. Secretary and Ms. Navarro, for being with us today. And, Mr. Secretary, I appreciate the many areas you've been willing to work with me on this. The topic of agriculture is a big concern in my state and certainly with me. And I know the Chairman did an excellent job expressing his concerns about the relocation of NIFA, ERS and you were kind enough to give me some time outside of the Subcommittee to express my concerns with you and I think you and I have reached an impasse. But I will look forward to see any future studies you're able to produce. But I'm going to count myself in the camp of, as the Chairman said, someone who doesn't agree with this particular move. But I have such limited time, I want to ask you a couple other questions today.

I've also had a little bit of a chance to talk to you about the issues around climate change and the USDA's role and expressed with you, which I think you share this concern, that it's very concerning when talk about climate change, which I consider a very pressing issue for us, and I think you've seen this particular majority is putting a huge focus on that, but often people want to lay all the blame at the feet of the farmers and not think about the opportunities there for farmers to be real participants. Many of them are, with our conservation programs, and we're fortunate to have another hearing tomorrow where the Acting Associate Chief of NRCS will be with us, so we're going to be able to talk about soil health and a lot of those programs.

But I'm particularly interested in this notion of how the USDA can continue to play an important role in assisting farmers and sequestering carbon in the soil. I think most people think about—when we're sequestering carbon, they all think, well, we should go plant a tree and not understand that organic matter in the soil holds a tremendous amount of carbon and can be a really big part of mitigating that.

And so I know it's a topic you're giving some thought to, but I'm just interested if you could talk to us a minute about the potential USDA role in measuring that or participating and anything you'd like to say.

Secretary PERDUE. Absolutely. I very much appreciate the question because, as you know, farmers and producers have been somewhat really very intense victims of climate change from droughts to floods to other things. And the types of things that USDA is doing from a research perspective, from an applied research and an extension delivery is trying to help mitigate those changes and also contribute.

You mentioned one that we've been really guilty of not talking about enough, of how farmers can be part of the solution of greenhouse gas emissions by capturing more carbon. Their practices that they are doing now regarding no-till, leaving that organic matter in the soil, and carbon sinks that way as well as cover crops, all three of those practices help to capture carbon in the soil.

And if you think about all the arable acres we have in this country, it's amazing the tons of greenhouse gas and CO₂ emission that

we could capture in our soils if we have, I think, the incentivization of maybe a carbon market from Agriculture to do that. USDA would love to play a part in that.

We think it could probably be developed in the private sector, but there has to be some sort of regulatory referee I think out there to quantify that and the degree of capture as well as making sure the rules are complied with and people don't—there have been other efforts here that haven't done that because they've been unregulated, and we think we could provide some help in that regard.

Ms. PINGREE. Do you see a role—from my conversations and what practices are going on now, I understand that there aren't readily acceptable measurement tools. And so kind of, as you said, you have to have a fair referee. Do you see a role for the USDA in doing more with that?

Secretary PERDUE. We do. Research and sensors and technology are being able to quickly identify, quantify, and measure the degree of soil capture in the soil would be one of those tools. And I think that technology is really available now. We just need to learn how to deploy it in a ubiquitous fashion.

Ms. PINGREE. There are seven climate hubs, apparently, as part of the USDA. Is that anything you're actively engaged with or that you're working with?

Secretary PERDUE. I thought we had ten, but it may be seven.

Ms. PINGREE. Even better.

Secretary PERDUE. I think there are ten there. And they are obviously in various regions, internationally even, and we have one in Puerto Rico that talks about different effects of climate change, how we can and how it can affect and inform our farmers about the mitigation techniques of climate, how they can be part of that solution. So they serve as practical research applications and real on-the-ground data—recovery data assessment tools around the country.

Ms. PINGREE. I'm about to run out of time, so I don't have time to follow up. But I'd like to learn a little bit more about what we're actively doing through those and I can follow up with you on that. But thank you for your time.

Thank you, Mr. Chairman.

Mr. BISHOP. Mr. Pocan.

AGRICULTURAL PROGRAMS AND FACILITIES

Mr. POCAN. Thank you very much, Mr. Chairman. I appreciate it.

And thank you, Secretary, for being here. I actually have a follow-up on two questions Mr. Moolenaar had right off the bat. I want to also add about the Margin Protection Program. About a quarter of the people in the program are farmers in Wisconsin. We lost 700 dairy farms last year. Our herds are down about 40 percent in the last decade. So, you know, milk prices are low, and quite honestly, the President's trade policies have really hurt a lot of dairy farmers. So the earlier we can get that going would be very much appreciated, because it impacts a lot of farmers, not just in Michigan, but also Wisconsin. So I really would appreciate that.

Also, to rural broadband, I know in 2019 we added the provision to make sure the speeds were a little higher. I think we were only

at three Mbps download. We're required—we made sure it was 25. But with the cut to funds for rural broadband, by the USDA's own report, 29 percent of farms in the U.S. don't have broadband. 39 percent don't have that speed of Mbps. So if you're almost at 40 percent of the farms with all the work that's happening—we just had someone in talking to us about, you know, tracking cows, et cetera via broadband—we really need that money more than you could imagine. And they say about 10—I think it's billion dollars is what's needed to actually—it's one estimate to get rural broadband out there, any cuts—a \$315 million cut is 3 percent of that. It's a big cut. So I just want to reinforce those two messages.

As you may know, the University of Wisconsin in Madison is home to one of the top plant breeding and genetic programs in the country. It's a large part. It has a very close partnership with the USDA, the Agricultural Research Service. The vegetable crop research unit has been working on innovative plant traits with farmers across the world. Out of that facility, however, it is really, really seriously outdated and needs to have a new vegetable crop research unit there working with ARS. I don't think right now it's on a list to do that, but if you could take a look at that, it is a seriously outdated facility.

Secretary PERDUE. We will. Unfortunately, we see a lot of those. I go on campuses across the country, and all the state buildings are new and modern, and some of our Federal buildings look the shabbiest of any on campus.

SNAP BENEFITS/SWINE SLAUGHTER INSPECTION RULE

Mr. POCAN. Yeah. So just if you could specifically look at that one, I would really appreciate it, because we would really like to get that—it's one of the top priorities for our university, looking forward on some of the agricultural programs they're doing.

Let me just go real quick to SNAP. So I know that with the work requirement, I just want to share a little experience from Wisconsin where this has failed miserably. It is not a good provision. From July 2015 to December 2018, over a 100,000 Wisconsinites lost their SNAP benefits, but only 31,000 were connected with jobs. And so when you have that big of a cut, this is going to have a real impact on people, and often these are noncustodial parents and families that aren't going to get that.

Realistically, Mr. Secretary, 6 years ago I did a week of SNAP of when we did a SNAP challenge here, \$31.50. I don't know if you've ever had a chance to do a SNAP challenge, but I'll tell you when you do, you have a different appreciation.

I bought a bag of oranges, I bought peanut butter, I bought the cheapest bread I could find, I bought my ramen noodles, I was ornery all week. You can check my office.

And, you know, you go to the Trump Hotel here in town and a cocktail could be \$25, right? But now we're at \$33.50? That has not kept up with inflation over the 6 years in a realistic way on food and food products.

So this is something that I really wish you'd take a look at, because it has not worked in Wisconsin. It's not worked the way I think people try to intend to. Instead it has been punitive, and that is a real problem.

And then the last area I think I can get to is under the monetarization of swine slaughter inspection rule. You know, as you're probably aware, meat packing workers are injured at a rate almost 2½ times other industries. They face illness at rates 17 times that of workers in other industries. It's estimated that—the USDA has estimated that the number of Federal inspectors in pork plants could decrease by 40 percent under the proposed rule, and I think we have real concerns over worker safety and on the product that comes out, on people's safety on eating the swine with this rule in place. So can you address that at all? We just have great concerns.

Secretary PERDUE. You know, I had shared some of those same concerns when they described that to me. What I found was most of this effort has to do with presorting the animals to make sure those from a visual perspective that don't look healthy initially are not processed along in between the others, which streamlines that process. We're not having a carcass that does not have a USDA inspector put that stamp on there. That's not the intention at all. The plant personnel who are doing that are the ones who are sorting and gathering and maybe even sending back prior to slaughter and that is a more efficient process. So the line speed, if you're uniform in that way, can operate in a better efficient fashion. What we're doing is asking the plant people to presort those animals. USDA inspectors are looking at every animal that's slaughtered.

Mr. POCAN. And we'll still be watching very closely.

Secretary PERDUE. I understand.

Mr. POCAN. On people as well. Thank you.

Secretary PERDUE. Sure. As will I.

Mr. BISHOP. Mr. Cuellar.

TRADE ON THE TEXAS BORDER

Mr. CUELLAR. Mr. Chairman, thank you so much.

Mr. Secretary, thank you for being here. I wanted to talk about trade. I'm a big supporter of what I call NAFTA 2.0. And, as you know, being from the State of Texas, Texas does a little bit of agriculture, and I want to talk about two things that affects us down there.

One of them has to do with the Department of Agriculture and how you support CBP in facilitating legitimate trade through agriculture inspections and other methods at the U.S. border. One of the things I would ask you to look at is if you can have your folks review to make sure there's sufficient of your personnel down there, because whether it's in Pharr, Texas or Laredo, Texas or wherever the case might be, there's been a lack of some of your folks down there. And if you tell us what we need to do to try to get the chairman and the ranking member of the subcommittee to put a little bit of money because we want to make sure we facilitate that trade through our ports of entry. So I would ask you to have your folks look at that, work with the subcommittee, and certainly we want to be helpful on that part.

Then I have another question about avocados before my time runs out.

Secretary PERDUE. We'll certainly look at the APHIS staffing there on the borders. You're hearing that they've been slowed down or not enough people to process in a timely fashion?

Mr. CUELLAR. Yes. That is one. The other one is—it has to do not with y'all. But as you know, because of, you know, the people coming across, they move CBP—they move 750 CBP officers from doing port inspections to what I call changing diapers and doing other things that are not their mission. And that has slowed down the trade. So I've been—I sent five suggestions to the CBP Commissioner, Mr. Kevin McAleenan, which he understands this very well. So I'm waiting for him to give us some ways that we can move the trade. So anything you can help us down there at the border to facilitate and what we need to do to provide you the proper resources, please let us know.

Secretary PERDUE. That cross-border commerce is very, very important not only to Texas, but to the overall agriculture economy of the United States. So it's really important we expedite those as much as possible.

Mr. CUELLAR. Right. And thank you for your effort last—I think it was last effort, last April, about making sure of the withdrawal. Because when it comes to that trade, there are three options. One, withdrawal, which is a mistake.

Secretary PERDUE. Right.

Mr. CUELLAR. Two, keep the status quo. And No. 3, look at this new trade agreement with a lot of improvement that we have done. So I certainly want to say thank you for your effort to make sure. Because every state, including Hawaii and Alaska—not only the 48 continental States—have trade with Mexico. Every day there is more than 1.5, 1.7 billion dollars of trade between the U.S. and Mexico. That's over a million dollars every single minute. So it's very important. I know you understand that. So I do want to thank you for talking to the President about the importance of those negotiations. Now, let me talk to you about avocados.

Secretary PERDUE. Right.

AVOCADO TRADE WITH MEXICO

Mr. CUELLAR. If you want to see a crisis at the border, it's when you stop avocados from coming in. As you know, there's—I sent you a letter, along with John Cornyn, Senator Cornyn, Ted Cruz, and other Texas members. And I think we are still waiting for a response. We sent it back in November. And basically what we are asking is, there's an APHIS final rule that was published in May 2016, dealing with avocados.

And I think what we are waiting for is the required operation workplan has to be signed; where we bring in the State of Halesco. Maybe some other states, to expand. Because I think right now we are just dealing with the State of Michoacan, in Mexico. But we are trying to expand it, and make sure there's no risk to the public. And unless, if I didn't get a copy of the letter. And it was sent only to Senator Cornyn and Senator Cruz. I haven't seen a response. But I would ask you to look at that, and if it hasn't been signed, I would ask you to do that.

So it's not only the trade agreement, but it's also this workplan. At least on that particular effort. And of course the work that you

all do at the border. And I have met some of your folks that do a heck of a job. And I would ask you to just keep working with us. I got about 20—19 seconds now. Fever ticks.

Secretary PERDUE. Yeah.

FEVER TICKS

Mr. CUELLAR. Fever ticks. We've been adding money on this issue. The quarantine in Texas—and that could affect the cattle industry. The quarantine is not shrinking. And we have added millions of dollars. It's not shrinking. We have to think outside the box, because if we think we are going to dip every cow, it's not going to work. We have to think outside the box. Because there's wildlife. There's animals across the Rio Grande. So I just—any way we can work with this, let us know.

Secretary PERDUE. OK.

Mr. CUELLAR. And that's very important, on that. So I just want to say thank you for the work that you all are doing.

Secretary PERDUE. Thank you, sir. I thought we were making progress on fever ticks. I'll have to check with APHIS again on that. But certainly that continues to be a problem, and can affect the whole Texas and larger cattle industry.

[The information follows:]

I agree with you that we must address wildlife and animals crossing the border. For this reason, APHIS used the additional funding provided in recent years to treat free-ranging wildlife for cattle fever ticks (CFT) as well as inspecting livestock crossing the border. Beginning in FY 2017, APHIS increased the use of feeders with medicated corn to treat tick infested white-tailed deer on private property and expanded these feeders to wildlife refuges in FY 2018. APHIS also used appropriated funding to collaborate with the Agricultural Research Service on several projects including: studies on anti-parasitic products that prevent or control ticks; on-going research to create cost-efficient ultraquiet sprayers for treating ticks found on wildlife; and research and testing on the release of natural parasites that target CFT. APHIS will continue to work with our partners to develop new strategies to prevent CFT infestations from occurring both within and outside of the permanent quarantine zone. While this continues to be a problem, we are seeing progress. In FY 2018, APHIS saw the number of newly tick infested premises decrease from 165 in FY 2017 to 110 (41 premises inside the quarantine zone, 69 premises outside the quarantine zone).

Avocados, I know, this is very important in Mexico. And we have discussed with them, we have some issues obviously with them over potatoes and things we would like to get some resolution over as well. But we don't want to start a guacamole revolution here, with no avocados.

Mr. CUELLAR. That would be the crisis at the border.

Mr. BISHOP. Thank you, Mr. Secretary. Mr. Secretary, is—

Secretary PERDUE. By the way—and can I respond?

Mr. BISHOP. Yes. Go ahead.

Secretary PERDUE. My staff just told me that letter of response on avocados was sent on February 1. So if you have not received—if your office doesn't have a copy, let us know. And we'll get you another copy.

Mr. CUELLAR. Yeah. I would like to see if we have a copy.

Secretary PERDUE. OK. All right.

[The information follows:]



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

FEB 01 2019

The Honorable Henry Cuellar
U.S. House of Representatives
2209 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Cuellar:

Thank you for your letter of November 28, 2018, cosigned by your colleagues, asking the U.S. Department of Agriculture (USDA) to expedite signing of an expanded operational work plan (OWP) for exporting avocados from Mexico. I apologize for the delayed response.

I understand your concerns and appreciate the importance of avocado imports to your State's economy. Officials with USDA's Animal and Plant Health Inspection Service are committed to finalizing this OWP, which will allow other states in Mexico—such as Jalisco—to export Hass avocados to the United States. We will continue to work with Mexico's National Service for Agricultural Health, Safety, and Quality as it addresses matters related to this issue. Of note, the volume of Mexican avocado shipments to the United States increased 20 percent overall from 2015–2018. I look forward to helping importers in your State and others further expand trade of this important commodity.

Promoting trade opportunities remains a top priority for USDA. If you have any questions, please have a member of your staff contact the Office of Congressional Relations at (202) 720–7095.

A similar response is being sent to your colleagues.

Sincerely,

A handwritten signature in cursive script that reads "Sonny Perdue".

Sonny Perdue
Secretary

Mr. CUELLAR. Thank you. Thank you, sir.

REORGANIZATION OF ERS UNDER THE CHIEF ECONOMIST

Mr. BISHOP. Thank you, Mr. Secretary. My turn again. Back to ERS, and the Chief Economist. You indicated that a copy of the beginning cost/benefit analysis had been furnished. I think there have been several requests from this subcommittee as well as from Senator Roberts and Senator Stabenow on the Senate side for the beginning cost/benefit analysis. And none of us, it's my understanding, have received that. What we have received are, again, anecdotal comments. But no cost/benefit analysis that led to the decision to consider this. Now the proposal to move ERS under the Office of Chief Economist doesn't reflect the differences between the two agencies. ERS is one of the 13 OMB designated principal statistical agencies of the United States.

According to the National Academy of Sciences, there is a mandate for these agencies, and I quote, "to be credible, trustworthy and unhindered in its mission, a statistical agency must maintain a position of independence from undue external influences, and avoid the appearance that its collection, analysis or dissemination processes might be manipulated for political or partisan purposes."

Now, its independence is safeguarded under the Code of Federal Regulations by the Under Secretary for Research, Education and Economics, who was designated as USDA's Chief Scientist. The Under Secretary specifically and uniquely directed to quote, "develop mechanisms to address scientific integrity," end of quote, in the Department. There's no such language in the Code of Federal Regulations with respect to the Chief Economist. In fact, the Chief Economist is charged with such functions as the coordination of economic analysis and checking for consistency in Departmental analytic consumptions, consistent with the Secretary's policy implementation.

These are very important functions. But they are not research. The Under Secretary for Research, Education and Economics is the sole person in charge with overseeing scientific integrity in the Department and is the person who can safeguard this, and not the Chief Economist. Your comments on that, Mr. Secretary?

Secretary PERDUE. Certainly. The designation that you indicated would not change if this were realigned under the Office of the Chief Economist. I guess one of the things that I fail to understand as far as any kind of undue influence—to which I concur—is that your Under Secretary for Research, Education, and Economics is a political appointee confirmed by the Senate there. I would suggest to you, if anyone is more subject to political influence, it would be someone appointed by the administration.

Mr. BISHOP. Sure. But Mr. Secretary, they have clearly designated different functions. The Chief Economist's function is basically to the Secretary, whereas the other one is directly responsible for maintaining the scientific integrity of the research.

Secretary PERDUE. I would hope——

Mr. BISHOP. Pursuant to the National Academy of Sciences designation.

Secretary PERDUE. I would hope, sir, that——

Mr. BISHOP. And the OMB designation.

Secretary PERDUE. I would hope that the Under Secretary for Research, Education, and Economics would also feel a little bit that he works for the Secretary of Agriculture as well. If that's not the case, we probably need to revisit that. The Office of the Chief Economist is a career position, of which it is the same as the previous Administration. And the Office of the Chief Economist is the chief user of the ERS data. So those are the reasons it does not appear that today we are going to be able to resolve this issue. But one of these days we are going to resolve our differences on this.

Mr. BISHOP. Yes, sir. And my time is about to expire on this. But we have these thousands of individuals and people with all of these years of experience in the agency, who have seen the interaction, and political interference from time to time. And they feel very strongly that they need to maintain the separateness that currently exists, in order to maintain that integrity for the research.

OK. Mr. Fortenberry.

INTERNATIONAL FOOD AID

Mr. FORTENBERRY. Thank you, Mr. Chairman. Mr. Secretary, I want to talk to you about two additional things: International Food Aid, and Rural Broadband. Let me turn to food aid first. International Food Aid is indispensable to America's humanitarian outreach. Our impulse is not to simply sit around while other people die. And we have done this for decades. It's a part of the fabric of who we are. Secondly, it's inexplicably intertwined with good diplomatic relations.

And third, very much related to our own national security and we create the conditions for stability throughout the world. Finally, our international food aid gives us great conditions for market access for us and our farmers, as well as, indirectly, becoming a price support mechanism. It's zeroed out in this budget. And that's not realistic.

Now, Andy Harris, Congressman Harris, said it very well. Congress's own law mandates that you meet certain budgetary caps and there's certain constraints there. However, I think, Mr. Secretary, you probably would realize that you were not going to not hear this from me, to place an accent mark and an emphasis on just how critical this programming is for the well-being of not just farmers and ranchers, but America and the world itself. Let me stop there, and let you respond. Then I want to turn quickly to rural broadband.

Secretary PERDUE. I don't think you are going to get any disagreement with me, sir.

RURAL BROADBAND

Mr. FORTENBERRY. Fair enough. Let's turn to rural broadband. The Chairman gave some anecdotes that I think demonstrate both the possibilities and then still the gaps. We have, in the last two budgets, given you \$600 million and \$550 million, this past year. Can you briefly unpack what the American Broadband Initiative is achieving?

Before you do that, I want to read some language that I have actually submitted for this year's appropriations process, which I eagerly anticipate the chairman will delight in. It says this. And

what I am driving at here is, broadband is more than a wire. It's more than a program. It has to nest itself within an ecosystem of what I call the potentiality for livability.

And so this is the language I submitted: "You should work on developing metrics that can impact across functions such as telehealth, telecommuting, precision agriculture and the economic benefit to diverse populations. Metrics that assess the quality of life, livability, impact on community inclusion, and vitality in building community social capital."

These are a little bit less tangible than miles of wire, than customers served. But it is actually a critical function to assure that the Broadband Initiative—that I think most of us agree with, as again, the 21st Century architecture for how we move forward with a whole list of concepts on rural development—ought to be considered.

So, these words are kind of open-ended, and it's a bigger challenge. But I think they are absolutely necessary. They're not abstractions. They're absolutely necessary to making sure that your initiatives around broadband actually complete the fullness of the mission of what we are trying to achieve.

Secretary PERDUE. I agree with you whole-heartedly. In fact, I think what you have articulated with the description is what I call the transformative moonshot opportunity of ubiquitous broadband. What we will see is the cultural transformation of rural America take place, because of, I think, as the chairman has talked about, sitting in parking lots of libraries or fast food restaurants, getting a signal there. But just the education component. The telemedicine component. The entrepreneur e-commerce component. The precision-agriculture component. All of that changes the culture. I do literally believe that ubiquitous broadband has the ability to bridge the urban-rural gap that we see dividing more and more in this country.

Mr. FORTENBERRY. I think we have got some work to do. That is very well-expressed. Thank you. Work to do, though, in translating that subset of subsidies and the mechanism by which we subsidize the provision of broadband into metrics that assure the outcome of this greater vision. Or else I am worried that we lay wire.

Secretary PERDUE. We would love to have your input as we continue to revise and reform the criteria of these applications.

Mr. FORTENBERRY. Right. Good.

Secretary PERDUE. And looking at that—

Mr. FORTENBERRY. OK.

Secretary PERDUE [continuing]. That's what we have spent almost a year doing, in order to try to get the criteria of unserved areas, which was the goal of that.

Mr. FORTENBERRY. Well, I welcome that comment. I think it is very important.

Secretary PERDUE. Mm-hmm.

Mr. FORTENBERRY. This shows an alignment of, again, imaginative possibility, and not just more money for traditional programmatic requests.

Secretary PERDUE. No, we are kind of like energy. All of the above.

Mr. FORTENBERRY. OK. Thank you.
Mr. BISHOP. Ms. Pingree.

ORGANIC DAIRY LIVESTOCK

Ms. PINGREE. Thank you, Mr. Chairman. Thank you again, Mr. Secretary, for being here today. And I do want to appreciate my colleagues. I won't ask too many questions about SNAP benefits. But I really appreciate and concur, they are exactly the same concerns I hear from my home State of Maine. So I whole-heartedly agree. I want to ask you a question about the origin of organic dairy livestock. You are always great about talking about protecting the integrity of the USDA Certified Organic Seal. And the 2018 farm bill reiterates that, protecting the integrity, effective oversight of organic production practices, to ensure organic products meet consistent standards for all producers. But there's no consistent enforcement of organic dairy standards.

The industry, organic dairy industry, has been waiting I think 15 years for this issue to be addressed. And the USDA actually removed the origin of organic livestock rulemaking from the Unified Regulatory Agenda in 2017. So it was there, and now it's gone. This is one place where I think everyone in the organic industry is very united. So, will you be planning to take regulatory action? And if not, why not?

Secretary PERDUE. When you say "everyone," we have found there's a good bit of division within the industry over the organic standards in dairy, and doing that. So we'd like to hear more of what your conclusions are based upon, so we can learn from that. But we would love to have a regulatory standard everyone feels that is fair and can comply with. But we hear, frankly, right now, a good bit of division over winners and losers in the dairy organic space. But we are willing to enforce those criteria. It is important to have integrity of the process. But I'd like to know more about what your concerns are in that area.

Ms. PINGREE. Well, that's news to me. So, and again, it may be a little hard to drill down on it right here. I know one practice I hear about quite a bit is taking conventional calves and moving them into organic herds. And many of the smaller producers feel that's a disadvantage. And I don't know if this is disagreement between the large producers and small producers. But I am of the opinion that we can arrive at a scientific basis for what organic integrity is. And maybe we just need to spend a little time talking about where the differences are.

Secretary PERDUE. We will do that. I think it's, my information is a little more complex than that. But we will talk about that.

Ms. PINGREE. OK. Well, I will take that question offline with you, and perhaps see if we can pursue it. I think there's just a general feeling that those standards need to be arrived at.

Secretary PERDUE. OK.

FOOD WASTE/INTERAGENCY BIO-GAS OPPORTUNITIES TASK FORCE

Ms. PINGREE. And that today, there are winners and losers, only they don't tend to be the small producers. They're the ones that operate with a higher standard. Let me just take another quick question. And I wanted to say that I appreciate how much the USDA

and you in particular have embraced the issues around food waste. When we talk about environmental problems, food waste is a tremendous source of methane gas when it ends up in a landfill. And yet another way we need to deal with that. And I think this afternoon the EPA and the USDA are having a joint event. And I appreciate being asked to participate.

I have a feeling we'll be busy voting on the floor, so I may not be there. But I just think moving forward on this, getting a liaison, continuing to do this work, is very important. And what I have learned, how much activity goes on in European countries in particular with all areas of the waste stream, they are just so far ahead of us. And that's not always surprising. But I am glad to see that you are embracing this and also working with the EPA, as it is an environmental issue.

I am interested in the establishment of an Interagency Bio-Gas Opportunities Task Force. I think that's called for in the 2018 farm bill. Because bio-gas can be an on-farm solution for both dealing with animal manure, which can be an enormous problem, as well as food waste, in the areas where we have seen it be successful. We have one operating in Maine. And it's just a really good solution. It produces bio-gas, which is a valuable thing, and reduces methane just being lost into the environment. So, I am wondering how—if you could give me an update on the establishment of that? And are there sufficient resources to prioritize getting that task force up and running?

Secretary PERDUE. Certainly. Again, that's part of the farm bill implementation. And I can't give you specificity this morning regarding the progress that we have made in the forming of that group. But I do know that USDA has been involved in the biogas digester areas. Particularly at large concentrated animal feeding operations that would help to, again, process this gas and the waste there in a very beneficial way. We'll continue to do that, and be informed when we get this council done. I do want to mention, back on food waste. I appreciate you mentioning that. Again, this is really a cultural issue. We're trying to start with the youth, over really making food waste at our plates a moral issue. Of just portion sizes and those kind of things. Learning to. Like, buffets, you see, "Take what you can eat, but then don't throw away the rest." And much of the waste comes from that area. This is a long-term cultural thing like smoking or seatbelts. I know we'll continue at it, to get the real impact over food waste.

Ms. PINGREE. Yeah. And when I worked on a comprehensive bill on food waste, that was one of the areas was really the public education. I think people have no idea we waste 30 to 40 percent. And some of the best efforts going on today are in schools. Share tables, or things to encourage young people. I am way out of time. But thank you very much for your work on that. And thank you, Mr. Chairman.

Mr. BISHOP. Ms. Lee.

SNAP TIME LIMIT WAIVER RULE

Ms. LEE. Thank you very much. Just a second. Let me just go back to the SNAP cuts. \$220 billion in SNAP cuts. And then with the new rule, it looks like over three-quarters of a million people

are going to lose their SNAP benefits. The reason I say it's cruel, and really morally wrong, is one, we have three-quarters of SNAP recipients are working, first of all, already.

Secretary PERDUE. Mm-hmm.

Ms. LEE. Secondly, two-thirds of SNAP recipients are children, the elderly, the disabled. And so you are talking about people who need food assistance, in the wealthiest country in the world. And so this is mean-spirited. It's wrong. And it's going to hurt a heck of a lot of people. And it's going to lead to more hunger. Would you clarify? Again, you said, you mentioned that, in your proposed rule, as it relates to the unemployment area waiver—I wasn't clear whether or not this is a blanket waiver? You're going to repeal that? Or eliminate that? Or are you doing this by unemployment statistics in a region? Or how is this going to work?

Secretary PERDUE. Regional statistics. In the rule, the regulations are, if a localized area has an unemployment rate at a factor times the national rate. I can't recall how many points above it is specifically. But then they can apply for a waiver, and it would be approved. What's happened, I was a governor, Ms. Lee. And what we did is, my role as governor was to draw down as much Federal money as I could. Because Georgia didn't have any skin in the game regarding our food stamp money. You folks were paying for it all. So my goal was to get all we can. We've seen states that have state-wide waivers where they may have one county that fits that criteria. But you also, in the farm bill, allowed for 12 percent exemptions for no reason at all. They can just designate 12 percent categorical exemptions.

Ms. LEE. OK. Well, I understand that, Mr. Secretary. But just—and again, I am using my district as an example. The unemployment rate may be coming down. But when you look at African Americans and people of color, it's not. And there are no jobs or job training programs, if in fact we wanted to reduce this, you know, this unemployment rate.

So this waiver is going to hurt people who are looking for jobs, and the jobs just aren't available because of the budget cuts in workforce training and all of the other areas and programs that we need to make sure that we do provide for jobs for communities of color and people of color. I hope you go back and look at that. Because you can't just look at the overall unemployment rate when you grant a waiver.

Secretary PERDUE. Well, maybe we can come—

Ms. LEE. Or repeal the waiver.

Secretary PERDUE [continuing]. And visit with you, and look at your district specifically from a—

Ms. LEE. And that's just an example.

Secretary PERDUE [continuing]. Demographic perspective.

INDUSTRIAL HEMP PROGRAM

Ms. LEE. OK. Now, let me ask you about industrial hemp. Because in the farm bill, we have legalized the production of industrial hemp. It's caused a lot of excitement across the country, and in California. Now, I understand you are working on the rules and the regulations about the production, insuring and marketing this relatively new crop. Some may be complicated, because it's new.

And so I'd just like to know where you are in the process of developing these regulations for industrial hemp, and when can we expect to see a draft? And also we said—I believe in the farm bill it was to implement it, as much sums as necessary. And I don't believe we have appropriated any funds yet for the Industrial Hemp Program. And so I'd like to find out how much you believe USDA is going to request or need to implement this.

Secretary PERDUE. Well, you are correct. And there's a lot of excitement and interest. It's probably created as much interest as anything in the farm bill. Maybe because it's new, or because it's CBD oil. And it's all the new fad of medicine in that regard. And it probably has a little bit of allure, because the plan is very, very similar to its Federally illegal cousin, the high-THC marijuana plant.

But the fact is, we are not expediting this like we are the dairy program. We're taking this slow. States will still have a primary responsibility in the regulation of that. They are submitting their applications to USDA now. We probably—it's 2019 planting season now. We won't have the rules and regulations out for the 2019 planting season. Our goal is to have them out in plenty of time for the 2020 planting seasons, where we approve the state lands, and the states will provide fees for participating. And they will be the primary regulator of the Federal rules in that regard.

Ms. LEE. OK. Thank you very much, Mr. Secretary.

Secretary PERDUE. Thank you.

Ms. LEE. And I look forward to meeting with you.

Secretary PERDUE. Thank you. Thank you.

ERS/NIFA MOVE

Mr. BISHOP. Mr. Secretary, my turn again. Going back to ERS and NIFA. Of course, we have discussed your proposal to relocate ERS and NIFA outside the greater Washington area. And now that your budget is out, I have some additional questions. And here's what jumps out at me. You request an increase of \$267 million to renovate the USDA Headquarters Complex. \$60 million to renovate the Carver Center in suburban Maryland. \$25 million to pay for the cost of moving ERS and NIFA staff outside the Washington area. It's a total of \$352 million this year. The renovations will vastly increase the seats available in USDA owned, rent-free space in the National Capital region.

Sufficient space will be available to keep ERS and NIFA in the Washington area and not incur relocation costs, buy-out costs, early retirement costs, likely commercial rent costs in a new location, not to mention the disruption of the agency's activities in the process of the transition. In fact, even without any renovations, you currently have 1,675 unoccupied seats in the Washington area right now. That's enough to provide for NIFA, whose lease is up in January, and probably ERS as well. How, in any way, does it make budget sense to move ERS and NIFA outside of DC when there is rent-free space here available?

Secretary PERDUE. Well, sir, if there were rent-free space available, why are we renting space for NIFA that expires in January? That's the—

Mr. BISHOP. Good question.

Secretary PERDUE. That's a great question, is it not? And we are doing a comprehensive space analysis of all of that. That's why our recommendations over this renovation gets a lot. But we have got other agencies. APHIS is in Riverdale. We've got other places out here in Patriot's Plaza. We've got a lot of utilization.

Mr. BISHOP. Just the question, Mr. Secretary, I just want to make sure that we have got the proper cost/benefit analysis up front.

Secretary PERDUE. And that's what—

Mr. BISHOP. Let me transition to another area. And you can respond later to that question.

Secretary PERDUE. Certainly.

[The information follows:]

USDA received 136 Expressions of Interest from 35 States to host ERS and NIFA. USDA has retained a consulting firm to evaluate those Expressions of Interest, which recently narrowed down the list to 67 possible locations. The consultant will provide a benefit-cost analysis during the site selection process, and the results of the analysis will be made available as soon as feasible.

RURAL DEVELOPMENT BUDGET REDUCTIONS

Mr. BISHOP. I have serious concerns about your budget proposal and staffing levels at Rural Development. This is the heart of USDA's mission, and the huge reductions to staff and resources are alarming to us. Compared to the 2018 actuals, Rural Development would lose more than 750 staff years, which is a cut of 17 percent. Rural Development would be cut by more than \$1.5 billion, a cut of 35 percent. And our home state of Georgia had 100 Rural Development staff on October 1st, 2017. But as of March 18th, 2019, it had only 76 people.

I know that your budget has to hit a number, but it is also a statement of priorities and values and from these reductions, I don't see Rural Development as a priority for USDA. With all due respect, how can you justify these cuts considering in your opening statement and your written testimony, you emphasized the importance of facilitating rural prosperity and economic development for our rural communities? Why are they not in the budget, and why doesn't your budget reflect those priorities and those values for Rural Development? I'm very passionate about rural America.

Secretary PERDUE. Well, as I am, and I think again, the contrast that you indicate really has to do with the way the budget is formulated, certainly. The Administration has decided that some of these programs through the Rural Utilities Service, and with EPA and their water program, certainly rural housing with HUD, and the Rural Business Service with the Small Business Administration be consolidated, and you will see some of the efforts in that regard. I can't necessarily say that I agree or disagree with that, although we are going to do the best with the value of money that we are given to facilitate those programs.

Mr. BISHOP. I have about 30 seconds left, and I'm going to yield that back and allow Mr. Fortenberry to go ahead, and I have one more round of questions that I want to get to.

Mr. FORTENBERRY. All right, OK.

Mr. BISHOP. And it won't be ERS or NIFA.

Mr. FORTENBERRY. My turn, Mr. Chairman?

Mr. BISHOP. Yes.

FARMER TO FARMER PROGRAM

Mr. FORTENBERRY. Thank you, thank you. Mr. Secretary let me talk to you about a small program that I am not only aware of. It was started by my predecessor, Congressman Doug Bereuter, called The Farmer to Farmer Program. So, the potentiality is enormous in terms of what we are trying to achieve with the full integration of U.S. agriculture into international markets, again, consistent with our diplomatic space initiatives that the Department plays a critical role in as well.

So, The Farm to Farmer Program is a USDA program, but then is outsourced to USAID. For my perspective, it has become fragmented over the years, doled out, is not adequately branded. Think about a farmer, a producer, who spends a lifetime with a specialty in grain sorghum or millet or rice or corn or livestock production that has a capacity to potentially do something overseas to help his neighbor to develop agricultural practices among those who are marginalized or poor. Again, taking the best of America's humanitarian impulse and sharing it with people worldwide.

That is the fundamentals of The Farmer to Farmer Program, but again, I think it is lost or never adequately developed a brand. I think this is an ideal program for USDA to take back that is completely consistent with your diplomatic missions, takes on a certain lyricism and poetry to what you're doing, but if it could be regenerated with inside your Department, I think the potentiality to reach the greater intentions of your mission are really there.

Again, it's a small program, but I am very interested in this because it is a hybrid program that cuts across multiple intended outcomes.

Secretary PERDUE. We would welcome that. I am not sure really the genesis of moving it to USAID. We were working with private sector partners who have experience as well as the World Food Program and Governor Beasley in that effort in some of these countries as well to do that. There is, certainly. I can almost see it like, I guess, its score, the big business executive's thing from a farmer perspective, you know, doing that kind of thing.

Mr. FORTENBERRY. Yes, you mentioned Governor Beasley doing a tremendous job with the World Food Program. Again, let's think creatively about the constructive partnerships that could potentially be out there that use our expertise of our farmers and their good heart and good will to be an adjunct to our diplomatic missions to help the poor around the world. This has huge potentiality and we have got a Foreign Agricultural Service that, from my perspective, doesn't really touch this at all as far as I am aware.

And yet, tremendous amounts of resources devoted there with embedded personnel and embassies throughout the world. Why couldn't this be folded under there? Why couldn't David Beasley's, or the World Food Program, which enjoys tremendous international stature led by the United States? Be a partnering component in solidarity with this?

Again, tie the extension model in our country has been a tremendous model if we get where the economic development largest of our own country comes from, but again, it is consistent with those

ideas as well. Transferring technology and assistance to those in need by the farmers who have the capacity at a certain point in life to be effective volunteers force worldwide. It is like a diplomatic agricultural corps.

Secretary PERDUE. I am not aware. I am not aware of whether that is a statutory move or administrative move, but I would be happy to explore that with you.

Mr. FORTENBERRY. Well, I would appreciate that. I kind of slogged through this in the last farm bill, and we got some modifications. Not fully to where I want to go because again, what I am talking about is a substantive realignment of the way in which the program has been implemented. I don't know if you have the flexibility to do that or not. Perhaps you do but again, I think this could serve many, many purposes that are consistent with the vision of the Department.

Secretary PERDUE. We do similar types of things, certainly, in our Foreign Agricultural Service, that I think is in 63 countries, so I think the potential is there.

Mr. FORTENBERRY. All right. I yield back, Mr. Chairman. Thank you, Mr. Secretary.

LIVESTOCK INDEMNITY PROGRAM

Mr. BISHOP. Thank you, Mr. Fortenberry. Mr. Secretary, this is not about ERS and NIFA. A constituent of mine whom I believe you know must be dealing with one of the more interesting and bizarre Livestock Indemnity Program cases in history. His flock of organic chickens are preyed upon by bald eagles. There are now close to 80 bald eagles on this property, as I have been told. I have been to his farm and I have witnessed three, four, five bald eagles in one tree. It is quite a sight to see, and it is quite a unique problem.

Since 2015, FSA has denied his claims to receive payment under the Livestock Indemnity Program on several occasions. He has appealed all of those decisions to the Office of Hearings and Appeals, which ruled in his favor every time, saying FSA's decisions were erroneous, but still, FSA refuses to act on the Livestock Indemnity Program applications.

It has been nearly 5 years, and he still has no closure one way or the other. Can you discuss why FSA could ignore the Office of Hearings and Appeals' rulings, and can you give me a sense of how many Livestock Indemnity Program applications are denied by FSA, and are they often overruled by the Office of Hearings and Appeals, and what becomes of them once they are overruled?

I understand that most Livestock Indemnity Payments are due to livestock that are lost to extreme weather. Is this just a case of FSA not having a lot of experience with predatory bird claims, or does the Office of Hearings and Appeals have the authority to determine the final payment or the settlement of this case? I mean, he has been waiting for five years and continually upheld by the Office of Hearings and Appeals, but USDA just refuses to pay him.

Secretary PERDUE. Well, those are good and complex questions. I will have to get back with you on the answer. I did not realize we could not comply with the Office of Hearings and Appeals ruling on that, but I will have to determine where we are, you know, and answer all the questions regarding the amount of livestock indem-

nity. Are there any other cases where it is not death or caused by a disaster or those sorts of things, but I am not aware of anything else from a predatory nature. I guess the sheep crowd could probably claim from wolves or bears or whatever, but I am not aware of those. But I am not aware that we could totally disregard the Office of Hearings and Appeals' decision.

Mr. BISHOP. It is our understanding and we have seen the decisions that have been referred back to FSA repeatedly with instructions from the Office of Hearings and Appeals, and FSA just does the same thing over and over again, almost as if they are determined that this individual and this farm will not get relief from FSA under the Livestock Indemnity Program.

Secretary PERDUE. I will get you a response on that. Hopefully, it will be more satisfactory than NIFA and ERS.

[The information follows:]

The National Appeals Division (NAD) has issued several rulings dealing with the referenced producer for 2015 and 2016 Livestock Indemnity Program (LIP) applications for assistance. None of the NAD rulings make any final determination on the producer's eligibility for LIP benefits. NAD merely ruled that the Farm Service Agency (FSA) erred when it initially denied the producer's LIP applications and determined that FSA must reexamine the loss evidence to determine if the producer had provided reliable records to substantiate their losses. In a subsequent appeal, NAD determined that FSA erred since a final decision on the LIP applications had not been made.

In response to the latest NAD ruling, FSA is moving forward to bring the 2015 and 2016 LIP applications to a close and has reached out to the producer with regard to these applications. FSA will issue a final decision and if the producer does not agree, the producer can choose to seek an administrative review of that decision.

CLOSING STATEMENT—CHAIRMAN BISHOP

Mr. BISHOP. All right. Thank you very much, Mr. Secretary. We will look forward to that. We know that you are definitely service-oriented, and you want to make sure that the stakeholders of USDA get the full customer service to which they are entitled.

Mr. Secretary and Ms. Navarro, thank you for being here today. We look forward to working with you as we continue the Fiscal Year 2020 Appropriations process. I know that there are a few things that you are going to get back with us on, and we look forward to submitting a few additional questions for the record, but we appreciate your diligence in getting the responses to us in a timely manner.

So again, I would like to thank you for your cooperation and thank you for the job that you work so hard to do for the constituents and the stakeholders of USDA, because we want to make sure that we continue to produce the highest quality, the safest, and most abundant, the most economical food, fiber, and fuel anywhere in the industrial world.

So, again, thank you for being here and with that, the subcommittee is adjourned.

Secretary PERDUE. Thank you, Mr. Chairman. Thank you.

WEDNESDAY, APRIL 10, 2019.

**ECONOMIC OPPORTUNITIES FOR FARMERS THROUGH
SUSTAINABLE AGRICULTURAL PRACTICES**

WITNESSES

**KEVIN NORTON, ACTING ASSOCIATE CHIEF, NATURAL RESOURCES
CONSERVATION SERVICE, USDA**

NATE POWELL-PALM, CERTIFIED ORGANIC FARMER, MONTANA

**JASON WELLER, SENIOR DIRECTOR OF SUSTAINABILITY, LAND
O'LAKES, SUSTAIN, MINNESOTA**

OPENING STATEMENT BY MR. BISHOP

Mr. BISHOP. The subcommittee will come to order.

Good morning, and let me welcome everyone to today's hearing.

First, I would like to give a shout-out to some of my colleagues, Ms. Pingree, Ms. McCollum, and Congresswoman DeLauro, for suggesting the topic for our hearing this morning. I am delighted that we are having the hearing.

Today's topic is sustainable agriculture, specifically the economic opportunities for farmers through such sustainable agriculture practices.

To be sure, farmers have known for a long time that implementing simple practices, such as crop rotation and no-till, can increase both soil health and the bottom line.

There is a renewed focus more broadly now on sustainability, and rightly so. Our farmers, consumers, and industry are more conscious than ever about how their actions will impact air quality, water quality, soil health, and animal life. Consumers want to know where their food comes from, and they are increasingly drawn to products that are produced in a sustainable manner.

That is why I am very excited about our witnesses and the discussions that we are about to have this morning. Agriculture is a leader when it comes to sustainability and conservation, and it deserves public recognition for what it has done and what it is doing in this area.

Moreover, sustainable practices can reduce the impact of natural disasters—and, unfortunately, as we have seen too often over the past several years, droughts and flooding have cost farmers billions of dollars—improve sustainability, and help reduce those negative impacts.

This is an exciting time for agriculture. New technology and research allow farmers to make more precise and cost-effective business decisions. They can increase yield, while at the same time decreasing waste. I think everyone can agree that it is a win-win. And that is what we want to convey today: Agriculture is doing its part.

One of the bigger challenges for farmers is just understanding all of the tools that are available to them. We discussed this yesterday with Secretary Perdue, as a matter of fact, and I hope we can explore that today here as well.

Our panel includes Jason Weller, a senior director for the Land O'Lakes SUSTAIN Program. I am pleased to note for some colleagues who have been on the subcommittee as long as I have that Jason worked for this subcommittee and then went to USDA and ultimately became the chief of NRCS.

Welcome back, Mr. Weller.

Mr. WELLER. Thank you, sir.

Mr. BISHOP. We also have Nate Powell-Palm. Nate is a young farmer from Montana who has taken sustainability to heart and he shows what is possible with a little hard work. Let me rephrase that and say a lot of hard work.

Finally, Acting Associate Chief Kevin Norton of the Natural Resources Conservation Service. He is here to fill out the picture of Federal resources that can help farmers undertake sustainable practices and to share his years of experience on the ground at NRCS with us.

So I will defer the comments from our ranking member, Mr. Fortenberry, until his arrival. But with that, I would like to recognize our distinguished guests for brief oral statements, and then we will proceed with questions. And without objection, the entire written testimonies will be included in the record.

So please proceed in any order that you wish. You can go left to right, you can go Mr. Weller first. It does not matter.

So if you would, we will start with Mr. Palm.

Shall I say Powell-Palm or Palm?

Mr. POWELL-PALM. Powell-Palm, please.

Mr. BISHOP. OK. Mr. Powell-Palm.

OPENING STATEMENT BY MR. POWELL-PALM

Mr. POWELL-PALM. Thank you, Chairman Bishop, and thank you, Ranking Member Fortenberry, when he is here, and distinguished members of the subcommittee, for the opportunity to testify today.

My name is Nate Powell-Palm and I am a first-generation grain farmer and cattle producer from Belgrade, Montana. On my farm, Cold Springs Organics, I raise just about 875 acres of durum wheat, yellow peas, grass hay, alfalfa hay, and cattle.

I got my start in agriculture when I was 9, when my parents let me purchase a steer to raise and take to the Gallatin County Fair. My parents themselves aren't farmers by profession, but certainly by heart.

From that experience with the 4-H calf, I became determined to get into the cattle business. When I was about 12 years old I applied for and was awarded a junior agriculture loan from the Montana Department of Agriculture for \$3,400 to purchase three bred cows, a little bit of fencing, feed, and a stock trailer to haul them around in.

After three calf crops, my small herd was growing, I was really enthusiastic. However, my bank account was not growing.

And so, in 2006, I became acquainted with certified organic agriculture. I purchased certified organic hay from a few really pio-

neering farmers in Helena, Montana, and over the next 2 years I learned about this world where farmers actually request to be certified and inspected and they are really interested in having the excellence of their farming practice recognized and to sell into a market where demand is outstripping supplies. Folks are really interested in purchasing and paying a premium for the crops that certified organic farmers are growing.

So in 2008, I applied for and received organic certification, and I just had my 11th annual organic inspection.

After my first organic inspection, I quickly joined the Montana Organic Producers Co-op, which is a 22-member regional marketing organization for grass-fed certified organic beef, and after joining it I was able to realize about a 30 percent premium on my calves and finished animals. And because of that premium and that stability in the market, I was confident that I could go out and start expanding my operation and thinking about leasing more land and possibly hiring someone.

CERTIFIED ORGANIC

Shortly after my junior year of college I sent out 90 cold call letters trying to tell local landowners that if they would lease to me, I would get their farm certified organic, I would be able to pay them above market rates, and I would be able to start a process of building soil on their ground. And I think that I got about 10 letters back and they were all really excited about the prospect of working with me. And so that is ultimately how I came to lease about 875 acres in the Gallatin Valley in Montana.

By 2017, I had 240 acres in a grain rotation along with the balance in hay and pasture. And while I had good markets for the wheats, I knew I could really improve my soil and my crop rotation if I could be raising and selling legumes, including yellow peas, garbanzo beans, lentils, but I just needed to find a customer, a contract customer.

So in 2016, I joined the Organic Trade Association, and during their annual fly-in, several farmers were invited to sit in on the Grain Council panel. And at this meeting, we really tried to express to grain buyers, large institutional grain buyers, that the folks who are buying grain really need to buy an entire rotation, not just wheat or not just one crop, because in order to diversify our farms we need to be able to sell those respective crops.

And so in that meeting there was a representative from Annie's Mac and Cheese, which is a subsidiary of General Mills, and the folks at Annie's reached out to me and said they wanted to reimagine their traditional pasta products by incorporating yellow peas into their rotation. And so, by doing so and working with me, they would give me a market for my yellow peas.

And just a brief history on yellow peas and why they are so fantastic. They fix nitrogen, which is the biggest fertility input that farmers have. And so, by fixing nitrogen, I am getting paid to grow my own fertilizer.

They are also going to purchase my durum wheat. And they are going to make this protein-packed certified organic product that is something that consumers are really interested in purchasing.

So the first batch of this pasta here hit the shelves in the spring of 2018, and we have our second edition of single origin pasta coming out, incorporating more farmers and more rotations from Montana.

And so when farmers can receive a premium in the market for sustainable practices it is a win-win. I chose organic to do that, and everything I have just shared with you is possible because of the trust consumers place in the organic seal. It is this transparent rigorous certification process that allows farmers to be economically compensated for clearly defined land stewardship practices.

In order for this opportunity to stay available to farmers like myself, USDA must accommodate and be accountable to advancing organic standards and to emphasize continuous improvement in an organic public-private partnership. And I hope others have the availability and this opportunity stays available to farmers in the future.

Thank you.

[The information follows:]

Thank you Chairman Bishop, Ranking Member Fortenberry and distinguished Members of the subcommittee for the opportunity to testify today.

My name is Nate Powell-Palm and I am a first generation, certified organic, grain farmer and cattle rancher from Belgrade, MT. On my farm, Cold Springs Organics, I raise 875 acres of certified organic wheat, field peas, straw, cattle and hay.

I got my start in agriculture when I was nine years old and my parents, who while not farmers by profession but certainly by heart, allowed me to purchase a calf to raise and sell at the Gallatin County 4-H Fair. From learning how to control and gentle a 1200 lb animal to keeping good business records, I fell in the love with the day to day work of livestock raising.

From that first experience raising one 4-H calf, I became determined to get into the cattle business. Towards the end of my 12th year, I applied for and was awarded a junior agriculture loan from the Montana State Department of Agriculture. With the \$3400 note, I purchased 3 pregnant cows, a stock trailer, feed and fencing and I was off to the races.

After 3 calf crops, my small herd was performing well and my enthusiasm for agriculture was growing daily. My ranch bank account however, was not. Indeed, I started a firewood chopping and delivery company when I was 14 in order to ensure I could make my loan payments. With each drop of the ax, my thoughts went to what I was missing in my understanding of farming.

In 2006 I first became acquainted with certified organic agriculture when I purchased certified organic hay for my cattle from two pioneering farmers in Helena, MT. Over the next two years, and hundreds of conversations, I learned about this other farming world- a world where farmers *request* to be inspected and certified to verify the excellence of their practices, where farmers sell their crops and livestock into markets where demand outstrips supply, and consumers are willing to pay a premium. A world which makes farming for a good living, possible. I learned about the world of certified organic farming.

Certified organic farming, in its essence, is the process of maximizing farm land's production potential by building the soil, increasing the soil carbon organic matter, suppressing disease and weeds through crop rotation, and enhancing natural resources on the farm such as riparian areas and wildlife habitat. Organic farming gives farmers the chance to omit synthetic pesticides, herbicides, and fertilizers from their farming practice and replace them with practices that strengthen rather than deplete their soil. Practices like crop rotation, cover crops and the incorporation of livestock manure.

Certified organic farming practices hold not only solutions to the financial volatility of farming but also, and maybe more importantly, offers potential answers to the unpredictable future facing all farmers and people. As the climate changes, we farmers need our land to be resilient. The largest possible sink for pulling carbon out of the air is building organic matter in the soil. Organic farming shines in this arena. According to Ghabbour, E.A. *et al.* 2017, certified organic farms sequester 26% more carbon than conventional farms. Increased organic matter (carbon) in the soil means increased water holding capacity- this is especially impactful as greater water holding capacity means that during periods of immense precipitation the land absorbs more water with less running off as flood water. In times of drought water holding capacity means there's more water in the soil for the crops.

And while increasing organic matter not only makes our farmland more healthfully adaptive to climate change, it also makes it more resilient to market change. By adopting organic practices such as crop rotation to build soil fertility, and control weeds and pests, farmers spend less money on off-farm inputs like synthetic herbicides, fertilizers and pesticides. In lean economic times, like the market conditions we are currently experiencing in conventional agriculture, less money leaving the farm means less chance of farmers defaulting on lines of credit, less farm bankruptcies, fewer broken families and communities, and one less generation of Americans who are forced to leave the farm due to farm insolvency. Facilitating a farming system which allows farmers to replace these expensive off-farm products with organic practices results in greater soil health and carbon sequestration. Certified organic farmers have fewer dollars leaving the farm while additionally receiving market premium due to the robust demand for organic food.

Indeed, according to Crowder et al 2015, organic farms are 35% more profitable than conventional farms.

Certified organic farming works because the rules are enforced. The National Organic Program, a division of the USDA, offers accreditation to certification companies who administer the certification process for farmers and food manufacturers. Farmers opt in to be certified, pay the fees necessary to administer the program, and gain access to the thriving organic foods market.

In 2008 I applied for and received organic certification via the Montana Dept. of Agriculture which is National Organic Program (NOP) accredited by the USDA. In 2018 I completed my 11th organic inspection.

After my certification was granted I quickly joined the Montana Organic Producers Coop, a 22 member marketing cooperative through which member producers sell certified organic, grass-fed beef to large institutional buyers, like Whole Foods. Individually, we are too small to qualify as a supplier but together, we have made a formidable certified organic supplier partner to a number of institutions. I currently serve as the Vice President of the Board for MOPC.

In conventional ranching, producers typically sell their calves to a feedlot shortly after weaning off the mother cows. Joining the Montana Organic Producers Coop allowed me to keep my animals and finish them myself on grass pasture (raising them all the way until they are large enough to harvest for meat) while receiving upwards of a 30% price premium. Because of this market, I was confident that I could go out and begin leasing larger pieces of land to expand my herd and ranching business.

Shortly before starting my junior year of college at Montana State University, I sent 90 cold call letters to nearby land owners sharing how, if I could lease their land, I would transition it to certified organic, improve and build the soil and be able to pay them an above market rent. I received 10 replies and began my expansion, ultimately leasing the 875 acres of organic land I farm today.

One of the multiple components to qualifying for organic certification is practicing a robust crop rotation, a farming practice where farmers don't grow the same crop year after year. To rotate my hay fields I decided to grow a 20 acre field of certified organic soft white spring wheat, the type of wheat one would use to make croissants or cookies. After selling this wheat crop, I found that I could nearly double the net revenue from a field by growing certified organic grain in rotation with my pasture and hay, thus allowing me to further consider growing my business and hiring other young people interested in farming.

My story is just one of thousands concerning the economic opportunities found in organic farming. In 2016 Penn State University published a study titled U.S. Organic Hotspots and their Benefit to Local Economies in which they found that when a given U.S. county realizes a high number of organic farms and food manufacturers, the average household income for that county is \$2,000 higher than the national average, and the poverty rate of that county is lowered by 1.35%.

By 2017 I had 240 of my acres in a grain rotation with the balance of my land in pasture and hay and had added an employee to help with the farming. While I had good markets for my organic wheat, I knew I could further improve my soil and productivity by raising legumes such as yellow peas, lentils, or garbanzo beans. I just needed to find contract customers.

In 2016 I joined the Organic Trade Association and attended their 2016 Policy Days Conference here in DC. At this conference, I sat in on the annual Grains Council meeting. Several farmers, myself included, noted to the grain buyers in the room, that in order to increase farm soil health, crop diversity and economic stability we need to have demand for all of the crops in our rotation, not just wheat. We need grain buyers to take our entire grain rotation. To do so we need food makers to be creative in what ingredients they use to make foods traditionally eaten by every day Americans.

In that OTA conference meeting was a representative for Annie's Mac and Cheese, a subsidiary of General Mills Inc. In 2017, the folks at Annie's reached out to me and said

that they wanted to re-imagine their traditional mac and cheese by adding yellow peas to their pasta recipe. In doing so, they would give me a market for my organic yellow peas (which by fixing nitrogen critically improves my soil fertility), buy my durum wheat, and deliver a protein packed certified organic elbow pasta to consumers who are eager to spend their dollars on products they know improve the environment, combat climate change, and support the economic sustainability of the farmer. The first batch of this pasta hit the shelves bearing my and my Farm's name and story in 2018, and was a resounding success. We have our second edition of single origin, complete crop rotation food products coming out this spring with more Montana organic farmers now participating.

Everything I have just shared with you is possible because of the trust consumers place in the organic seal. This trust stems from the guarantee that through the National Organic Program organic unconditionally means organic. It is a transparent, rigorous certification process which allows farmers to be economically compensated for clearly defined land stewardship practices by which all certified organic farms agree to abide through the certification process. Since 1990 the organic industry has grown from \$1 billion dollars to \$50 billion in 2017. And this double digit growth is not stopping. According to Nielsen. *UPC Scan Data of 100,000 Households*. (2016), 82% of all American households have certified organic products in their refrigerator or cupboard. This market growth, consumer trust, and farming community impact is only possible through a fully funded National Organic Program who's critical job it is to maintain an unflinching accountability to the highest of organic practices and standards.

As we see though out the country, the challenges of farming, including climate change, are resulting in farmers being forced to give up their agricultural heritage and profession. But we do have a solution: certified organic farming.

Mr. BISHOP. Thank you, Mr. Powell-Palm.
Mr. Weller.

OPENING STATEMENT BY MR. WELLER

Mr. WELLER. Good morning, Mr. Chairman and Mr. Fortenberry and members of the committee. I really appreciate the opportunity to be here today.

Mr. Powell-Palm, drop mike. I think you just summarized really the sustainability journey that in part we are trying to advocate for. My former colleague, continued colleague, Mr. Norton, and I have been friends and peers for a long time, and we have been in the space of sustainable agriculture through USDA.

Let me talk a little bit, back up a little bit, and first talk about my pride in terms of public service in having served, of course, this committee, but also in other Federal offices. But, of course, really proud of my time and being a colleague of Kevin Norton and the NRCS team at USDA.

But also equally proud of my time now working for a farmer cooperative. And so I joined the Land O'Lakes team about 2 years ago. And in part working for a co-op, having the discipline, but also responsibility to work for America's farmers and for members of our cooperative system to help them be successful.

And that has really been a shared vision between USDA and ultimately our cooperative owners and our cooperative system, is how do we help farmers like Mr. Powell-Palm be economically successful, but also not just be successful 1 year, it is really for year over year, multiple seasons, multiple crops, if not multiple generations.

And so, ultimately, that is what we aspire to do through Land O'Lakes, but also through USDA, and how do we help ensure the economic and profitability success of producers like Mr. Powell-Palm, but also ensure the vitality, the productive capacity of our environment and our soils and our waters to grow for generations to come.

So none of this is possible, and in part I just want to also then commend the committee for its leadership and talk briefly about how the programs that you all oversee and invest in truly are an investment in the public trust, in this case providing for the foundation upon which the science, the conservation programs, the practices, the delivery infrastructure, to take all this expertise out in the field and allow for producers like Mr. Powell-Palm to be successful.

THE NATURAL RESOURCES CONSERVATION SERVICE

And so more than ever now, seeing it from the private sector and seeing it from where I work with the cooperative system hat, you have to have a place like USDA, and in particular an organization like NRCS. It is the only thing like it on Earth. It is a special place that employs visionaries and leaders, people like Gilbert Borrego from New Mexico, Tim Griffiths from Montana, Dr. Dave Naugle from Montana, Jane Hardisty from Indiana, Leonard Jordan from Georgia.

There are leaders and visionaries across this organization who toil and work day in and day out to provide service to the public,

but also crucially service to the farmers, and it is upon their shoulders upon which we now stand. And much like how in other sectors where the public has invested in science that return on investment not only creates an internet or creates an aerospace industry, it also creates a really successful and vibrant agriculture sector.

So coming to Land O'Lakes, the Land O'Lakes story. We are a 98-year-old farmer co-op. We started in St. Paul, Minnesota, 98 years ago as a dairy creamery. And this cooperative system approach, where farmers are coming together to co-invest for their shared benefit, to invest in innovation, but also then in shared support for each other is really the cooperative way.

And so I am really proud to be now working for a Land O'Lakes cooperative system where now I represent and proud to be here talking for and speaking on behalf of 3,700 owners across the whole system, include dairy operators, row crop farmers, local and regional farmer cooperatives, and independent ag retailers, collectively coming together.

And Land O'Lakes as a board having the vision and to create now the unit I work for, this team called Land O'Lakes SUSTAIN, where our goal is to help our cooperative system build up the capacity and expertise to work in partnership with NRCS, but then also to be able to then work directly with growers like Mr. Powell-Palm across the United States to help them identify conservation opportunities on their lands.

In this case, conservation being in balance, the balance being profitability and ensuring they are successful for this crop season, but also always having that stewardship hat on and ensuring the long-term capacity of their fields to be productive year over year.

And so I am excited for today's hearing. This is a really important topic. And that is about our future ability not to just feed ourselves, but the world, but always holding in balance this ability to address changing weather, extreme conditions. But ultimately helping that family farmer be successful and stay on the land and be able to pass that asset and that land in that rural community, keeping that intact and allowing it to be passed on to future generations.

So thank you very much for today's hearing. I look forward to the conversation.

[The information follows:]

Testimony of Jason Weller
Senior Director of Sustainability, Land O'Lakes SUSTAIN
Before the U.S. House Appropriations Agriculture, Rural Development, FDA & Related
Activities Subcommittee
April 10, 2019

Chairman Bishop, Ranking Member Fortenberry and Distinguished Members of the Subcommittee, I am Jason Weller, former Chief of the Natural Resources Conservation Service at USDA and currently Senior Director of Sustainability at Land O'Lakes SUSTAIN.

Every day, farmers, ranchers and private forest owners make stewardship decisions that impact over 1.4 billion acres of non-Federal rural lands – or over 70 percent of the landmass of the contiguous 48 states. If we care about the long-term ability of these working rural lands to continue to feed, clothe, and fuel the world while also ensuring a resilient environment that provides us high-quality and abundant natural resources, then it is in all of our interest to find collaborative and innovative approaches to help these private land managers be successful. The bottom line is this: On-farm conservation is not just good for the environment, it also supports a stronger rural economy through increased resiliency and profitability for farmers and ranchers.

Crucially, no one entity or sector has all the answers and capabilities to accomplish alone what is needed, not the public sector nor the private sector. But because of surging innovation and growing consumer interest in sustainability, I am more excited and optimistic about our future and path forward than I have ever been in my career. At Land O'Lakes, Inc. – the third largest farmer-owned cooperative in the country – we define agricultural sustainability as working with our farmers to protect soil, water, and air natural resources in a way that is economically viable. We're uniquely positioned to lead the way on this work as a "farmer-to-fork" cooperative that spans the value chain, with more than 3,600 members including dairy farmers, ag producers, local independent ag retailers and farm supply co-ops. Our network of member-owner ag retailers and local co-ops, who serve as farmers' trusted advisors, are especially critical to our delivery of new stewardship solutions, technology and innovation to the farm gate. In my role at Land O'Lakes, I work with a team of innovators supporting farmer-led stewardship. I am proud of what we've achieved and appreciate the opportunity to briefly share examples with the Subcommittee.

Today I would like to outline two key areas that I see as significant emerging opportunities:

1. Advancements in technology help farmers to target conservation with the best return to both their bottom line and the public's bottom line.
2. Growing consumer and marketplace interest in understanding how agricultural products are grown offers an opportunity to support agriculture and advance stewardship.

New Technology

While Silicon Valley and the automobile industry race to be the first to market with “driverless” cars and automated vehicles, farmers have been using auto-steer and satellite-driven tractors and combines for over 20 years. Innovation and technology have been at the core of agriculture for as long as we have been husbanding animals and selecting seeds. But what’s exciting is the pace and degree of innovation that is now occurring in agriculture, that will now help us advance not just production, but also the stewardship of our natural resources.

The future of agricultural conservation is precision. Just as farmers use “precision agriculture” tools to optimize their production and minimize inefficiency, precision conservation tools and planning advice help farmers reduce “waste” in their production systems. Waste in the context of conservation refers to a wide range of issues, including lost top soil, organic matter, and fertilizers; excess irrigation water and farm equipment usage; and misplaced herbicides and pesticides. The availability of robust data, analytics and insights allow farmers and agricultural retailers to employ practices in a far more targeted and impactful way than ever before.

For instance, an analysis by USDA’s Natural Resources Conservation Service (NRCS) of conservation adoption in the Western Lake Erie Basin estimated that a relatively small number of the acres in this large watershed have an outsized impact on water quality. In this case, just 25 percent of the cropland acres in this watershed are the source of 80 percent of sediment losses, 66 percent of the surface losses of phosphorus, and 59 percent of the surface losses of nitrogen. Of note, these losses are not occurring on 25 percent of the farms in the watershed or even 25 percent of the fields. These sediment and nutrient losses are occurring across the entire watershed on a micro scale, based on the diversity of soil types, topography, and management systems used by farmers. In a watershed with almost 4.9 million acres of cropland (a land area equivalent in size to the States of Connecticut and Delaware, combined), how do we help farmers understand where these losses are occurring on their farms and in their fields?

Thanks to precision conservation technology, farmers in the Western Lake Erie Basin and across the country now have a better look than ever before at where opportunities exist in their fields to maximize production and minimize environmental losses. And these precision conservation tools highlight for farmers the financial opportunities for different field management systems. The most effective conservation practices are those that have an economic benefit to the farm, either by increasing yield and revenue or eliminating waste. Often where a crop field is not profitable, that is also the portion of the field that is experiencing the greatest topsoil erosion or nutrient losses. By focusing on net profitability, these precision tools can help farmers achieve their business goals while also improving their stewardship of natural resources.

Truterra® Insights Engine

At Land O'Lakes, we're proud of our work to develop and deploy new ag tech for precision conservation. Our Truterra Insights Engine is a first-of-its-kind, interactive on-farm stewardship digital platform that will help both farmers advance their goals for stewardship and financial return-on-investment, and food companies measure sustainability progress. One of the biggest challenges in agricultural sustainability is the lack of comprehensive tools that can quantify results and demonstrate system-wide progress on conservation adoption and results. Truterra Insights Engine fills that critical need. It can bring together the value of stewardship practices with the agronomic expertise and technological capabilities of agricultural retailers to create field-customized insights for farmers. Today, 20 agricultural retailers across the Midwest, Western Canada, and in the Chesapeake Bay region are using the Truterra Insights Engine to help farmers identify opportunities on their farms to improve their profitability and increase their stewardship.

Land O'Lakes/CalBio Collaboration

Livestock farmers are also benefiting from new technology. For example, anaerobic digesters are a promising option to manage manure capturing methane and either combusting it for energy generation or processing it as a replacement for natural gas. In some cases, digesters are also opening new revenue streams for farmers, and even helping them to establish regulatory certainty.

Land O'Lakes is leaning in on driving innovative stewardship solutions for our dairy members. In June 2018, Land O'Lakes and California Bioenergy LLC (CalBio) launched a first-

of-its-kind collaboration to support the financing, installation and management of on-farm methane digesters to generate renewable compressed natural gas (“R-CNG”) fuel in California – creating an innovative farmer-led model for “barn to biogas” that can shape nationwide solutions to agricultural methane emissions reduction and unlock new revenue streams for dairy farmers.

As one of the nation’s largest agricultural cooperatives, Land O’Lakes is uniquely positioned to tap into the potential power of California dairy farmers to generate renewable energy from farm waste. CalBio provides the expertise needed to develop, execute and manage on-farm methane digesters, as well as market R-CNG credits in California, in a manner that is cost effective for farmers. This effort with CalBio will also help Land O’Lakes dairy member-owners in California to meet new state standards that call for a 40 percent reduction in dairy and livestock manure-related methane emissions from 2013 levels by 2030.

Food System Partnerships

According to Nielsen, now nearly half of U.S. consumers say they would definitely or probably change their consumption habits to reduce their impact on the environment. And the consumers are voting with their wallets: In 2018, consumers spent almost \$129 billion on sustainable consumer goods (up 20 percent from only 2015). Recent surveys support the above findings, estimating that 83 percent of consumers consider sustainability when buying food, and 66 percent of consumers say it’s important that their food is produced in a sustainable way. And a consumer food survey by Deloitte revealed that this growing interest in agricultural sustainability holds across all age, income, and U.S. regional demographics.’

No longer a fad, agricultural sustainability is a growing market force. As a result of this expanding consumer interest, the food system is gearing up to meet new marketplace demand. From global restaurant chains to grocery retailers, from consumer packaged goods companies to food ingredient processors, both iconic brands and new startups are exploring ways to better connect with consumers on how their products support environmental quality.

This new marketplace provides an exciting opportunity for agriculture. As consumers desire a more authentic experience and greater understanding into how their food is produced, farmers and ranchers have a new audience to share their stories and communicate as to how they steward the environment. This new marketplace also offers a channel to connect consumers and farmers through the food value chain, ultimately helping incentivize good soil and water management.

Food System Partnership in the Chesapeake Bay Region

Land O'Lakes has sought to build and expand this new agricultural sustainability marketplace to drive measurable conservation progress. In 2018, Campbell Soup Company, Environmental Defense Fund and Land O'Lakes launched a project to test a value chain approach to support sustainable agriculture on farms in the Chesapeake Bay region through improved environmental and farm profitability outcomes. With the leadership and on-the-ground work of The Mill, an agricultural retailer headquartered in Bel Air, Maryland, we're using the Truterra Insights Engine to support agriculture while advancing soil health and water quality goals in the region – benchmarking farmers' stewardship across cropland acres that grow wheat that ultimately ends up in Pepperidge Farm Goldfish Crackers.

The initial pilot includes 10,000 acres across 228 farms in Maryland and Pennsylvania, and we have learned a great deal. For instance, a large majority of the crop fields benefit from practices to improve soil health. Over 90 percent of the acres use no-till crop residue management and about 55 percent of the acres use cover crops, reducing soil erosion and improving soil fertility and quality. We also now know that farmers use effective strategies to reduce the risk of losing valuable nutrients from their fields. 50 percent of assessed acres are using variable rate technology to help farmers precisely apply fertilizers at the right rate and locations.

This project uncovered potential opportunities, too. For instance, only 25 percent of the fertilizer applications on these acres used products like fertilizer stabilizers and advanced nutrient modeling technology to keep nutrients on the fields and reduce the risks of loss to the atmosphere and water resources.

Conclusion

I commend NRCS for its leadership and for being on the forefront of these opportunities to advance innovative solutions for conservation. During today's hearing, I look forward to further highlighting examples of how Land O'Lakes and our network of agricultural retailers and conservation partners are contributing towards delivering on the promise new conservation technology and food system partnerships.

Mr. Chairman, Members of the Subcommittee, I truly appreciate the opportunity to be here today to discuss the work agriculture is doing to provide solutions that benefit both the farm economy and the environment.

Mr. BISHOP. Mr. Norton.

OPENING STATEMENT BY MR. NORTON

Mr. NORTON. Thank you, Mr. Chairman, Ranking Member Fortenberry, and the subcommittee members. I really do want to take this time to express our appreciation to you for your continued support of the conservation programs that Jason spoke about. In fact, I am really having trouble getting my thoughts together after the inspirational message that he had around our partnership with agriculture producers, and it really is a lot of what I wanted to talk about with you all today.

It is a great honor and opportunity to be here with you. As the Natural Resources Conservation Service, we were born out of the Dust Bowl 70 years ago, over 80 years ago, a terrible environmental disaster that brought birth to our agency. And we have moved forward hand in hand with agricultural producers ever since.

Our model is trained conservationists on the farm with the individual producer, working with their land resources. Their business model is their model, it is different from one farm to the next. Their capacity to accept change is something that they have to deal with themselves, and it takes a professional conservationist working with them on their farm to make that happen.

It is a model that has worked well. It is a partnership. Number one, our number one partner—and we will talk more about partners—but our number one partner is that private landowner. Seventy percent of the United States of America is under private ownership in agriculture production, and they are the person that we need to be working with if we are going to make meaningful change and support to the agriculture community.

It is an effective model, as I said earlier. Our farmers, ranchers, forest landowners, they are on the front lines of weather volatility. As Jason mentioned, we had fires in the West, in the Central Plains, we have had just as recent as a month ago the bomb cyclone. Those farmers, those ranchers, those forest landowners feel the effects of those.

Our conservation programs actually create a buffer to a certain extent to those kinds of events, does not solve them. But if we can help minimize the risk, then they have a greater opportunity to be successful on the other side of this event with all the other support that might come their way through the agriculture community.

We are in the community. We have 2,100 offices scattered across the country. Those individuals are living in those communities, they are a part of that community. Our employees feel the same things those farmers are feeling as they are dealing with the events of weather, the climate, the changes in the markets. They are right there in those communities with them, so they understand. And it is a great model that we have.

We work with producers large and small, whether it is a small producer just getting started that is growing his operation, as we have heard from Nate. There are folks out there that are just like that. We work with them.

We work in the urban agriculture space. We do hoophouses. We work in these food deserts to help create opportunities.

In my home State of Louisiana, we have a visible presence in New Orleans and have helped stand up a farmers market there through the USDA programs and wonderful produce. It rivals anything you will see in a grocery store and it is right there on the street corner available to the folks that don't have access to those fresh fruits and vegetables and produce. So we are in the community, we are a part of that.

You know, I think back in my time how agriculture has changed. And as it has changed, it has created great opportunities. Our objective from the very early part of our agency has been to treat each acre on an individual farm within its needs and capabilities, including the landowner or the producer's goals and objectives. As we move to precision agriculture, we are seeing a greater ability to actually do that.

BENEFICIAL DEVELOPMENTS IN AGRICULTURE

I will share with you real quickly about a farmer that is a friend of mine. Ten years ago in the State of Louisiana I went out on his operation, he had embraced geospatial technologies, precision agriculture, had a cotton stripper on his farm. The GPS unit had gone out, his yield monitor was not working like it was supposed to be, it was parked there.

His father-in-law, who he was renting and operating on his place, could not conceive, he had a cotton crop to get out of the field, but would not take that working piece of equipment, except for a yield monitor, would not take it to the field and get that crop out. And he said: You have to understand that if I put that piece of equipment in the field without the data it is going to return to me I have lost my year's work in understanding what is going on on my farm.

He was able, because of the data he was given through this precision agriculture technology, he was able to identify the places on his farm that were not productive that he was putting more resources in than it was returning to him in terms of profit. He was able to make those changes.

And they are now, through the use of our programs, he used the Conservation Reserve Program for some buffers, he used the Environmental Quality Incentives Program, even the Wetland Reserve Program, and he was able to take those marginally productive areas that were really costing him money and take them and put them into a conservation use.

So we have those kinds of success stories all the way across the landscape and things that we are encouraging with the programs that you all have provided us the resources to deal.

As these things have changed, as agriculture has changed, the farm bill has drawn us to a greater investment and a greater and a broader mission as an agency. If you go back to the 1985 farm bill, the first one, that had the conservation title in it, it was about soil erosion and wetland conservation, that was it. That was really the focus.

And you look at every successive farm bill since, they all have challenged us to work with producers in a broader landscape to expand our work, to look at water quality, wildlife habitat, grazing land resources, all those kinds of things.

And I will say this. When you go back to the Dirty Thirties, the Dust Bowl, to today, I would say the American agriculture producer has a great story. We are sustainable. We produce more food on less cultivated acres than we did back in history. We are removing streams from the 303(d) list, water quality, impaired streams, we are removing those from the 303(d) list.

We have through the farm bill, conservation programs, and the private landowners utilizing our programs delisted the black bear, the smelt, several different species. And there are, what, 12 other species, Jason? He envisioned the Working Lands for Wildlife.

We put the wheels to that thing and we have probably 12 other species that are probably not on the—actually more, but I am comfortable with 12—that are not on the Endangered Species List because of the engagement with the private landowners using these conservation programs.

We have a tremendous success story. It is all driven by locally led conservation, not making decisions here, having these resources, moving them out, as you all have given them to us, to the local level, because the things that are going on in Maine are different than the things going on in Georgia. The needs of those producers are different, the crops, the climate, the variability.

The Plains. I was raised in Oklahoma, the Plain State of Nebraska, I am very familiar with living out in that kind of an environment, very different. We need to have our conservation programs locally driven.

So I will just close real quick. We have a lot of work going on, the climate hub space. Those are just tremendous, 10 of those around the country. We are using those to assess our natural resource conditions, what is going on in these events like this, so that we can make adjustments as we have through the history of our programs to be better and more effective with the agriculture producer, to promote resiliency, to mitigate drought through those kinds of things.

I will leave you with this closing remark. And I want to take you back in time. As I was preparing for this, as a young man in the Future Farmers of America, I remember a quote, and it just rings real true to me. It is from William Jennings Bryan. It says, “The great cities rest upon our broad and fertile prairies. Burn down your cities and leave our farms and your cities will spring up again as if by magic. But you destroy our farms, and the grass will grow in the streets in every city in the country.”

And I believe that is true. I believe that working relationship we have with agriculture, I believe we are sustainable. I think it is the partnership of the Federal investment with the private sector through the programs that you have authorized us to do that we can have a stronger, more resilient, and sustainable agriculture years into the future so that our children enjoy the blessings that we have today.

Thank you very much, Mr. Chairman.
[The information follows:]

Testimony of Kevin Norton
Acting Associate Chief, Natural Resources Conservation Service
United States Department of Agriculture
before the
Agricultural Appropriations Subcommittee of the
United States House Committee on Appropriations
April 10, 2019

Introduction

Chairman Bishop, Ranking Member Fortenberry, and Members of the Subcommittee, thank you for the opportunity to appear before you today to discuss the Natural Resources Conservation Service (NRCS) and the manner in which we help America's farmers, ranchers, and forest landowners realize economic opportunities through the adoption of conservation practices and systems. When implemented and maintained over time, these efforts can also help mitigate the impacts of a changing climate and increased weather volatility. I appreciate the ongoing support and leadership this Subcommittee has provided for voluntary, private lands conservation, and the improvement of our soil, water, and other invaluable natural resources as embodied in the recent support for the 2018 Farm Bill.

Since the establishment during the Dust Bowl – the greatest environmental disaster of the previous century – of the Soil Conservation Service, our predecessor agency, NRCS has recognized that the adoption of conservation practices must not only address critical resource issues but do so in an economically beneficial manner for producers. NRCS programs provide

producers with the technical and financial assistance needed to incorporate the beneficial changes that our conservation practices can bring to improve the resiliency of their operations.

While NRCS does not provide agronomic advice, working in concert with many partners, including public and private entities, agricultural operators, and private landowners, the agency provides conservation technical and financial assistance that enables agricultural producers and their operations to thrive and remain sustainable. More than 70 percent of land in the United States is held by private landowners. Decisions those landowners and operators make every day not only have an impact on their land but that of their neighbors, their watersheds, and ultimately the entire U.S. population.

The 2018 Farm Bill built upon our existing conservation programs, including the Environmental Quality Incentives Program (EQIP), Conservation Stewardship Program (CSP), the Agricultural Conservation Easement Program (ACEP), and the Regional Conservation Partnership Program (RCPP). NRCS, through its unique delivery system, provides assistance to individual landowners across the Nation through local field offices. Through these programs, NRCS continues to make strides helping farmers, ranchers, foresters, and other private landowners restore and enhance our Nation's natural resource base in a voluntary, incentive-based fashion. Perhaps most importantly, the decisions surrounding the implementation and prioritization of these programs and funding are made on the local level, through Local Working Groups and State Technical Committees to ensure local needs are addressed. In this manner, NRCS is attuned to the threats that face our Nation's farmers at the farm level and tailor our assistance to help them recover from and mitigate the impacts of extreme weather events.

NRCS Conservation Practices – Improving Agricultural Resiliency

Farmers, ranchers, and forest landowners are experiencing increased vulnerability to their operations from climatic extremes and variability in temperature and precipitation and from events such as fires, invasive pests, droughts, and floods. Within the last year alone, we have seen fires across the West and our prairies, hurricanes pummel the Southeast, volcanic eruptions in Hawaii, extreme drought in the Texas Panhandle, and just last month, historic snowfall and flooding across the Northern Plains and Midwest. That weather is not something producers can plan for on a daily basis, those impacts will take years, in many cases, for full recovery.

While other USDA agencies provide assistance with mitigating the economic risks of natural disasters, NRCS helps producers understand their soils and landscapes and the vulnerabilities to their agricultural systems from these conditions of increased weather volatility. Specifically, we work to improve soil health through conservation, restoration, and improved management of croplands, forests, wetlands, and pasture/rangeland. This work increases carbon sequestration and builds resilience to variable climatic conditions and extreme weather to protect food and fiber production. We also provide assistance for disaster recovery through reseedings and other measures to address soil erosion and water-quality issues, debris removal, streambank stabilization, etc.

Conservation Programs. NRCS offers a suite of working lands and easement programs that provide assistance to agriculture producers and others for addressing their natural resource

concerns. The suite of working lands programs includes the EQIP, the CSP, and ACEP. Each of these programs assist producers with implementing land stewardship practices and activities. Under the easement programs, NRCS restores, protects, and enhances wetlands and grasslands and assists third parties with protecting agricultural lands. The RCPP incorporates features from EQIP, CSP, and ACEP in coordination with third parties. NRCS is continuously working to achieve environmental benefits in a cost-effective manner and to improve more effective ways to leverage technical assistance to convey the economic return to the producer through environmental improvements. NRCS does not seek financial gain on potentially marketable environmental services.

Soil Health Management System (SHMSs). NRCS is helping producers implement SHMSs with the best available understanding of soil health and conservation. Instilling Farmer to Farmer programs as well as local soil health networks to facilitate exposure of practice implementation are an effective means to increase impact. SHMSs are combinations of location- and situation-adapted NRCS practices built into systems that minimize soil disturbance and maximize soil cover, living roots, and diversity in combination with system-adapted nutrient and pest management. These systems increase farm resilience through adaptation, increased water-use efficiency, decreased erosion, and increased mitigation through carbon sequestration by increasing biomass (e.g., use of cover crops), reducing tillage (reducing carbon loss and fuel use), and increased fertilizer efficiency. The 2018 Farm bill defined cover crops as a “good farming practice,” thereby reducing disincentives for implementing soil health practices. The 2018 Farm Bill further emphasizes soil health by recognizing soil testing and remediation as EQIP practices, for example.

Nitrogen Stewardship. NRCS provides technical and financial assistance for the development and implementation of enhanced nutrient management plans that improve nitrogen use efficiency, reduce nitrogen use and agricultural nitrous oxide emissions, reduce costs, and improve water quality. NRCS field staff are trained to provide nutrient management planning and implementation assistance to USDA clients using nutrient movement risk assessment tools and by implementing practices to reduce agricultural emissions.

Livestock. NRCS actively works with producers in grasslands systems (pasture and range) as well as confined operations (feedlots and dairies). Practices such as prescribed and rotational grazing, range planting, and forage and biomass planting ensure that grassland areas are maximizing productivity, sequestering carbon, and increasing resiliency to conditions such as prolonged droughts. NRCS technical specialists are also working with producers to improve manure handling to decrease emissions of greenhouse gases such as methane, improve water quality, and increase energy production.

Agroforestry and Herbaceous Wildlife Habitat. NRCS continues promotion of conservation practices such as the windbreaks, silvopasture, riparian forest and herbaceous buffers, and upland wildlife habitat. Improved woodlands have significant carbon sequestration benefits as well co-benefits such as decreasing erosion, increasing flood control, enhancing soil fertility, and improving water quality, air filtration, and wildlife habitat.

Improving knowledge of soils, ecological sites, and land-use. NRCS Soil Survey, National Resources Inventory (NRI), and Conservation Effects Assessment Project (CEAP) Programs

build the foundation of knowledge to better direct land-use decisions for improving on- and off-farm resources in rural area as well as program policy. Through these efforts, we better understand land and soil characteristics, land use trends, and impacts of conservation practices on water, soil, and air quality.

The Snow Survey and Water Supply Forecasting (SSWSF) Program. The SSWSF collects high elevation snow data in the Western United States and provides managers and users with snowpack data and water supply forecasts. NRCS field staff collects and analyzes data on snow depth, snow water equivalent, and other climate parameters, and the data are used to provide estimates of annual water availability, spring runoff, and summer stream flows. The water supply forecasts are used by individuals, Tribes, organizations, and units of government for decisions relating to agricultural production, hydroelectric power generation, fish and wildlife management, municipal and industrial water supply, reservoir managements, urban development, flood control, recreation, and water-quality management.

Plant Materials Centers. NRCS plant material centers have been developing plant materials that are more resilient to changing conditions while providing farmers with a marketable crop. For example, the issue of saltwater intrusion because of storm surge has become increasingly problematic within the United States' coastal zones. Managing the impact of saltwater intrusion from storm surge situations will require producers to use more adaptive agricultural practices. NRCS is currently identifying vulnerable areas of saline impacted soils along the East and Gulf coasts through the compilation of GIS mapping, remote sensing imagery, and soil survey information. Our scientists are improving the agency technical resources and updating vegetative recommendations for Practice Standards that address this resource concern. These

resources will aid field staff with assessing the saltwater inundation/intrusion problem and assist with providing sound technical recommendations. We are also improving the knowledge of the economics of growing value-added conservation plants as an alternative to abandoning salt impacted lands.

Economic Impacts and Opportunities

It is vital that NRCS, our partners, and other stakeholders develop opportunities for demonstrations that illustrate the economic benefit of conservation on agricultural lands. As private sector companies, crop advisors, and partner organizations develop ways to quantify the economic benefit of conservation practices, we must also develop more robust case studies and financial information to remain a relevant and trusted partner to private landowners, effectively advise producers, and inform others about the economic impact of conservation actions taken by the nation's farmers and ranchers.

NRCS offers opportunities for third parties to engage with moving the country's natural resource efforts forward through partnerships and other arrangements. For example, third parties may:

- Serve as Technical Service Providers where they provide direct technical services such as conservation planning, design, and implementation assistance to farmers, ranchers, and non-industrial private foresters;
- Engage as a partner through RCPP or through one of our other programs or initiatives. Partners typically provide their expertise and technical and financial resources;
- Engage as a partner offering to enhance agency outreach efforts with underserved or other communities; and

- Contribute to the development and testing of innovative conservation approaches through the Conservation Innovation Grants (CIG) or otherwise.

As a non-partner, the private sector may utilize agency tools that are available on-line, our soil survey, or NRI if these resources enable them to improve or enhance their services to agriculture operators and others.

Adoption of conservation tillage results in real monetary change. For example, as determined through the CEAP:

- Fuel use has been reduced by 812.4 million gallons of diesel equivalents, roughly the amount of energy required annually by 3.2 million average households.
- Continuous no-till has been adopted on 21 percent of acres and accounts for 35 percent of the reductions in fuel use and emissions.
- Corn Belt and Northern Plains production regions account for 58 percent (~29 percent each) of the fuel and emission reductions.

Through a CIG award, the National Association of Conservation Districts collaborated with Datu Research to develop a number of case studies exploring the financial impact of implementing soil health practices on farms. A CIG project with Farmland LP, a sustainable farmland investment firm, showed that the firm could provide a market rate of return to its investors while farming in a way that is not just sustainable but regenerative. Beyond these efforts, there are also a multitude of pilot projects and initiatives underway that are exploring ways to financially incentivize conservation. For example, the state of Iowa in 2017 created an oversubscribed

program that provides a per acre reduction in cover crop premiums for farmers who implement cover crops. Our hearing panel colleagues Land O'Lakes in 2017 launched its SUSTAIN Innovation Financing program, which allows Land O'Lakes co-op members to leverage their co-op member equity to take out loans for large-scale, on-farm conservation projects. The Nature Conservancy, using CIG funding, is exploring how good conservation farming can lead to reductions in public drain tax rates paid by producers in Michigan and nearby States.

NRCS has been working for many years to make available to farmers, ranchers, and forest landowners the ability to sell environmental services from conservation practices carried out on their operations.

- NRCS funded the Pinchot Institute (through both a CIG award and a RCPP award) to explore ways to aggregate environmental credits among small private non-industrial forest landowners.
- NRCS funded another CIG project that enables rice producers anywhere in the country who undertake conservation measures to reduce methane emissions (e.g., alternate wetting and drying, dry seeding) and potentially receive economic return for their efforts.
- USDA recently highlighted Bare Ranch in California, which has undertaken conservation efforts with NRCS to demonstrate that a ranching operation can reduce more carbon than it emits after implementing a conservation plan.

These are but a few of the many examples where corporations have made commitments to help meet sustainability goals through reliance on their producers.

Conclusion

Mr. Chairman, Ranking Member, and Members of the Subcommittee, our CEAP modeling efforts are giving us greater understanding of where practices need to be placed to realize the greatest environmental benefits. The information also supplies data producers can use to work independently or with others where they can gain the greatest return on investment.

The nation's farmers and ranchers are on the front lines of the risks posed by increased weather volatility. I thank you for letting me summarize how NRCS is assisting private landowners, producers, and others with implementing measures to improve Agriculture's resiliency. I look forward to taking your questions.

Mr. BISHOP. Thank you.

At this point let me recognize Mr. Fortenberry. We deferred his opening statement earlier.

And, Mr. Fortenberry, would you like to make an opening statement? If so, I recognize you for that purpose.

OPENING STATEMENT BY MR. FORTENBERRY

Mr. FORTENBERRY. Yes, Mr. Chairman. Thank you very much for recognizing me. I apologize for my tardiness. If you knew where I was, though, I think you would be happy by the distraction. It was at a meeting on conservation.

Let me just truncate my opening remarks. I want to tell you all three things: Conservation is development, sustainable business is good business, and stewardship is a noble value.

And what we have in our society, what we have in our economy, what we have in our agricultural policies is an alignment of these three variables, that sustainability can be good business when thoughtfully developed in harmony with other needed outcomes of the economy, that the value of stewardship is something that unites and does not divide, and that all of this can actually be a new way to think of the term development.

It is not just building more and more, it is using what you have in a responsible manner, which actually creates the opportunity for enhanced income, well-being, and longevity of the very practice, whether it be a farm or a business.

And so this is a very important discussion. I want to thank you, Mr. Chairman.

As a bit of an aside, several years ago I undertook a project, it is a little bit remote from the considerations here, but it is related to this idea of stewardship. It got hot in Nebraska and I turned the air conditioner on and it didn't work. So I called the repairman after I did what I could do in lay terms. And he opened it up and there was a mouse that had gotten in there and chewed the wires.

So he replaced the capacitor, turned it back on, and it started to smoke—the capacitor, not the mouse. And he said, "Jeff, just sorry, it is done." So OK, that is \$3,000.

I started to think through this. I am highly interested in the whole concept of distributed energy generation, which is a component, an emerging field actually, in agricultural production. And so I began to look at the financial dynamics of installing a geothermal system. And it is complicated.

But after having worked with the HVAC company, having used the Federal tax credit, having leveraged the energy loan program in my own State, having gotten a rebate back from the manufacturer, and having gotten a certain subsidy from my own utility, the financial package made enough sense for me to tip that balance.

I wanted to do it anyway because of the example it sets of moving toward a more sustainable future, energy future, but we went ahead and did it.

Now, the payout is a bit longer than I perhaps would have liked, but nonetheless, I will probably get 20 years of cost-free energy from that once the initial capital is paid off.

Again, there are barriers to entry here, but if we can overcome them through smart public policy and certain subsidies when nec-

essary where there is not a market dynamic that can sustain this, but the larger externality costs certainly justify it, where there are young new generations of people who are actually expanding the agricultural family.

I come from a production ag State. That is the backbone of who we are. We help feed America and feed the world and we are very proud of that. There are a lot of young people who may never have access to a thousand-acre grain production facility because they just don't have the land or the capital, but they are starting to do niche markets, organic farming, farm to table, participating in farmers markets, being employed elsewhere but doing this on the side.

This is exciting news. And the Department of Agriculture's program or the agricultural programs at the University of Nebraska are growing, because there is a convergence of fields—conservation, international development, environmental security and stewardship programs, along with traditional agronomy and animal husbandry and other programming elements.

So I think this is actually a very exciting time to discuss all of these things, Mr. Chairman. And I really wish we could get beyond getting into political lanes when we are confronted with the hard, hard realities of extreme weather events and the reasons for those and actually look toward the solutions that move us toward a sustainable energy future that reduces our overdependence on hydrocarbons to run our economy and looks for the harmonious balance of sustainable development that you talked about, Jason.

By the way, Derek Kilmer, Congressman Kilmer from Washington State, I think could be your brother. You look very much alike.

Do you agree with that? Does the panel agree?

I am sorry to divert like that, but I am looking at you and thinking that at the same time.

Mr. WELLER. There are worse comparisons.

Mr. FORTENBERRY. So actually, instead of all of what we are talking about being somehow reasons for divisiveness, are actually reasons for consensus.

Thank you, Mr. Chairman.

Mr. BISHOP. Thank you, Mr. Fortenberry.

Votes have been called. We will try to move through this as quickly as we can and we will reduce the normal questioning time from 5 minutes to 3 minutes.

Let me start off. Both Mr. Fortenberry and I have both had some unfortunate recent experience with natural disasters in our districts. In my case, it was Hurricane Michael and in his case it was the devastating floods that washed through much of the Midwest a few weeks ago. Obviously, we can't stop Mother Nature, but we can mitigate the devastation that she wreaks, at least to some extent.

Would each of you care to discuss how you think sustainable practices can contribute to farmers' and communities' abilities to withstand natural disasters and to bounce back?

SUSTAINABLE DISASTER SOLUTIONS

Mr. NORTON. I will weigh in here real quick.

You know, whenever you look at this idea, you can't stop a natural disaster and it is going to have impacts.

I actually have heard from a farmer in Nebraska that is very much engaged in the cover crop effort, and he showed me pictures. The flood engaged his property. And the damage that he had is not near as visible as other properties that were not using cover crops, those kinds of things.

So you can do the best you can, be as healthy as you can, and then whenever the illnesses, the storms hit you, hopefully you aren't hit as hard and you are more resilient and able to respond back. Certainly you all have given us some tools through the appropriations and programs. We have used the Environmental Quality Incentives Program to go back in and repair work that we had done on farms back through history. There is the Emergency Conservation Program that also provides resources to do that work. And then we are there with the communities.

In your State specifically, irrigation systems that we have put in place, we are back in there cleaning them off, repairing them, and reestablishing irrigation, which is critical to some of the crops that are produced in Georgia.

So we engage, move in, as I said, we are right there in the community, we move in very quickly and start trying to work to help producers.

Mr. BISHOP. Mr. Weller.

Mr. WELLER. I am sorry, I still have goose bumps from Mr. Fortenberry's opening remarks.

Really passionate, sir. Thank you very much for your illustrative and insightful comments.

Real quick. What we are trying to do through our system is really to help our producers best manage their soils. And Kevin talked about that. Nate has talked about it as well. And that soil management is really the foundation of our food system. It not only feeds us, but it is how you care for that most valuable asset, the farmer. This really will help farmers withstand strong storm events, variable weathers, drought, and flood.

And so it is really then working through our cooperative system, helping farmers identify the right mix of practices on their farms and in their fields, to help improve the soil carbon, the soil organic content, the structure. But really the physical, chemical, and biological properties of the soil system will help it better withstand extreme weather.

Mr. BISHOP. Mr. Powell-Palm.

Mr. POWELL-PALM. Thank you.

We have to both be resilient in our environmental practices, but also for the economic reality of the farm. And so when we have markets that reward farmers for their ecological stewardship, we also have the ability to have more resilient farms from a business point of view. Organic farms are 35 percent more profitable than the average farm.

And so when you hit weather events, which are going to be inevitable, the ability to bounce back from that setback is the difference between a community closing shop and people leaving and being able to recover after a natural disaster.

Mr. BISHOP. Thank you.

Mr. Fortenberry.

Mr. FORTENBERRY. Mr. Chairman, since I gave a longer opening speech, why don't I defer to the rest of the panel who may have questions before we have to vote and just yield back.

Mr. BISHOP. Thank you.

Ms. Pingree.

SOIL QUALITY

Ms. PINGREE. Thank you, Mr. Chair.

And I have to say this kind of made my week, and it is a short week. But I am so grateful to the chair for having this hearing, which I think is a really important topic for all of us.

I am thrilled to listen to the ranking member talk about his renewable energy system and how he put all that together, so that is critically important.

And yesterday we had Secretary Perdue in here and we got a chance to talk to him a little bit about the positive side of what agriculture can do with carbon sequestration and opening up carbon markets to farmers and how we are going to go about doing that.

So to me it is a big week, I can go home now. Actually we are going home, so it works out.

I don't have a lot of time to ask questions, but I would be interested, Mr. Norton, to hear a little more about the process of how we use some of these wonderful conservation practices that we already have and better quantify what is going on in the soil so that farmers can take advantage of potential carbon markets out there.

I get really frustrated in this wonderful debate we are having about climate change and it is incredibly important that we do tackle this. But so often people's understanding doesn't go beyond planting a tree. And while I come from a forested State, we love trees, I also want to understand this topic we have been discussing a little bit today, recognizing that farmers play this amazing role in sequestering carbon in the soil, but we have to have good conservation practices.

And then more importantly, we have to be able to measure that and be able to have that sustainable in a market. And I know that is something that best rests at the Conservation Service. And so can you talk a little bit about where you are with that and how you see us moving forward?

Mr. NORTON. Certainly. So number one is we do have a tool called the COMET tool that actually does give producers the opportunity to quantify, look at their operations, start quantifying the services, the carbon things they are sequestering. So we have that going on.

Beginning in 2011, we started a process through our Conservation Innovation Grants of going out to the private sector, to research entities, to nonprofits, and helping build that science behind the carbon sequestration. We rely heavily on the Agricultural Research Service and our land grant universities to also fill that space.

We are making headway. We are having conversations today with organizations around the soil health and how we can quantify the buildup of carbon in those soils so that farmers can begin to

communicate, potentially access markets, and make exchanges on those benefits. So we are working in that space.

Ms. PINGREE. I am going to quickly cut you off, because I am going to run out of time and I want everyone else to have a chance.

Jason, do you want to comment at all?

And, Nate, I will follow up with you after the committee so I can ask more questions.

But are farmers using these tools?

UTILIZING NEW TECHNOLOGY

Mr. WELLER. They are. And this is in part through Land O'Lakes.

We have made an investment through Land O'Lakes SUSTAIN to build that kind of technology that leverages the public data that USDA has created and many of the tools that Kevin just talked about and puts it into a platform where then one of our sales agronomists from one of our co-ops can go out and work with a producer like Nate and not just understand the flux and the complexity, but actually visualize where in their field they are gaining carbon, where they are losing carbon, where erosion is occurring, and how then to mix and target the right conservation system on that field to reduce the loss of carbon, if not increase the adoption of carbon in the soils.

Ms. PINGREE. Great. And, again, I will follow it up.

Thank you for your wonderful testimony, Nate.

I yield back.

Mr. BISHOP. Ms. McCollum.

Ms. MCCOLLUM. Thank you, Mr. Chair.

Good to see you, Mr. Weller. Thank you for being here. It is always good to have one from Minnesota here.

And to Mr. Powell-Palm, having spent so much time at the Richland County Fair as a youth, congratulations on your 4-H win.

ADJUSTING TO EVERPRESENT CLIMATE CHANGE

I am going to focus a little more on climate change. This is a copy of a map that the Star Tribune published, working with the University of Minnesota Center for Forest Ecology. Scientists looked at three scenarios, one with a major decrease to CO2 emissions, one with a minor decrease, one with no decrease.

Under the scenario where there is no decrease in CO2 emissions, scientists estimate by 2070 most of Minnesota's boreal forests will disappear and our State's ecosystem would resemble that of Kansas.

No offense to Kansas, but we like our trees in Minnesota, being the Land of 10,000 Lakes.

So producers are already facing climate change, and you gentlemen know that well, whether extreme weather or disasters caused by weather that is so extreme.

So could you—maybe I will address both questions at the same time to Mr. Weller—can you talk maybe a little bit about what Land O'Lakes SUSTAIN is doing to help with the adaptation of climate change?

And, Mr. Powell-Palm, any recommendations for this subcommittee—I know your generation is very concerned about cli-

mate change—what we can do to help producers like yourself make the adjustments?

Thank you.

Mr. WELLER. So it starts first with building the capacity for our agronomists in the field. These agronomists work through local farmer co-ops and ag retailers. Every day they are out working with growers to identify the right agronomy system or practices on their fields that are ultimately going to help them to be the most profitable and productive.

But we are now weaving into this agronomy conversation, it is now a sustainability stewardship conversation. And so for us addressing extreme weather and a changing climate is about what is the right mix of soil management and nutrient management practices that will help that farm be profitable and be more resilient, but also reduce the loss of soil carbon and nitrous oxides into the atmosphere.

That is something we start with the farmer, to help them achieve what is most profitable and effective for that farm. And then through our system we are linking those farmers back downstream with food companies. So we have food company partnerships, like with Campbell Soup Company and with Tate & Lyle, which is an ingredient manufacturer company, who are very interest in climate change. And so now we are creating a farm-to-fork system.

Ms. MCCOLLUM. I see the clock running, so we will follow up more back home.

Mr. WELLER. Absolutely, OK. Thank you.

Ms. MCCOLLUM. Mr. Powell-Palm.

Mr. POWELL-PALM. Thank you so much for the question.

A recent study came out showing that certified organic farms sequester 26 percent more carbon than a regular conventional farm. And why that is so impactful is that we—and not to—I realize—I will follow with Representative Pingree—but, OK, that we need a market, adoption of processes and technology needs a market incentive.

Consumers want to purchase certified organic food. And so through that market we are able to monetize those practices and reward producers for those practices.

And so by fully funding the National Organic Program and making sure that we are trying to pursue as much as we can the support of those programs that have already been proven out to have a market possibility, then we are able to see a lot more quickly adopted practices.

Ms. MCCOLLUM. Thank you, Mr. Chairman.

Mr. BISHOP. Ms. DeLauro.

Ms. DELAURO. Thank you very much, Mr. Chairman.

Just a quick note. I don't know whether Mr. Weller looks like Mr. Kilmer, but I feel very proprietary toward Mr. Weller. He served as staff with this subcommittee for many, many years, including when I was chair.

And what a delight to see you on this side of the table, Jason. It is really great.

Let me just see if I can in 3 minutes get most of this in.

NAVIGATING BUDGET CUTS

NRCS' budget request cuts, a \$40 million cut from the Agricultural Conservation Easement Program, elimination of the Conservation Stewardship Program. The House farm bill also proposed eliminating CSP. That was rejected, I might add, on a bipartisan basis.

So to you, Mr. Norton. Look, you are not here to defend what you are doing about the budget, but could you shed light on what the impacts would be if we allowed these cuts, other cuts to conservation to be enacted?

Let me also say there is a \$16 million cut to sustainable agriculture in the budget. I don't know what are the negative efforts of that.

To Mr. Powell-Palm, we have the withdrawal of rules related to organic animal welfare standards. Tell me about the rollbacks there and the impact on organic farmers.

So let's go. Mr. Norton, where do we go on the budget, what impacts?

Mr. NORTON. So certainly it is a process and that is how this is moving forward. We will do with the resources that you all give us, we are going to do the best we can to be as effective with those resources.

Ms. DELAURO. I understand. Are you going to—just tell me if you can do—if you are of the view you can do more with less. I got a yes or no here, because my time is running.

Mr. NORTON. So, no, we can't.

Ms. DELAURO. OK.

Let me ask you, Mr. Weller, about the cut to sustainable agriculture.

Mr. WELLER. So we are working very hard to build upon public-private partnerships. And we are working very hard then to link our farmers and our local cooperative system with NRCS at the State and local level.

And so cuts in the NRCS capacity on the ground, the professionals that work in the field, but also the programs they deliver, if they are cut or reduced that absolutely impacts the ability for our farmers to do what is needed.

Ms. DELAURO. To be able to do for sustainability. Thank you.

Yes, on the organic farmers and the trust in the public in organic farming.

Mr. POWELL PALM. Absolutely. So the Organic Livestock and Poultry Practices rule, which was not finalized, is a critical component of moving our industry forward.

As I said in my opening statement, organic farmers want to be regulated because they have a relationship with consumer trust. And as we are continuously moving toward continuous improvement we are hoping that we can see OLPP come to fruition and actually being finalized because the consumer expects it of us and it makes sure that we have consistency in the rulemaking process.

Ms. DELAURO. OK. We should be moving in that direction.

Thank you all very, very much.

Thank you, Mr. Chair.

Mr. BISHOP. Thank you.

We are pressed for time and I apologize, but I am so happy that our witnesses were here. I think this was very, very helpful.

To Mr. Weller, Mr. Norton, Mr. Powell-Palm, thank you all for being here today. We really appreciate your taking the time to come out and share with us your knowledge and your experience and to give us your advice and counsel.

From the testimony, I am excited about the future of farming and I believe that we have the responsibility to protect our planet and the environment. But farming needs to be economically viable in order to keep farmers like Mr. Powell-Palm, the people Land O'Lakes represents, and the people USDA serves in business.

Again, thank you all for your testimony.

With that, the subcommittee will stand adjourned.

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